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## Foreword



In one of our lead news stories this month, community pharmacists have called on the Minister for Health to ensure that community pharmacy teams are included in any State 'pandemic bonus scheme'. The IPU has said that the efforts of pharmacists and their staff in providing face-to-face healthcare and ensuring continued medicine supplies to patients were unparalleled and deserve equal recognition with all other front line workers.

You can read more about this on page 4.

Furthermore, on page 6, the profession has stated that ending the underutilisation of Ireland's 1,900 community pharmacies should be a post-pandemic priority. This is according to the Irish Pharmacy Union (IPU) who has called for the immediate introduction of a new Community-Pharmacy Triage System within its pre-budget submission published recently.

It was, with unparalleled gratitude to Irish pharmacists, that members of the public received vital medicines, health and wellbeing advice and that the vulnerable and those in need were protected and kept safe.

Now more than ever before, it has become clear to everyone that pharmacists are one of the most critical members of Ireland's health service family, embedded in the heart of every community.

With this in mind, we recently launched the search to find The People's Pharmacist 2021. Nominations received were overwhelming, highlighting once again how the profession is viewed by the public, your customers. With over 700 nominations, the shortlisting process was no easy task but on page 17 of this issue and across the next eight pages, we highlight the finalists and the tremendous work they have been carrying out in communities across the province.

Through this Award, we are enabling the public to have a voice in recognising the unwavering support and spirit that makes pharmacists the backbone of our health service in every community across Ireland.

All finalists have gone forward to a public vote. Don't miss the December issue of IPN where the winner will be revealed – alongside our annual Top 100 Covid Heroes listing.

Elsewhere we have a fantastic clinical section looking at issues within Men's Health as well as Elderly Care, including contributed articles on skincare, nutrition, ophthalmology and depression. Our CPD focuses on Oral Chemotherapy Medications, a pertinent and not often discussed issue for community pharmacy.

Meantime, I hope you enjoy the issue.

Irish Pharmacy News is circulated to all independent, multiple Pharmacists and academics in Ireland.

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**IPN** IRISH PHARMACY NEWS

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## Pandemic Bonus must include Community Pharmacists

The Irish Pharmacy Union (IPU) has called on the Minister for Health to ensure that community pharmacy teams are included in any State 'pandemic bonus scheme'. The IPU has said that the efforts of pharmacists and their staff in providing face-to-face healthcare and ensuring continued medicine supplies to patients were unparalleled and deserve equal recognition with all other front line workers.

Speaking in advance of the IPU AGM, IPU Secretary General Darragh O'Loughlin said, "Community pharmacies have long been the most accessible and accessed aspect of Ireland's health service. Right throughout the pandemic and through each lockdown pharmacies maintained a full service and they have risen to every challenge.

"During the public health emergency members of Government publicly commended the role of pharmacies. Pharmacy teams went above and beyond,

providing an essential service to patients and the public in extraordinarily difficult circumstances.

"Maintaining services came at considerable cost to pharmacies and pharmacy staff. The vast majority of pharmacies were hit by significant extra expense in order to remain open. Furthermore, we saw worryingly high levels of stress, anxiety and burnout among pharmacists during the pandemic.

"As the pressures of each COVID surge impacted on the health service and GP practices largely pivoted to telephone consultations,

pharmacies devoted their limited resources to providing medicines, services and care to patients and the public as the only remaining walk-in health professionals available in most communities."

Concluding, Darragh O'Loughlin said "As we emerge from the COVID-19 pandemic, it is essential that the unstinting efforts made by everyone on the front line of healthcare are recognised appropriately by Government, including the vital role played by the 13,300 people working in the community pharmacy sector."

## Pharmacy amongst the 'Best Managed'

Meaghers Pharmacy Group have been named as a Deloitte Best Managed Company for the seventh consecutive year. Said Managing Director Oonagh O'Hagan, "This has resulted us being listed in the "Platinum Club" coupled with lots of hard work.



Oonagh O'Hagan, Managing Director, Meaghers Pharmacy

"I wouldn't be holding this award today if it wasn't for the incredibly hard work, resilience, tenacity, innovation and commitment from my entire Team at Meagher's Pharmacy Group who have adapted and pivoted our direction and our strategy to look after our customers in an ever changing new world."

Meanwhile, McCabes Pharmacy Group also made the list, only this year as a Gold Standard.

Ireland's Best Managed Companies Awards programme promotes and recognises excellence in Irish/Northern Irish owned and managed companies and is the only awards scheme on the island of Ireland that considers a business' performance from every perspective. Entrants to the programme compete for the designation in a rigorous process that evaluates the calibre of their management abilities and practices in addition to the strategy, capability, innovation, culture and financial performance of their companies.

## Medicine Shortages

The Health Products Regulatory Authority has been notified of a shortage of the following products:

- Adizem-XL 180mg Prolonged Release Capsules - PA1688/001/005
- Celebrex 100mg Hard Capsules -PA23055/006/001
- Doxatan 4mg Tablets - PA0126/202/003
- Innohep 10,000 IU/ml Solution for Injection - PA0046/060/002
- Mydrilate 1.0% w/v Eye Drops - PA22709/003/002
- Odrik 2mg Hard Capsules - PA2010/005/003
- Voriconazole Accord 50mg Film Coated Tablets -EU/1/13/835/001

Meanwhile, Pfizer, in agreement with the European Medicines Agency and the HPRa have informed pharmacy professionals of the following:

- All CHAMPIX (varenicline) batches that were found to contain levels of N-nitroso-varenicline above the acceptable level of intake set at EU level are being recalled.
- Based on the available data, there is no immediate risk to patients currently taking this medication.
- The recall will result in further shortages of CHAMPIX
- For patients who are already on CHAMPIX, it may not be possible to complete treatment and healthcare professionals may consider switching
- Alternatives will vary from market to market but may include nicotine replacement therapy (NRT) and bupropion.
- Healthcare professionals should also take into account the need to consider dose tapering, as the summary of product characteristics (SmPC) states that "At the end of treatment, discontinuation of CHAMPIX was associated with an increase in irritability, urge to smoke, depression, and/or insomnia in up to 3% of patients."
- Healthcare professionals should advise patients undergoing treatment not to discontinue CHAMPIX without consulting them.

## Heart Failure in the Community

The Minister for Health Stephen Donnelly TD has welcomed the news that a new service, funded by Sláintecare, providing heart failure diagnostics and care in the community, has reduced waiting lists from 6 weeks to six months.

Galway University Hospitals is running the community-based service with Primary Care Centres in Tuam, Gort, Claremorris and Galway City. The service allows patients to receive care closer to home in a Primary Care Centre. GPs can refer their patients with suspected Heart Failure directly to the service for tests and diagnosis, making it easier for patients to access routine care related to their heart condition.

Minister Donnelly said, "Direct access for GPs to diagnostics allows patients to be treated in a community setting, going to hospital only where necessary, meeting the Sláintecare vision of shifting care appropriately, away from a hospital centric model.

"Patients in Galway are experiencing better health outcomes and a better quality of life - saving themselves hours of travel time, and hundreds of euros in travel expenses now that they can access routine heart check-ups and care closer to home and avoiding a trip to Galway University Hospitals.

"This new model of care is reducing pressure on hospital services such as Outpatient Cardiology (OPD), Emergency Department (ED) and Acute Medical Units (AMU)."

Recent results from the service show that:

- \* Over 1,000 patients have received diagnostic tests through the service;
- \* 88% of patients of the service have come through a GP referral;
- \* 89% of patients received tests within 6 weeks of referral;
- \* 55% had appointments in 2 weeks or less;
- \* This is compared to common wait-times of up to 33 weeks for the hospital service.

## Regulatory Requirements Threatening Medicines

Chair of Medicines for Ireland, David Delaney, was recently an invited live speaker at Ireland's National Parliament Seanad (Senate) Special Committee on the Withdrawal of the UK from the EU.

The industry group has warned that imminent regulatory requirements threaten medicine supplies from Britain to Northern Ireland.

The Brexit agreement for Northern Ireland, designed to avoid a hard border on the island of Ireland, leaves Northern Ireland within the EU's regulatory system for pharmaceuticals.

The Northern Ireland Protocol states that the "marketing authorisation holder" – the company or other legal entity authorised to market a product – for any medicines sold in Northern Ireland must be in the EU, the European Economic Area or Northern Ireland but not in Britain.

It is this requirement which is forcing medicines manufacturers to invest in reorganising regulatory filings, packaging and licences

on bespoke boxes of medicines for Northern Ireland to service a market in European teams that would be like making special arrangements in the Republic for medicines being sold in Mayo.

David commented, "Before the power cut issues in Dublin today impacting Parliament, we planned to focus on urgently needed solutions to ensure stable patient access to medicines in Northern Ireland and beyond.

"Many thanks to the Committee Cathaoirleach (Chairperson) Senator Lisa Chambers for the invitation to speak and at the new date in October, to express the views and suggested solutions of Medicines for Ireland and Medicines for Europe who represent companies who supply the majority of medicines daily across the island of Ireland, and throughout the EU.

"There are challenges upcoming to patients' access to medicines in Northern Ireland and beyond. Time is running out to fix this. Thankfully, the European Parliament will shortly consider legislative changes to help the situation. But, we haven't seen the proposals yet. The UK and Irish Governments and their regulators have worked tirelessly on related solutions. Let's redouble all our efforts.

"With many political representatives engaging with the Committee from Northern Ireland, EU and the U.S. such as Congressman Richard Neal and EU Commissioner Mairead McGuinness, the expert analysis of solutions and issues for the island of Ireland is a great service and legacy from this Committee. We look forward to playing our role too."

## New Concept Store for Hickeys

The West St Drogheda pharmacy team alongside Kenny Robertson, Retail Director of Hickeys' Pharmacy, Uniphar Group were delighted to welcome Drogheda and District Chamber Council member Linda Ennis to officially launch Hickeys Pharmacy's new concept store recently.

The newly refurbished store features an extensive range of Health and Wellness lines as well as leading Skincare and Beauty brands.



## Pharmacy Triage System Could Revolutionise Healthcare

Ending the underutilisation of Ireland's 1,900 community pharmacies should be a post-pandemic priority, according to the Irish Pharmacy Union (IPU). The IPU has called for the immediate introduction of a new Community-Pharmacy Triage System within its pre-budget submission [1] published recently.



Dermot Twomey, President, Irish Pharmacy Union

of three main services: use of emergency medicines, a minor ailment scheme and a minor injuries service.

Mr Twomey explained how a Minor Ailment Scheme would operate, "This would provide medical card patients with access to over-the-counter treatments free of charge and direct from their pharmacy. It would eliminate the need for GP visits for over 40 minor ailments including hay fever, migraine or common skin conditions.

"Minor ailment schemes operate successfully in many other countries such as the UK, Netherlands, Canada and Australia. The experience in Scotland shows us that it could eliminate one in 20 A&E visits and one in seven GP visits. With GPs consistently citing concerns over their capacity, at the stroke of a pen the government could free up over 1 million GP appointments a year."

Pharmacies' importance to the public has grown significantly during the pandemic and, according to community pharmacist and IPU President, Dermot Twomey, it is time to double down and make this a permanent aspect of our healthcare system. "Pharmacies kept their doors open throughout each lockdown, while the majority of people are now visiting GPs less often. This has meant that two out of five people now cite the pharmacist as their most important healthcare provider, a sharp increase on previous years.

"Pharmacies are open at convenient times, most services require no appointment and half the population lives within 1km of a pharmacy. This all explains why, with 1.5 million visits to pharmacies every week, it is the most accessed part of our health system. But despite years of promises, successive governments have failed to expand the range of services that pharmacies can provide," he said.

### Community Pharmacy Triage System

The Programme for Government commits to expanding pharmacy services.

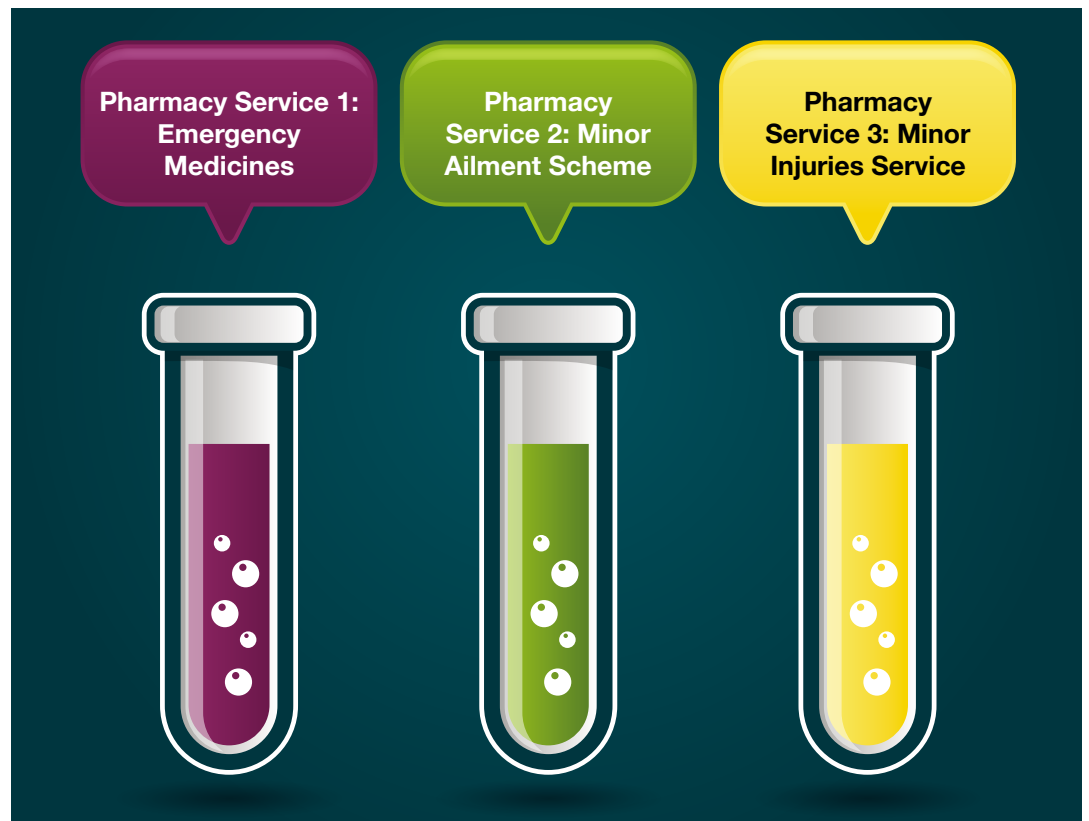
However, in the absence of any indication that this will be delivered, the IPU has developed and submitted proposals for a Community Pharmacy Triage System. Such a system, as operates in many other jurisdictions, would comprise

"As the government moves past the pandemic crisis and seeks to reform the delivery of healthcare in Ireland, they have to get serious about realising the potential of pharmacies as providers of primary healthcare within the community. A properly empowered pharmacy sector could deliver a revolution in community care from 1,900 locations across the country"

While the pharmacy profession is eager to do more to help patients it is essential that it is adequately resourced to do so. "Pharmacies cannot be expected to keep doing more for less. Last year pharmacists dispensed 81 million medications under state schemes and, despite this being a 3% increase, income remained unchanged. This is part of a longer-term trend that has inflicted €1.7 billion worth of cuts on the sector over a decade and has undermined pharmacies' ability to continue providing the services that people need and want."

"As the government moves past the pandemic crisis and seeks to reform the delivery of healthcare in Ireland, they have to get serious about realising the potential of pharmacies as providers of primary healthcare within the community. A properly empowered pharmacy sector could deliver a revolution in community care from 1,900 locations across the country.

Pharmacists have been ready and waiting for years but need the government to match that ambition."



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## President Post for Daragh

### Dungarvan Pharmacist elected President of FIP Community Pharmacy Section

Dungarvan pharmacist Daragh Connolly has been elected as President of the Community Pharmacy Section of the International Pharmaceutical Federation (FIP). FIP is the global body representing pharmacy, pharmaceutical sciences and pharmaceutical education.



Daragh Connolly, President of the Community Pharmacy Section of the International Pharmaceutical Federation (FIP)

Extending the IPU's congratulations, Secretary General Darragh O'Loughlin said, "Daragh Connolly has been a leading figure within community pharmacy in Ireland for many years. As a former IPU President he is a passionate and effective advocate for the sector and we are delighted that he will be bringing his expertise to a global stage.

"This is an endorsement of Daragh's personal acumen and also reflects the high international esteem in which Irish community pharmacy is held.

In a year in which Irish pharmacies have played such an important role in their communities, it's

heartening to see Irish community pharmacy having such an impact on the world stage."

"It is crucial that community pharmacies across the world continue to collaborate to drive development and progress in the pharmacy profession. With Daragh at the helm, we have every confidence that this will continue."

"It is fitting that Daragh's appointment has been announced as we are set to mark World Pharmacists Day which this year focuses on the theme of Trust. Public trust in Irish pharmacies has never been higher: Ipsos MRBI's annual Veracity Index for 2021 shows that pharmacists are now the most trusted profession among any sector in Ireland, surpassing nurses for the first time."

Daragh Connolly is a third generation pharmacist and qualified from the University of Portsmouth in 1997. He is the operator of Haven Pharmacy Connolly's on Main Street, Dungarvan which has been run by the Connolly family since 1973. Connolly served as President of the Irish Pharmacy Union from 2016 until 2020."

## Pharmacy Role in Mitigating Health Risks

Pharmacists must be allowed to do more to manage respiratory conditions in communities if the urgent need to address the harmful effects of air pollution on health is to be met, the International Pharmaceutical Federation (FIP) has said.

The expansion of pharmacists' roles in mitigating the health threats of air pollution is among several actions described in a call to action issued by FIP, marking the United Nations International Day of Clean Air for Blue Skies.

The call to action is based on priorities identified by a round table of experts organised by FIP in collaboration with The Clean Breathing Institute (TCBI) earlier this year. "Air pollution is one of the top 10 threats to global health, according to the World Health Organization, with harmful effects manifesting in cancer, stroke, allergies, chronic obstructive pulmonary disease (COPD) and asthma, among other serious conditions. FIP believes that pharmacists, at the hearts of communities and uniquely positioned to triage and manage people with respiratory symptoms and diseases, have the potential to make a huge impact on health outcomes," said FIP CEO Catherine Duggan.

The FIP call to action recommends pharmacy services that identify and reduce risk factors, such as smoking cessation, education on nasal hygiene and optimisation of inhaler technique for patients with COPD or asthma, as well as services that screen for vaccine hesitancy and social vulnerability. However, the federation recognises that policies are needed in order to increase public awareness of air pollution and pharmacists' related roles, and to scale up pharmacy education in this field. Recent findings of a survey by FIP and TCBI support a need for an expanded role for pharmacists in air pollution and respiratory health, and FIP has called for incentives to encourage these services to become mainstream practice.

## Pharmacy Group Research on Breast Cancer

A survey carried out by CarePlus Pharmacy shows 6 in 10 (61%) women in Ireland do not regularly check their breasts for lumps or abnormalities.

The independent pharmacy network surveyed over 800 women online in their research, which also found that;

- 52% of respondents had been directly or indirectly affected by an incidence of breast cancer
- 43% said they didn't check themselves regularly because they forgot
- 22% said they didn't check themselves because they don't know how
- Only 27% of the women who responded reported that they check their breasts every month, as is recommended by doctors

The survey was conducted ahead

of Breast Cancer Awareness Month held last month (October).

To support the initiative, CarePlus Pharmacy - and its sister brand StayWell Pharmacy - will distribute thousands of awareness leaflets throughout their Irish branch networks on behalf of Breast Cancer Ireland.

Breast Cancer Ireland says that 1 in 9 women will be affected by the illness during their lifetime, with approximately 3,700 cases being diagnosed annually. Early detection plays a huge role in treatment and recovery, which is why experts recommend women monitor their breasts for any changes.

Lee-Ann Hyland, Director of Marketing for CarePlus Pharmacy, says, "We decided to conduct this survey following a discussion around awareness amongst our female colleagues immediately after the tragic death of Sarah Harding. The survey shows that the majority of women are aware of the importance of checking their breasts, but that awareness is not being translated into action. If, by distributing information from Breast Cancer Ireland we make an impact in the life of a single Irish woman, then this will be a worthwhile exercise. The message is simple: check yourself and speak to your doctor if you are in any way worried."



# Building a culture of Mentoring in Pharmacy

## IOP launches a Mentoring Programme for pharmacists, by pharmacists

In October of this year, the Irish Institute of Pharmacy (IOP) launched its first Mentoring Programme for pharmacists. This evidence based, formal yet flexible programme is bespoke to pharmacists working in all practice areas and is the first of its kind offered to pharmacists in Ireland. Applications were invited from pharmacists from all sectors and all career stages, and the response exceeded places available. Another programme will be launched in May 2022.

**Here, Sarah Chambers, Mentoring Programme Manager for the IOP gives an overview of the mentoring programme to date. We talk about Mentoring in Pharmacy - the opportunities and challenges, the practicalities involved and we also hear the perspectives of some of the many pharmacists involved in building a mentoring culture in pharmacy.**

**So, Sarah, what exactly is mentoring?**

Mentoring is an important component of CPD and personal growth. It supports the development of a profession through supportive, nurturing relationships. A mentor acts as a sounding board and shares skills, knowledge and expertise whereas a mentee is supported through a transition in learning and is encouraged to develop their full potential. The relationship or partnership may cover a variety of contexts and when successful, it benefits the mentor, the mentee, the profession and patients.

**Why does it matter in pharmacy, right now?**

**Pharmacists are uniquely placed to mentor one another.** As a profession, we understand the challenges we face and the opportunities that exist and so are uniquely placed to be that sounding board, to ask those powerful questions or give some empowering advice to support and embed professional learning and growth.

Mentoring is one way to **harness the knowledge within the profession** such as understanding patient needs and experience, navigating the business and regulatory environment and the skills and experience of pharmacists and their teams. It is a way to **help others** by sharing access to this knowledge. It can work to reduce silos and barriers to entry across the profession and help participating pharmacists to **broaden perspectives and networks**.

Pharmacists flourish when they have the opportunity to **connect**

**with each other** - be it through training days or webinars. Pharmacy can be a solitary profession and Covid-19 has heightened this sense of isolation. Mentoring can address the sense of professional isolation many pharmacists feel and support people to remain professionally optimistic. The opportunity is here to be a profession that prioritises supporting and nurturing relationships as part of our professional identity. That feeling "it's not just me" or that sense of "giving back" and sharing your expertise is so important

Mentoring is a building block to becoming understood as a

profession, using our experience and unique position within the healthcare setting to develop the skills to build, influence and maximise performance. The IOP mentoring programme is working to build the belief in and understanding of mentoring across the profession and to drive a culture of self-leadership and leading others.

**What are the challenges or potential barriers to developing this mentoring culture in pharmacy?**

Mentoring is widely recognised as critical to the development of healthcare professionals yet it is not without its challenges:



**Having a formal structure for mentoring within our profession will**

1. Build our professional identity,
2. Expand our collective experiences
3. Build an effective support network of mentors for every stage of our career.

  
**Emily Kelly**  
Mentoring Pilot Steering Committee Member



**Before mentoring I was unsure how I could use my experience to help others.**

**Now I feel more confident in my own skills and happy I have given back to a profession that has been good to me**

  
**Margaret Doherty**  
Supervising & Superintendent Pharmacist  
Raphoe Pharmacy, Co Donegal



**Mentoring has been one of the most rewarding things I have done.**

**Try it. you will surprise yourself.**

  
**Margaret Doherty**  
Supervising & Superintendent Pharmacist  
Raphoe Pharmacy, Co Donegal

**1. Mentoring must be led by the profession.** Adopting a mentoring culture is something that has to be driven from the ground up, right across the profession because people see and feel the value of it for them and their teams. Developing a mentoring culture in pharmacy will take focus, learning and role models across the profession. The IOP mentoring programme was launched as a result of pharmacists who attended the initial Mentoring Skills Training back in 2019. These pharmacists recognised the value of adopting mentoring skills for their own development and that of their teams and the profession as a whole and wanted to know how they could work together to make mentoring more accessible for pharmacists. This proactivity is vital - taking responsibility for how and what happens in the profession.

**2. Mentoring takes time and effort and the benefits are not guaranteed.** A successful mentoring relationship takes effort and commitment. Mentoring is a volunteer role and often happens outside of your working hours. The effort you invest in building trust during the initial stages sets the scene for the relationship that follows so this time is not something you can rush through and tick off.

### How could this work in practice?

Earlier this year, 32 Pharmacists across Ireland recently completed a three month virtual Pilot Mentoring Programme, so we have seen that this can work in

**“**

I was initially nervous that I mightn't be able to help my mentee as he was working in a different sector- the worry was gone at the 1st meeting. The setting is different but it was easy to relate to what he was saying.

**”**



**Riona Tumelty**  
Senior Pharmacist in Oncology Clinical Trials at Tallaght University Hospital.

**“**

My mentee helped me develop my communication and leadership skills.

He gave me a new perspective on things and I learned a lot in the process.

**”**

It impressed me how much he achieved in such a short timeframe and it was nice to know I helped in some way



**Riona Tumelty**  
Senior Pharmacist in Oncology Clinical Trials at Tallaght University Hospital.

practice. The focus of the pilot was on supporting newly qualified pharmacists with their CPD and ongoing reflective practice as well as testing the validity of our evidence based framework. The programme was flexible by nature with orientation training and ongoing support provided by the programme team. Matching of the mentors and mentees was completed by the programme team based on mentee preferences, mentor experience, personality descriptors and diversity. The mentoring pairs reflected the breadth of the profession with both inter and intra practice area matching.

On average, during the Mentoring Pilot, mentoring pairs met for 60 minutes virtually every 3-4 weeks, outside of work, with time spent

for preparation and reflection in addition to this. This was during the pandemic, where pharmacists were already incredibly busy so it was humbling to see pharmacists giving their time to the mentoring relationship. Pharmacists who were involved fed back that mentoring actually gave them energy and that they looked forward to the sessions in their week.

### Outcomes

Pharmacists who took part in the pilot completed surveys prior to mentoring and at the end of the programme to see whether the pilot programme was impactful.

- 100% of pharmacists involved said the programme met their expectations and that they would want to be involved in continued mentoring initiatives.
- Improvements were seen in confidence and competence with reflective practice for the mentees.
- Improvements were seen for the mentors in their mentoring skills such as setting clear goals, acknowledging strengths, setting expectations and asking powerful questions.

### Who is involved?

This initiative is pharmacy-led and it is pharmacist volunteers who are driving this work nationally. The mentoring programme is for pharmacists, by pharmacists and is simply facilitated and supported by the IOP Mentoring Programme Team.

The **IOP Mentoring Programme Team** includes accredited coaches and a Mentoring Programme Manager to deliver a programme that is evidence based yet flexible in structure to accommodate the realities of the profession day to day.

The **Mentoring Steering Group** is sponsored by the Executive Director of the Institute, Dr Catriona Bradley, who is also an accredited coach. The steering group's role is to ensure appropriate governance and oversight of the programme and includes members of the programme team, influential members of the pharmacy profession as well as learning and development specialists.

More than 100 Pharmacists are now part of the **CONNECT Mentoring community** who meet quarterly to connect, learn new skills and discuss mentoring and its practice in Pharmacy.

This community is supported by **10 Mentoring Ambassadors** - pharmacists from across the profession who are leading the charge in bringing mentoring and its principles to life in pharmacy.

Here, two of our ambassadors share their experiences of being involved in the pilot mentoring programme.

### How can pharmacists who are interested in mentoring get involved?

#### 1. Sign up for some Mentoring Skills Training

Since 2019 over 100 Pharmacists have completed Mentoring Skills Training to date with additional training sessions to be offered in early 2022. The response to the training, run in conjunction with Kingstown College, has been hugely positive with pharmacists appreciating the practicality of the content and how applicable it is to their day to day work. Here's what some of the previous participants had to say about the programme;

*"I found it really interesting and helpful, and not purely from a professional perspective. The facilitator did a great job of keeping*



*the course running on track and making us all feel comfortable to express opinion and ask questions. I liked the added references the facilitator gave us to back up points in the learning, and also liked to hear from other participants - it was more interesting since many of us worked in different areas."*

*"My listening skills, with colleagues, manager and patients have been positively affected. I think the recommendations of assigning goals and assessing progress will stand to me and encourage me to professionally not shy away from challenges. It has made me realise that I would really like to take part in a formal mentoring contract, both as a mentee and a mentor, in the future."*

## 2. Join the CONNECT Mentoring Community

Our new CONNECT Mentoring community will give pharmacists who are interested in mentoring a place to come together as a community to connect, learn and share. As a member of the mentoring community you will receive regular updates on the programme and be invited to CONNECT events where you can;

- CONNECT with like-minded pharmacists across the profession on a quarterly basis at events, exclusive to you.
- LEARN about putting mentoring skills into practice and how the mentoring programme is developing. Think peer-led,

bite size, practical learning as well as regular updates on the programme.

- SHARE your ideas and your feedback so that together, we continue to build on the great work already happening.

The IOP are committed to supporting this CONNECT community to shape the future of mentoring for pharmacy. So far, we have invited pharmacists to join this CONNECT community if they have either completed the IOP Mentorship Skills Training and/or participated in our recent Pilot Mentoring Programme. If you would like to get involved get in touch with the IOP Mentoring Programme Team at [mentoring@iop.ie](mailto:mentoring@iop.ie).

It is time to cultivate a culture of mentorship within the Irish pharmacy profession. You can find out more on the Mentoring Homepage on the IOP website.

### About the IOP

The role of the Irish Institute of Pharmacy (IOP) includes the development and implementation of a CPD system for pharmacists in Ireland and the development of pharmacy practice in line with international best practice and evolving healthcare needs. The IOP supports pharmacists to engage with CPD and commission education and training programmes in line with National Policy.



### The Mentee's perspective - Providing me with the skills to navigate career steps with confidence and awareness

My name is Emer Lane and I am a community pharmacist in Cork. I qualified as a pharmacist in 2018 and have spent my career so far in community. I decided to take part in the IOP Mentoring programme as I was at a crossroads in my career. I spent much of the pandemic in Dublin and found I needed a change and felt mentoring would provide me with the guidance I required.

A key part of my mentoring experience was reflective practice; reflective practice in terms of my actual practice as a pharmacist rather than focusing on the clinical attributes. Myself and my mentor, Clare Fitzell, spent time exploring the trials and triumphs of my current role: the aspects I enjoyed, the areas I needed to improve to bring more fulfilment to my day-to-day practice and areas I didn't enjoy - how could I tackle them in a different way to improve the overall outcome.

We discussed how important it is to have your own learning and development as an ongoing priority. To take every opportunity, try new things, different areas and allow yourself to create your own career path - not only to think outside the box but to have the mindset to think and act as though there is no box. I suppose to a certain extent we can as "newly-qualified pharmacists" assume a certain career path without intention, without considering what we really want and without realising the ability and capability of our degree and career skillset.

Clare encouraged me and continues to encourage me to be actively present in my role as a pharmacist. Make connections in a wider healthcare environment, increase your knowledge, gain various perspectives and skillsets

and most importantly be motivated and encouraged by what you do - be your own best advocate.

Very few times in your career will you have the protected time to work with a mentor - to reflect on where you are now, where you want to be and how to get there. Having a mentor has endless benefits, just think back to your pre-reg/intern year and all you gained from your tutor. Before I completed this programme, I had some experience of the advantages I would gain from it since I completed my pre-reg and foundation pharmacist training with Boots Ireland who champion a mentoring environment. This programme cemented for me the fundamental role this relationship has, especially in the early years of one's career. I kept notes from my meetings with Clare and know I will undoubtedly refer to them in the future. Clare has provided me with the skillset needed to navigate each career step with both confidence and awareness.

I will end in saying a simple thank you. Thank you Clare for your uplifting and inspiring words and your practical and sensible advice to help me navigate my career. I'll take with me that if you never try you will never know. It won't always be perfect, it won't always be easy, but it should always be rewarding. Have an appreciation for what you do - not everyone has the privilege of our career.

*Emer Lane was partnered with Clare Fitzell, a mentor on the Pilot Programme*



### The Mentor's Perspective - A refreshing experience which helped me see I have a lot to give

Participating as a mentor in the Pilot Mentoring Programme was a refreshing experience. This opportunity helped me to regain my own confidence in the knowledge, skills, experiences that I have gained throughout my time as a pharmacist. Initially I was a little dubious that I would have what it took to help guide and advise my mentee, a newly qualified pharmacist, but the pilot experience really helped me to see that I have a lot to give.

I met with my mentee roughly every three weeks over a three-month period. We scheduled our meetings in advance for a time that suited us both and used Zoom to host the meeting. Although many people had become used to using online platforms for meetings, I wasn't, so was apprehensive about getting to know my mentee and sharing my own experiences this way. I settled in quickly though and loved the convenience of the online meetings. I was surprised how easily I could build rapport with my mentee and this in turn made for effective mentoring sessions.

Feedback following the pilot was positive and encouraging, boosting my own confidence and reassuring me that I could make a difference to the concerns and dilemmas of a fellow pharmacist. The opportunity for my mentee to be heard was highly valued and appreciated by my mentee. I'm glad that I could share uncomfortable and difficult lessons I have experienced over my career so that my mentee could learn from them. I encourage every pharmacist to consider taking part in this rewarding programme.

*Nadira Callachand*

## Pharmacists Urge Minister on Free Contraception Scheme

Community Pharmacists across Ireland have said called on Health Minister Stephen Donnelly to follow through with his commitment on a free contraception scheme.



Kathy Maher, Community pharmacist/Chairperson, IPU Pharmacy Contractor's Committee

contraception for women in the upcoming budget. This would be an extremely progressive development. However, placing pharmacies at the centre of any free contraception scheme would undoubtedly improve its efficiency."

The IPU's pre budget submission also advocates for oral contraception (the Pill) to be available without prescription. According to Maher "this would make access as easy as possible for women and greatly reduce pressure on GPs. Eliminating the requirement for GP involvement would be significantly more cost effective for the Government."

"Previous research in Ireland has shown that almost half of women would favour being able to access contraception from a pharmacy, so the Minister should follow through to ensure that this becomes a reality. The barriers to accessing contraception are not all financial; non-financial barriers to access, including the need to get a doctor's prescription, often cause

even greater difficulty and need to be addressed urgently.

"The Pill is one of the most widely used forms of contraception in the world. It is a safe and well-studied medicine and has been used by women for almost half a century. Pharmacists would be provided with training on the dispensing of the pill and on the selection and supply of the most suitable contraception."

Ms Maher also warned that Ireland should not fall behind its European counterparts, "France will offer free contraceptives for women up to the age of 25 from 2022 and women in the UK will be allowed to access two types of contraceptive pill over the counter after a short consultation with their pharmacist. Ireland must do the same and ensure that women can directly access contraception in pharmacies as it has been shown to be safe and effective in other countries."

She concluded, "We welcome the Minister's ambitions and we hope that they are implemented without delay. Providing women with better access to contraception by making it free and available without prescription means they will be given the freedom of choice and unwanted pregnancies will be reduced."

The Irish Pharmacy Union (IPU) has said plans to introduce free contraception for women in Budget 2022 would be greatly enhanced by placing pharmacies at the heart of this service. The IPU has been calling for free access to female contraception for several years and for the prioritisation of women's health. It has re-iterated this call in its pre-budget submission which has been provided to the Minister for Health, Stephen Donnelly.

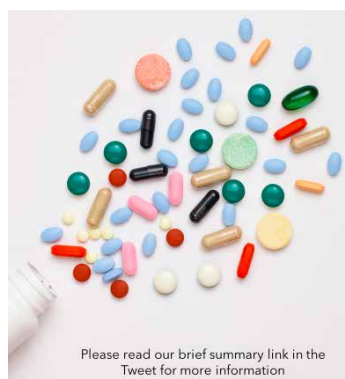
Kathy Maher, a community pharmacist and Chairperson of the IPU Pharmacy Contractor's Committee said, "Earlier this month Minister Donnelly stated that it was his ambition to introduce free

## Recruiting Community Pharmacists for Short Interview

PhD candidate, Ashleigh Gorman is recruiting community pharmacists for a short interview about how they manage medicines prescribed to older adults.

The research study which explores community pharmacists' role in managing appropriate polypharmacy for older adults in primary care in the Republic of Ireland (RoI), is being conducted by the School of Pharmacy and Pharmaceutical Sciences in Trinity College Dublin, in conjunction with the School of Pharmacy, Queen's University Belfast.

During the interview you will be asked about your experiences of managing appropriate polypharmacy for older adults, your views on how to improve the management of appropriate polypharmacy for older adults and the barriers and facilitators associated with how this could be done.



Please read our brief summary link in the Tweet for more information

### Participants wanted

**Who are we looking for?** Community pharmacists in the Republic of Ireland

**What is involved?** Short interview about how you manage medicines prescribed to older people

### Interested?

Please contact: Ashleigh Gorman, PhD Candidate  
[gormanas@tcd.ie](mailto:gormanas@tcd.ie)

## Women in Vision

The inaugural Women in Vision and Eye Research (WVER) Ireland conference took place at RCSI University of Medicine and Health Science recently. The conference brought together a community of academic and clinical medicine experts to share research and ideas that addresses key topics in all aspects of the field of eye care.

Organised by the RCSI School of Pharmacy and Biomolecular Sciences, the conference was addressed by speakers including Miss Julie Silvestri, Consultant Ophthalmic Surgeon Clinical Director at Belfast Health and Social Care Trust; Dr Sarah Atkinson, Lecturer in Stratified Medicine (Vision) at the School of Biomedical Sciences, Ulster University; and Dr Joan Ní Gabhann-Dromgoole, Lecturer in Immunology and Ophthalmology at the RCSI School of Pharmacy and Biomolecular Sciences.

Opening the conference, Professor Hannah McGee, Deputy Vice Chancellor for Academic Affairs at RCSI, said, "The Women in Vision and Eye Research committee was established in 2019 to address the gender disparity experienced by women in science, by providing a platform that recognises and supports excellence in eye care and research. We are delighted to host a conference focused on the latest scientific discoveries that is also uniquely aimed to support and promote the visibility of women at all stages of their careers."

The conference recognised the life and legacy of Dr Kathleen Lynn, pioneering doctor, socialist and public-health campaigner. Professor Louis Collum, Ophthalmologist at the Royal Victoria Eye and Ear Hospital (RVEEH), delivered a keynote address exploring her contribution to ophthalmology and healthcare. The inaugural Dr Kathleen Lynn award will be presented to the best overall early-stage researcher on the day.

The free event is organised by the WVER Ireland committee: Dr Joan Ní Gabhann-Dromgoole and Dr Emily Greenan from the RCSI School of Pharmacy and Biomolecular Science, and Diana Malata, Advanced Nurse Practitioner at RVEEH.



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# Ireland Celebrates World Pharmacists Day

“Pharmacy: Always trusted for your health” was the theme of World Pharmacists Day on 25 September.

At a time when trust barometers have found that distrust of societal leaders has increased and distrust of information sources is at a record high, fuelled by the Covid-19 pandemic and the infodemic around it, and when vaccines hesitancy remains a major hurdle, public trust in pharmacy is more important than ever.

For many years, pharmacists have consistently been named among the top five most trusted professionals in national surveys.

Educators are also consistently in the top five and, according to a recent survey, scientists are the most trusted people in the world.

Community pharmacies across Ireland marked the occasion. McKesson Ireland commented on their social media, “McKesson Ireland are grateful for all of the amazing work our pharmacists do for each of our patients around Ireland. Thank you for your hard work in delivering patient care. This has been especially important throughout the Covid-19



**WORLD PHARMACIST DAY** I I O P  
IRISH INSTITUTE OF PHARMACY  
**September 25th**

pandemic.” Sarah O’Connor, CEO of the Asthma Society of Ireland added, “A big thank you to all the pharmacists in Ireland who help and support respiratory patients and their families to manage their condition. We need your help to transform asthma management in Ireland - we believe in the impact of the intervention you make with patients to help them understand more about their asthma.”

The Irish Institute of Pharmacy echoed these sentiments stating, “The IIOF would like to thank

all pharmacists nationally and internationally for their tireless efforts and dedication not only during the pandemic but every day of the year.”

Allcare Pharmacy commended their local pharmacists saying, “Today on World Pharmacist Day, we celebrate all of our Pharmacists and their Pharmacy teams who deliver the best customer service and patient care to all of our valuable patients and customers across Ireland every day.”



“This year’s World Pharmacists’ Day, 25 September), is an opportunity to pause and consider the important role played by pharmacists in meeting the ongoing healthcare needs of people in Ireland and across the world. Whether in hospitals, in the community, or in research, teaching or regulation, pharmacists contribute their skills and knowledge every day to counter illness and to improve health, wellbeing and safety. This year, we are again reminded of the impact of the pandemic on people across our communities, on our healthcare services and on the many pharmacists who have worked on the frontline since March 2020. On World Pharmacists’ Day, PSI is proud to recognise the vital contribution of our 6,800 registered pharmacists and to acknowledge the many roles they play, including that of being Ireland’s most frequently accessed healthcare professionals.”



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was never going  
to stop me”

Alex Scott MBE  
Ambassador



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# Antimicrobial Stewardship – How Can Pharmacists Get Involved?



Written by Olivia Gallagher MPSI, Senior Antimicrobial Pharmacist, HSE Community Healthcare East

With World Antimicrobial Awareness Week coming up from the 18th-24th of November 2021, many of us are considering how we can contribute to the cause by increasing awareness and reducing resistance.

The overarching theme globally this year remains 'Antimicrobials: Handle with Care'. The campaign encourages all stakeholders including policy makers, healthcare providers and the general public to recognise that everyone can champion antimicrobial awareness.

As community pharmacists there are many resources available to support your active involvement in antimicrobial stewardship (AMS) and improve your knowledge in this specialist area of interest.

Within the HSE, a Senior Antimicrobial Pharmacist (AMP) has been recruited for each Community Healthcare Organisation (CHO) area. These AMPs play a central role in coordinating and managing the delivery of antimicrobial stewardship across the CHO and nationally. To support your education in antimicrobial stewardship, the following resources are recommended by the AMPs:

## 1. Irish Institute of Pharmacy (IloP)

We are pleased to announce that a new eLearning module on AMS has been designed specifically for community pharmacists by the IloP, in collaboration with AMRIC and is now available on the IloP platform for continuing professional development (CPD). It has been sub-divided into three parts: 'Setting the Scene', 'From Principles to Practice', & 'Case Studies'.

These can be completed in their entirety or accessed and completed individually when necessary or desired. The first module aims to highlight the basic principles of antimicrobial stewardship and the basic concepts of antimicrobial resistance as well as explaining the function of AMRIC and the national initiatives underway in Ireland to safeguard patients taking antimicrobials. The second module focuses on safety issues for those patients taking antimicrobials, the

safety concerns around various classes of antimicrobials and the resources available to support AMS. The final module reflects on the role of the community pharmacist in optimising antimicrobial use, how AMS can be incorporated into practice and how we can communicate the principles of AMS to relevant stakeholders e.g. patients, carers, nurses, doctors etc.

## 2. HSeLanD



HSeLanD is the Health Service Executive's online learning and development portal. It contains over 200 eLearning programmes, resources, assessments and planning tools to support you in your role and in your continuing professional development. It is a free resource and is open to all, not just HSE staff. You simply need to create an account and browse the platform.

AMRIC (Antimicrobial Resistance and Infection Control), in collaboration with the AMP group, has devised a series of education modules for HSeLanD which cover an array of topics around the subjects of Infection Prevention and Control (IPC) and AMS. Some of the most relevant modules available which relate to AMS in the community/ primary care setting include:

- a. AMRIC Introduction to Infection Prevention and Control and Antimicrobial Resistance



Antimicrobial Resistance and Infection Control Team

- b. AMRIC Antimicrobial Stewardship in Practice

- c. AMRIC Prevention and Management of Urinary Tract Infection

The suite of modules also includes a number of IPC modules which are very relevant to community pharmacists.

## 3. www.antibioticprescribing.ie

This is the National Antibiotic Prescribing Guidelines for Treatment of Infections in the Community. This website is an invaluable resource which includes a breakdown the various treatments and conditions regularly treated in primary care as well as many useful resources such as information on safe prescribing of antimicrobials, key messages from AMRIC as well as advice on antimicrobial use in pregnancy, renal impairment, paediatrics and penicillin allergy. This website is co-ordinated and updated regularly by a panel of antimicrobial pharmacists, GPs, microbiologists, infectious disease specialists and other consultants as well as having input from community pharmacists. It is used widely by GPs across the country and we recommend that all community pharmacists should be familiar with its content and refer to it as a primary source of guidance on antimicrobial dispensing.

For those community pharmacists carrying out dispensing and Medication Use Reviews for patients in long term residential care facilities, it can be difficult to find supportive, practical resources to aid in the safe dispensing and review of medication. The website has a section dedicated to antimicrobial use in long term care facilities including resources on antimicrobial prophylaxis, catheterised patients and results from a recent nationwide study on the antimicrobial use in HSE Residential Care Facilities for Older Persons. This report contains key findings and key recommendations which may form a useful base for

quality improvement initiatives for multidisciplinary teams in your long term care facilities.

## 4. Get Involved

World Antimicrobial Awareness Week encourages everyone to 'Go Blue' to raise awareness of antimicrobial resistance, one of the leading global threats to public health. You can 'Go Blue' in your community pharmacy by encouraging staff to wear blue and/ or donning your pharmacy with blue balloons and bunting. This encourages a conversation with patients about the importance of avoiding unnecessary antibiotic use this winter. [www.undertheweather.ie](http://www.undertheweather.ie) is a very useful resource to signpost patients towards, or use in your pharmacy to print information for patients. This website provides information aimed at the public to encourage self-care measures they can take to control symptoms of self-limiting infections such as conjunctivitis, sore throat, coughs, colds and many more. Stickers are also available from [www.healthpromotion.ie](http://www.healthpromotion.ie) or by emailing [healthinfo@hse.ie](mailto:healthinfo@hse.ie) to encourage children to 'fight the bugs' without antibiotics. As trusted healthcare professionals, one small conversation or intervention can have a lasting impact on your patients. **Will you 'Go Blue'** for antimicrobial resistance this November?

## 5. Twitter

Follow @AntibioticPresc on Twitter to keep abreast of the most recent updates to the Antibiotic Prescribing website as well as many other updates including upcoming events and webinars.



## 6. Contact Us

If you wish to contact your local antimicrobial pharmacist for advice, our details are all available on the 'About Us' section of [www.antibioticprescribing.ie](http://www.antibioticprescribing.ie)



# THE PEOPLES PHARMACIST AWARD



## Finalist

### Jonathon Morrissey

Lockdown during Covid brought about many health challenges.

Through vigilance and rapport with their patients and the public, community pharmacists are well placed to identify changes in behaviour and early signs of mental health problems including anxiety, depression, post-traumatic stress disorder, and substance or alcohol abuse.

It was within this remit, that Jonathon Morrissey became an invaluable and critical member of the wider community team within Clane – working with local Garda in identifying and supporting those most at risk.

One of Jonathon's key nominations came from local Garda Shane Smyth who told us, "We would have been lost without Marron's pharmacy. Throughout Covid they helped me support the most vulnerable in the community that most people could not see needed help.

"Their happiness, professionalism, helpfulness and care for the community is second to no one. Every member of staff goes beyond what anyone could be asked for and everyone leaves the store feeling better, both for the medical help and with a smile.

"In my role as the Community Garda I see what goes on behind the scenes and I wanted to let you know that Marron's Pharmacy ensures that the people of Clane's physical and mental health is always their primary goal. Our small town would be lost without them."

This was just one nomination from numerous, that we received for Jonathon. Both he and his pharmacy team are viewed as a critical member of the community family within Clane. For another nominee, his expertise and care during this extremely challenging time, ensured the children could return to school. Whilst the youngest member of the family has a compromised immune system which meant they couldn't attend a walk-in centre for Covid vaccination, Jonathon 'went above and beyond' in administering the vaccine in the pharmacy, alleviating a lot of stress and ensuring the family were protected.

Jonathon told us, "I love my patients. I always have. They are why I love doing what I do. They are why I teach this to other pharmacists because I think the pharmacy profession is amazing. Frequently we are not good, as a profession, at promoting our work. It's always humbling to receive recognition from your customers that you are making a difference and through this Award, pharmacists are able to once again remember why they are doing what they do.

"Dispensing medicines is important but it is and there is so much more to be done by us all."



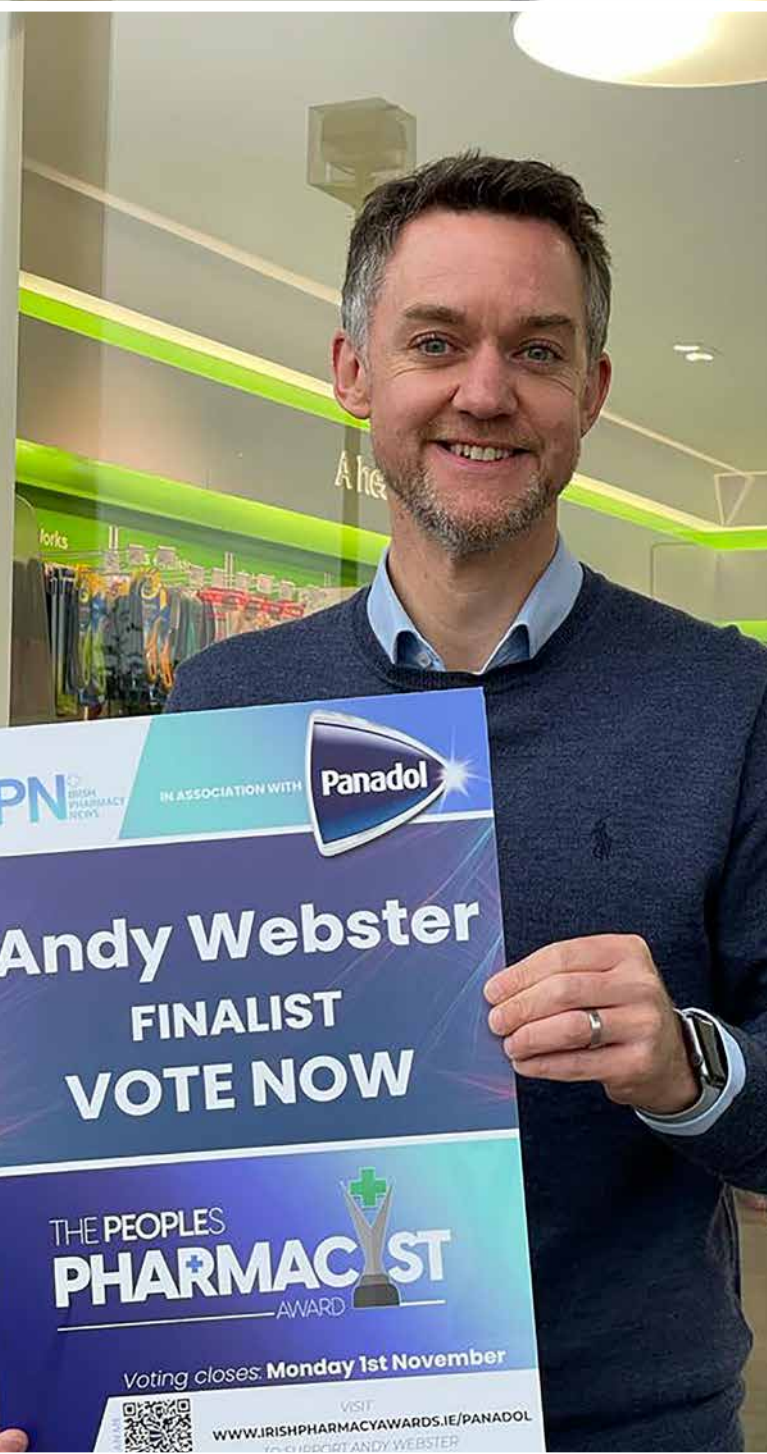
In association with Panadol

# THE PEOPLES PHARMACIST AWARD



## Finalist

### Andy Webster



he keeps such a close eye on her care. He has also delivered medications after-hours and late at nights when we needed it."

Sharon and her family also encountered the generosity of the wider community when DIY SOS Ireland ensured their home was adapted for their daughters care.

"Andy ensured he also donated time and services for the finishing touches the DIY SOS team needed. It is an honour to nominate him for The People's Pharmacist Award."

Andy has also made great efforts in protecting the elderly and most vulnerable within his community; ensuring flu vaccine supplies were in stock when the local GP surgery had none left. His customers have 'total and complete faith' in his care and knowledge.

Andy comments, "Having been a pharmacist in Limerick for over 18 years, the last 18 months have been challenging, but they have also shown the best in community pharmacy.

"My team in Annacotty have gone above and beyond to deliver services to our area at a time when many people's needs have changed immeasurably. The real value of a community pharmacy is that it integrates into the heart of a community.

"From young families, to the elderly, to schools, sports teams and everything in between. Our aim is simple - to make everything a little bit easier for people."

Andy Webster, Pharmacist and Owner at Halley's Pharmacy in Annacotty, Limerick has made a huge and measurable difference to the lives of his customers and patients.

From one with a diabetic child who relies on Andy's expertise and knowledge to help with their care, to remaining in the pharmacy after hours to help those who have been unable to access emergency services.

Sharon Mulcahy nominated Andy in recognition of his commitment to her family during recent months.

After her daughter suffered a near-drowning accident in 2019, the support given by Andy and his team at Halley's Pharmacy has been a lifeline.

She says, "Andy has been so committed to all of his customers, going above and beyond to accommodate everyone. Halley's Pharmacy been my local pharmacy for sixteen years, I personally can't thank them enough for the amazing dedication they have shown towards me and my family. The support he and his staff have given has made such a difference to our lives.

"There has been times Andy will remind me which medication my daughter needs, and when as



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1. Laska EM et al. JAMA 1984; 251(13): 1711-1718

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## TOUGH PAIN RELIEF

# THE PEOPLES PHARMACIST AWARD



## Finalist

### Catherine Power



“Living as someone with a disability and with subsequent constant medication needs, it is a life saver to have Catherine at hand. I never have to worry about my prescriptions or running out of medication; she has streamlined all of these for me so I never need to worry.”

For one local customer, who says she didn't understand the real value of her local pharmacy until she became very unwell, Pharmacist Catherine Power has been a vital part of her care package.

Catherine, Superintendent Pharmacist at Moorefield Pharmacy in Newbridge, has displayed a wealth of knowledge, care and compassion to all her customers and patients within her local pharmacy community but during the last 18 months that dedication has gone even further.

Catherine's nominee says the pharmacy is a vital link in the chain of ongoing treatment and care - an essential and expert link. “Catherine and her team take time to explain, to reassure and nothing is too much trouble for them.

“As someone who suffers from an acquired brain injury, my medication list can be quite endless. I suffer from epilepsy, psoriasis, eyesight problems, hearing loss and breathing issues but with Catherine as my community pharmacist I am never concerned as she takes complete charge of my needs.

Catherine comments, “For me working through the pandemic has really highlighted the importance of the community aspect of community pharmacy. During the past few months we have had tears, laughter and kind words with patients at the counter as we adapted to the ever changing and developing place the pharmacy holds.

“We, as a team, have worked hard to provide a service to our customers and allay their worries and fears during this difficult time. Having this effort acknowledged in such a lovely way by one of our patients is incredibly rewarding and makes our hard work worthwhile.”

# THE PEOPLES PHARMACIST AWARD

## Finalist

### Ellen Davis

Pharmacists have always been trusted health care professionals, but they left no doubt that they are heroes during the pandemic.

Across the country, community pharmacists have played a crucial role in helping to keep healthcare services going and accessible; consistently visible on the frontline, often taking on new roles outside of their remit, and expanding and providing their expertise.

One such pharmacist is Ellen Davis, Pharmacist and Owner at Davis Pharmacy in Eyrecourt, Galway who has been shortlisted as a Finalist.

When one of Aileen Howard's children fell ill, she knows exactly who stepped up. She comments, "Ellen went above and beyond for our family when it was needed the most.

"Whilst the necessary medication could not be sourced for the child at Crumlin Hospital in Dublin, or anywhere nearby, Ellen spoke directly with the hospital and was able to make up appropriate dosing. She checked in with the hospital, she liaised with us every step of the way.

"Ellen is a tremendous asset to our community. She is extremely knowledgeable, kind and compassionate – but more than that she truly cares about her customers who are more than just customers, they are neighbours, friends and family."

A nominee added, "Ellen is amazing to everyone in our village for advice and support she is always on hand to give advice. I would even go to Ellen before trying to make an appointment with my local GP.

"The whole community respect for her as both a friend and as a professional. We are blessed to have Ellen in our village."

Ellen says, "Community pharmacy is typically at the heart of all communities, across Ireland. It has been challenging during the last 18 months but truly an honour to be able to provide assistance to our customers and patients.

"When the pandemic is over, we will still be here, doing what we are passionate about and offering the same service. I am very humbled to have been nominated for this Award."



In association with Panadol

# THE PEOPLES

# PHARMACIST

## AWARD



# Finalist

## Nigel Moloney



to attend for an hour or two but he unhesitatingly volunteered his time and attended our vaccine roll out for 6 full days in 3 different sites, all on his own time.

Nigel Moloney, Co-owner and Supervisor Pharmacist with CarePlus Pharmacy in Carrigaline has become recognisable during the pandemic due to his efforts and work with the homeless community in Cork.

Making sure no-one misses out, he has dedicated a huge part of his time to assisting this sector and last Christmas also helped organise the distribution of over 500 care packs for men and women in need.

Dr Anna Marie Naughton, GP with the Adult Homeless Integrated Service says, "Nigel Moloney has made sure no-one misses out, as he has dedicated a large part of his time assisting the homeless community in Cork.

"Nigel has a longstanding relationship with the homeless services, we have worked closely with him providing medication for people with severe and enduring mental health, addiction including alcohol, polysubstance issues and the use of methadone substitution in heroin addiction.

"During our roll out of the Covid vaccine in homeless services during the summer, Nigel was an essential part of the team. We contacted him to help us with the vaccine. We had hoped for advice and that he might be able

"He was so patient and methodical. It was a very complex undertaking and the presence of a qualified pharmacist managing the vaccines with crucial and no vaccines were wasted or unaccounted for. He provided training to the clinicians onsite. He was completely professional, a pleasure to work with and has already volunteered to assist with any booster rollouts."

Comments Nigel, "Pharmacists in all communities can be a shoulder to cry on, not just someone who dispenses your medicines. It has been heart-warming and hugely rewarding to be part of the homeless projects around Cork.

"Our aim is simple - to provide the same level of care and attention to those who are marginalised or socially excluded as we do to those who attend the pharmacy in person. To have been recognized for this work was not expected, but so hugely appreciated. I am delighted at the light this Award is shining on the excellent and dedicated work being carried out by pharmacist colleagues across the country and anything that highlights the ongoing needs of the homeless people in our communities is most welcome as we start to enter the winter months."



# THE PEOPLES PHARMACIST AWARD



## Finalist

### Bairbre Boyle

Bairbre Boyle, Supervising Pharmacist & Pharmacy Manager at Healthwise Pharmacy, Greene's Corner in Dungloe has been nominated for her prompt actions in dealing with a patient who walked into the pharmacy suffering from acute anaphylaxis after eating prawns.

"Bairbre is kind, knowledgeable and shows empathy to all the patients and customers who cross her path," they comment. "She has all the qualities a good community pharmacist should have."

She required double treatment with adrenaline pens before being taken to hospital – medical staff confirmed she was in acute anaphylactic shock but thankfully she returned the following day to express her gratitude and made a full recovery.

James Cassidy is Director/Owner of Healthwise Pharmacy Group and he says, "The list of personal tributes and accolades are too numerous to mention for Bairbre. I personally endorse her for this Award."

"Bairbre always goes above and beyond for her patients and staff, from opening the Pharmacy early on a regular basis to give a personal shopping service to an elderly patient (this started at Christmas but became a more regular feature throughout the pandemic) to regular personal deliveries to patients.

"She also offers mental health counselling, which we all know is so important during these times. Several patients have made it known that Bairbre has personally saved them from bad outcomes by being there and being approachable and encouraged others to seek out her counsel which is always given freely."

Bairbre comments, "It is an honour to be nominated for this Award. It came as such a surprise."

"I must say - you're only as good as the team behind you. I am so proud of my staff- in how they acted and supported me in that emergency situation and in general- they always go above and beyond."

"As a pharmacy team we worked hard to provide a good service and to ensure everyone stayed safe as the pandemic unfolded. We always endeavour to provide a high level of care to both our patients in the community and in the two local hospitals that we look after. It is nice to be acknowledged for our hard work during these trying times."



In association with Panadol

THE PEOPLES

PHARMACIST

AWARD



Finalist

Anna Gudmundsdottir



maintain socially distancing and lessen my risk of catching Covid.

"I could list her attributes for days, but there aren't enough words to describe how amazing she has been to me and my family during what would have been an otherwise extremely challenging and difficult time. Anna really is the heart of our community."

Anna comments, "When Covid first arrived on Ireland's shores we knew as a pharmacy it was time to step up for our community. My priority has always been for the safety of our customers and that has meant ensuring they always have access to medicines and their health needs addressed. I am overwhelmed that my customers have valued this so much by nominating me for The People's Pharmacist Award."

"I think it's important to add that my job wouldn't be possible without the help and support of my pharmacy team who have all worked to the best of their ability in order to help the pharmacy remain open during a very difficult and worrying time."

"They too went above and beyond in making sure patients received their medication while cocooning by doing home deliveries and offering additional assistance."

Also shortlisted as a Finalist is Anna Gudmundsdottir, Supervising Pharmacist at Haven Pharmacy in Dunshaughlin.

Anna was nominated by a patient from her local community who has described her as a 'lifeline' when it comes to her care.

Not only that, but she has been described as a pharmacy professional who not only exhibits knowledge and expertise in abundance, she is a 'breath of fresh air' for all customers; always taking time out of an incredibly pressured and busy day to check in on others and those around her.

Having been diagnosed with cancer at the beginning of Covid, Anna and her pharmacy colleagues have consistently gone above and beyond, dropped chemotherapy medication directly to the door, calling the patients GP to check on dosing and prescriptions and even bringing necessities from home to the hospital while visiting was restricted for families.

"Furthermore, Anna organised for my whole family to receive our Flu vaccines at a time when no-one else was in the shop, to help me





# THE PEOPLES PHARMACIST AWARD



## Finalist

### Hilary Dolan

Finalist Hilary Dolan, Pharmacist and Owner at The Mill Pharmacy in Coolaney, Sligo has been described by her customers as the pillar of her community.

“Hilary always provides service with a smile. She has stepped up over and beyond during this pandemic and has been a friend, a counsellor, a medical advisor and a breath of fresh air to both young and old during this season,” said one customer.

Hilary quite literally saved the life of her nominee, June Boyle. During a routine eye test in June of this year, it was identified June had a bleed on the brain. However, with GP surgeries remaining closed, it was her on-call GP who had to contact Hilary out-of-hours to open the pharmacy for high dose steroids for the swelling to her brain, prior to June getting to Galway University Hospital.

“I have the best pharmacist in the world,” reflects June. “What rapidly turned into a medical emergency and a fight for life for me was terrifying but Hilary ever faltered in her care and compassion.

“Her fast action and quick response literally saved my life. I have since been diagnosed with stage 4 cancer. Hilary has been remarkable. Her support has been invaluable.

“She brings the medication to my house on days there is no one to

pick it up. She explains and goes through everything so thoroughly as she knows my brain takes bit longer to process information. Her patience, kindness, positivity is truly remarkable. I am grateful everyday to have such an amazing support pharmacy in my village.”

Hilary comments “Without a doubt, nomination for such an Award is an enormous honour for me, professionally, but also, to a far greater extent, personally.

These past 18 months have been unparalleled in the challenges that they have brought about, not least in our community.

“Yet, to read such sincere and heartfelt comments from June, a woman who has exuded class and courage throughout the challenges that have come her way over the pandemic, is a touching reminder of why I became a pharmacist.

“While any recognition for my work is of course welcome, the appreciation of my patients here in Coolaney, where immense hospitality and friendliness is a given, is as fulfilling an Award as I could ask for.”



In association with Panadol

# United Drug Values the Importance of Mental Health

October was mental health awareness month and depression and other mental health illnesses have increased in prevalence during the pandemic. In 2020, 41% of adults felt symptoms of anxiety and depression compared with 11% in 2019 (CSO.ie, 2021).

In September 2020, United Drug and its 3 sister companies voted on who the next charity partner would be. The response was overwhelmingly in favour for AWARE, your supporting light through depression. Showing that as a collective, they value the importance of mental health in the workplace and in daily life. From this United Drug and allies have committed resources to raise awareness for the valuable resources and support available from AWARE and fundraise to support the same.

AWARE seeks to create a society where people affected by stress, depression, bipolar disorder and mood related disorders are understood, supported, free from stigma and are encouraged to access appropriate therapies.

AWARE aims to achieve this vision through support services, programs, information and resources for those suffering and family members of those with mental health concerns. This support includes a dedicated support line, support mail and support and self-care group services.

Evidence of an increased demand for AWARE's support line was shown in 2020 with a 36% increase in support line calls in 2020, with peaks over 80% increases in the early days of the pandemic. This demand has been a sustained into 2021 with almost 16,000 calls being received into the support line in the first 6 months of the year.

AWARE can't provide these vital support services without access to resources.

To align with AWARE's mission and support their vision United Drug, LloydsPharmacy, TCP



1: At the Spinc in Glendalough on the 25th September.

2: The Galtymore Mountain team after hiking 8km in the rain.

3: Preparing to hike the 13km Spinc route at Glendalough.

4: Tough terrain and even tougher weather couldn't stop the Galtymore Team.

5: Team Spirit: The three hikes over two weekends provided a much needed opportunity for colleagues from United Drug, TCP, Lloyds Pharmacy & Median Health Care to interact safely in person and for a good cause.

The group hikes were also a great opportunity for colleagues to safely reconnect after in some cases as much as 18 months away from the office. The teams embodied what it means to come together and win as one team. Well done to all who participated, great team spirit was shown indeed.

United, they showed that when asked, they show up, no matter what the weather or the challenge, to rally behind the goal of improving mental health across the republic of Ireland.

Fundraising for AWARE is continuing with colleagues taking initiative to complete their own challenges into October for Mental Health Awareness month. Other members from across UD/ LloydsPharmacy/TCP/Median also doing their own challenges.

To join us in support of a good cause, you can donate today via the corporate charity site: <https://mckesson.blackbaud-sites.com>

**References:**

<https://www.cso.ie/en/releasesandpublications/ep/p-sic19wbg/socialimpactofcovid-19surveyfebruary2021well-being/>

and Median Colleagues joined forces to Hike for AWAREness in September and October.

For this initiative, the challenge level was stepped up:

Hiking up Galtymore Mountain in Co. Tipperary or completing a 13km trek up to the Spinc at Glendalough Co. Wicklow. Because we know, that dealing with depression and other mental health concerns is not a walk in the park. Sometimes it feels like climbing a mountain in weather so bad you can't see the summit, like our team climbing Mt Galtymore experienced.

Or, it takes longer than you thought it would, like the teams hiking in Glendalough experienced on their 4-5 hour route to the spinc.

That's the real challenge of dealing with mental health challenges, it takes endurance.



# Grow your Business with United Drug

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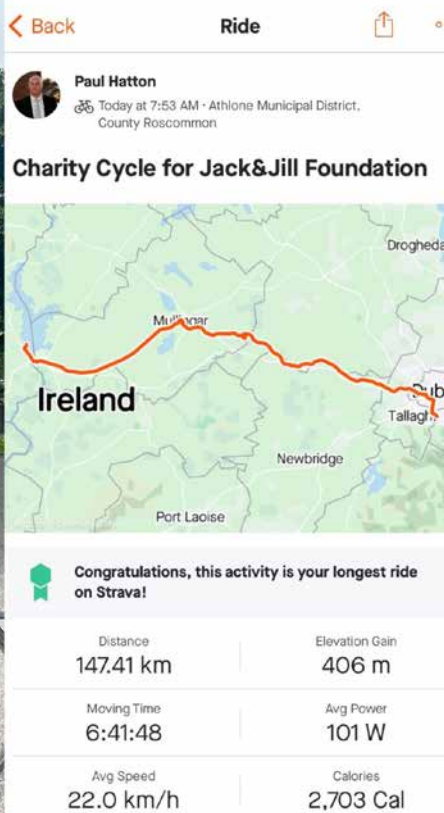


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## A Commute with a Difference

Congratulations to Paul Hatton, National Field Sales Controller, Ireland with Perrigo as he recently dusted off his helmet and began a commute with a difference.



Paul Hatton, National Field Sales Controller Ireland, Perrigo

Paul cycled from Roscommon to Dublin (a distance of 147km) in an astounding 6 hours and 41 minutes in aid of a local charity – the Jack & Jill Foundation.

During this immense challenge Paul helped raise over 127 home nursing hours for Jack & Jill families across the country.

The Jack and Jill Foundation recently won the Charity Excellence Award for Digital Innovation for Incognito 2020, which was announced by the Charities Institute Ireland.

Pre-Covid, #Incognito20 involved two collections of original artworks which were to be sold in April and September 2020 across two art galleries in Dublin and Cork. In a very challenging time, the team were able to quickly move from an in-person event to an online event.

The exhibition sold out in a day, and collectively, Incognito has seen over 11,800 original pieces of art sold over the five years since its inception, raising over €625,000 for Jack & Jill.

This is Incognito's third prestigious award in five years, having won previously for creativity, staff engagement and now digital innovation.

## New Ipsos MRBI Survey

Young people are still less likely to get vaccinated for Covid-19 compared with the population overall, according to the latest research carried out by Ipsos MRBI for the Irish Pharmaceutical Healthcare Association (IPHA), the representative organisation for the originator biopharmaceutical industry.

The research shows that vaccine hesitancy is at 13% in the 18 to 34-year-old age group. That figure is composed of 8% who said they would refuse a Covid-19 vaccine and 5% who said they were unsure. In the population overall, Covid-19 vaccine hesitancy is 9%, with 6% saying they would not get vaccinated for the disease while 3% are unsure.

Overall, 91% of people either intend to get vaccinated for Covid-19 or have already received a vaccine for the disease, according to the research. The results show that 2% of people will take a vaccine but, when combined with the cohort that has received at least one Covid-19 vaccine dose, or 88% of the sample\*, that number rises to 91%. Just 6% of people would refuse a vaccine – a proportion that has remained relatively stable since the start of the year.

Bernard Mallee, Director of Communications and Advocacy at IPHA, said, "Even though vaccine hesitancy is more prevalent in younger people than the overall population, Ireland's vaccination rate in the community is still among the highest in Europe. There should be no room for complacency, though. It is vital that we engage with people of all ages in continuing to build trust in science and in facts, and in maximising vaccinations across the eligible population. We have clear evidence of the real-time effectiveness of vaccination for Covid-19. Strong public health messaging on safety – whether during trials or in the community – helps to build public confidence."

## Fresh Hope for Lung Disease

Tuberculosis (TB) is still one of the biggest infectious killers in the world. Multiple drug resistant (MDR) TB has become a global health emergency, an emerging European crisis, and an important Irish public health concern.

Now a research team based in the Trinity Translational Medical Institute (TTMI) at St James's Hospital are offering fresh hope for improving treatments for what remains a deadly disease, by focusing on identifying potential host-directed therapies that can target a patient's own immune response to help them recover from TB.

The research team has previously discovered that human immune cells change the way they use energy when they become infected. This change results in the generation of lactate, which was once considered a waste product of metabolism. New work by the team has shown that lactate can influence cells in the lung environment, to support immune defenses against infection and

at the same time limit collateral damage to the delicate lung caused by excessive inflammation. The research team is based in Professor Joseph Keane's TB Immunology lab at TTMI.

Dr Cillian Ó Maoldomhnaigh undertook this research as part of a PhD project funded by the National Children's Research Centre and the Royal City of Dublin Hospital Trust. He said, "Lactate has an immediate and striking effect on the metabolic function of human immune cells and reduces their ability to change their metabolism in response to subsequent infection. This has the knock-on effect of reducing inflammation, which can cause damage in the lung. We've also found that lactate can promote a cell's waste removal processes,

allowing it to effectively dispose of the infection."

This waste removal process, called 'autophagy', also plays a role in a wide range of other disease states such as Crohn's disease, cancer and heart disease, this indicates that lactate may hold therapeutic potential in many disease settings.

Senior author on the paper, Dr Sharee Basdeo, Clinical Medicine, TTMI is excited about the impact this work may have. She added, "Our data indicate that aerosolised lactate delivered to the lungs may hold potential as a host-directed therapy for people battling lethal pneumonias – such as TB and Covid-19, where there is destruction of pulmonary tissue due to an unchecked pro-inflammatory response."

# COLD & FLU?



**NEW**



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PA0074/067/006  
Date of preparation: 6/21 CCF: 23764

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#### ABBREVIATED PRESCRIBING INFORMATION

Product Name: Brupro Cold & Flu 200 mg/30 mg film-coated tablets. Composition: Each film-coated tablet contains 200 mg ibuprofen and 30 mg pseudoephedrine hydrochloride. Description: Yellow, round, film-coated tablets. Diameter: approx. 11 mm, height: approx. 5 mm. Indication(s): Adults and adolescents aged 12 years and older: For the symptomatic relief of nasal/sinus congestion with headache, fever and pain associated with the common cold and flu. Dosage: 1 tablet every 6 hours if necessary. For more intense symptoms, 2 tablets every 6 hours if necessary, to a maximum total daily dose of 6 tablets (equivalent to 1200 mg ibuprofen and 180 mg pseudoephedrine hydrochloride). The maximum total daily dose of 6 tablets must not be exceeded. For short-term use. The patient should consult a doctor if symptoms worsen. The maximum duration of treatment is 4 days for adults and 3 days for adolescents aged 12 years and older. In situations where the symptoms predominantly consist of either pain/fever or nasal congestion, administration of single entity products is to be preferred. Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms. The tablets should be swallowed whole without chewing with a large glass of water, preferably during meals. Contraindications: Hypersensitivity to ibuprofen, pseudoephedrine hydrochloride or to any of the excipients; Patients aged under 12 years; Pregnant women during the third trimester of pregnancy; Breast-feeding mothers; History of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy; Active, or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding); Severe heart, liver or renal (glomerular filtration below 30ml/min) failure; Conditions involving an increased tendency to bleeding; Patients with known hypersensitivity or who have experienced asthma, urticaria, or allergic-type reactions after taking ibuprofen, aspirin or other NSAIDs; Severe cardiovascular disorders, coronary heart disease (heart disease, hypertension, angina pectoris), tachycardia; Hypertension; Diabetes; Pheochromocytoma; History of stroke or presence of risk factors for stroke; History of myocardial infarction; Closed-angle glaucoma; Urinary retention; History of seizures; SLE; Use of MAOIs. Warnings and Precautions for Use: Concomitant use with other NSAIDs including cyclo-oxygenase (COX)-2 selective inhibitors should be avoided. If symptoms persist beyond the recommended maximum duration of treatment with this medicinal product (4 days for adults and 3 days for adolescents), measures to be taken should be re-evaluated, in particular the possible usefulness of an antibiotic treatment. Acute rhinosinusitis, suspected to be of viral origin, is defined by moderate intensity, bilateral rhinological symptoms dominated by nasal congestion with serious or puriform rhinorrhoea, occurring in an epidemic context. The puriform appearance of rhinorrhoea is common and does not systematically correspond to bacterial superinfection. Sinus pains, during the first days of the illness, are associated with congestion of the sinus mucosa (acute congestive rhinosinusitis) and most often are resolved spontaneously. In the event of acute bacterial sinusitis, antibiotic therapy is justified. Special warnings related to pseudoephedrine hydrochloride: Discontinuation in development of hypertension, tachycardia, palpitations, cardiac arrhythmias, nausea or any neurological signs such as onset or worsening of headache. Refer to the SPC for other warnings on use and discontinuation requirements. Precautions for use related to pseudoephedrine hydrochloride: Discontinue treatment several days before surgery if volatile halogenated anaesthetics are to be used due to risk of acute hypertension. Athletes: Possibility of positive results in doping tests. Interference with serological testing: Pseudoephedrine has the potential to reduce iobenguane I-131 uptake in neuroendocrine tumours, thus interfering with scintigraphy. Special warnings related to ibuprofen: Bronchospasm may be precipitated in patients suffering from, or with a history of bronchial asthma or allergic disease. Do not take in cases of asthma without prior consultation with a doctor, as an acute asthma attack can be precipitated, particularly when allergic to acetylsalicylic acid or an NSAID. Patients who have asthma associated with chronic rhinitis, chronic sinusitis and/or nasal polyposis have a higher risk of allergic reactions when taking acetylsalicylic acid and/or NSAIDs. Refer to the SPC for more information on medication overuse headache (MOH), blood clotting disorders, gastro-intestinal bleeding, ulceration or perforation

## If you need effective relief take it. If you don't don't.

(discontinue immediately in these cases), history of gastro-intestinal disease (ulcerative colitis, Crohn's disease), alcohol, risk of arterial thrombotic events (particularly at a high ibuprofen dose of 2400 mg/day), serious skin reactions. Discontinue at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity. Consider carefully in uncontrolled hypertension, congestive heart failure (NYHA II-III), established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease and high doses (2400 mg/day) should be avoided. Precautions for use related to ibuprofen: Monitor the elderly carefully, due to increased frequency of NSAID-related undesirable effects, particularly gastro-intestinal bleeding and perforation, which can be fatal. Monitor in history of gastro-intestinal disease (such as peptic ulcer, hiatus hernia or gastrointestinal bleeding). Monitor urine output and renal function initially in heart failure, chronically impaired renal or hepatic function, patients taking diuretics, hypovolaemia as a result of major surgery. If visual disturbances occur during the course of treatment, a full ophthalmological examination should be carried out. Interactions: Refer to the SPC for detailed information on interactions. Combination of pseudoephedrine with: Non-selective MAOIs (iproniazid); Other indirectly-acting, orally or nasally administered sympathomimetics or vasoconstrictor agents,  $\alpha$ -sympathomimetic drugs, phenylpropanolamine, phenylephrine, ephedrine, methylphenidate; Reversible inhibitors of monoamine oxidase A (RIMAs), linezolid, dopaminergic ergot alkaloids, vasoconstrictor ergot alkaloids; Volatile halogenated anaesthetics: Guanethidine, reserpine and methyldopa; Tricyclic antidepressants; Digitalis, chinidine or tricyclic antidepressants. Concomitant use of ibuprofen with: Other NSAIDs, including salicylates and COX-2 selective inhibitors; Digoxin; Corticosteroids; Anti-platelet agents; Acetylsalicylic acid; Anticoagulants (e.g.: warfarin, ticlopidine, clopidogrel, tirofiban, eptifibatid, abxiximab, iloprost); Phenytoin; Selective serotonin reuptake inhibitors (SSRIs); Lithium; Probenecid and sulfapyrazone Diuretics, ACE inhibitors, beta-receptor blockers and angiotensin-II antagonists; Potassium sparing diuretics; Methotrexate; Cisplatin; Tacrolimus; Zidovudine; Sulphonylureas; Quinolone antibiotics; Heparin; Ginkgo biloba. Pregnancy and Lactation: Contra-indicated during breastfeeding and the third trimester of pregnancy and should only be given if clearly necessary during the first and second trimester. Ability to Drive and Use Machinery: Minor or moderate influence on the ability to drive and use machines. Patients who experience dizziness, hallucinations, unusual headaches and visual or hearing disturbances should avoid driving or using machinery. Single administration or short-term use of this medicine does not usually warrant the adoption of any special precautions. Undesirable Effects: Common: Gastrointestinal discomfort, dyspepsia, abdominal pain, nausea, vomiting, flatulence, diarrhoea, constipation, minor gastrointestinal blood loss in rare cases leading to anaemia. Refer to the SPC for other undesirable effects. Marketing Authorisation Holder: Rowa Pharmaceuticals Ltd., Bantry, Co. Cork. Marketing Authorisation Number: PA0074/067/006. Further information and SPC are available from: Rowex Ltd., Bantry, Co. Cork. Freephone: 1800 304 400 Fax: 027 50417. E-mail: rowex@rowa-pharma.ie Legal Category: Not Subject to medical prescription. Date of Preparation: May 2021. Adverse events should be reported. Reporting forms and information can be found on the HPRA website ([www.hpra.ie](http://www.hpra.ie)) or by emailing Rowex [pv@rowa-pharma.ie](mailto:pv@rowa-pharma.ie)

## LloydsPharmacy Launch Winter Health Index

Covid-19 has brought health into focus for many of us and LloydsPharmacy research shows 6 in 10 (61%) adults have made changes to their life to help make their health more of a priority. With this new focus on health, LloydsPharmacy is launching their first ever health index to track progress related to these positive changes people are making to their health.



Denis O'Driscoll, Superintendent Pharmacist, LloydsPharmacy

still high in Ireland there is a possibility of co-circulation of flu and Covid-19 this winter, therefore the flu vaccination is crucial to protect those most at risk of serious illness.

82% of those over the age of 65 are planning to get the flu vaccine and 12% of people have started taking vitamins or supplements as a result of the pandemic.

Covid-19 has clearly had an impact on the flu vaccine uptake, as well as an increase in those planning to get the vaccine, research shows that 4 in 10 adults (40%) claim they are more likely to get the flu vaccine this year specifically as a result of the Covid-19 pandemic.

In 2020 LloydsPharmacy saw a 50% increase in flu vaccine uptake and even higher numbers are expected in pharmacies around Ireland this year due to the ongoing pandemic. Flu

vaccination is a crucial step in protecting not only personal health but also protecting at-risk groups including those 65 and over, people with impaired immune systems, those with a BMI over 40, pregnant women, healthcare workers, carers as well as cancer patients.

Two thirds of those who have prioritised their health more since Covid-19 are eating healthier, with just over half (51%) spending more time outdoors. Strong immune health is important as the winter months approach to fight off colds and flu.

The research shows that two thirds of adults (66%) currently take a daily vitamin or regularly take supplements with the incidence highest in those aged 18-44. This is backed by trends in LloydsPharmacy stores which saw an increase of 20% in vitamin sales over the last year. Vitamin D is the most popular vitamin or supplement taken by respondents who take a daily vitamin followed by a multi-vitamin; this trend can be seen in LloydsPharmacy and accounts for a third of the category growth over the last year.

Along with Vitamin D, Vitamin C is

also vital for protection from colds and flu and building a strong immune system. For people who don't consume enough Vitamin C and D rich foods, taking daily vitamins will ensure they reach the recommended daily intake of each vitamin, boosting their immune system for the winter months ahead.

Denis O'Driscoll, LloydsPharmacy Superintendent pharmacist says, "Covid-19 has really brought our individual and collective health into focus for people. Across our pharmacies we saw trends such as an increase in vitamin sales and more people booking flu vaccinations that showed that to be true. LloydsPharmacy have launched our first winter health index so we can track the behaviours and attitudes of people in Ireland to their health.

"As Covid-19 continues to circulate in communities around Ireland and people go back to school, college and offices it's crucial that people make their health a priority this winter by booking a flu vaccination in their local LloydsPharmacy and discussing their vitamins and supplements needs with the team in-store."

The Winter Health Index has been created to monitor people's changes in attitudes and actions surrounding healthier living, preventative health measures, and a better understanding of their overall health. Research has been conducted by Empathy research on behalf of LloydsPharmacy.

The first index shows there is an increase in people planning to get the flu vaccine this year as 57% of the public plan to get the flu vaccine compared to only 46% of adults last year- an increase of 11%. With incidence of Covid-19

## Cough in Pharmacy

During winter, most coughs are caused by viruses such as colds and flu and can be safely managed at home using OTC remedies. Coughs are classified as "acute" or "chronic". An acute cough is most common and lasts up to three weeks. It's usually caused by a cold or flu virus and most improve after one to two weeks.

Chronic cough lasts for eight or more weeks. The most common causes include acid reflux, asthma, TB, COPD, bronchitis and smoker's cough. Red-flag signs include:

- Coughing up blood
- Unexplained weight loss
- Night sweats
- Cough worsening after three weeks
- Shortness of breath
- Voice changes

- Lumps/swellings in neck
- Chest pain

### Dry or chesty cough?

A dry cough is caused by inflamed airways due to a viral infection such as a cold or flu. A chesty cough produces phlegm. This is caused by the lungs producing extra fluid due to an infection.

It is important to get a detailed overview of the patient's symptoms. Is their cough productive? How long have they had the cough and what action has been taken? Pharmacists should ask if a patient has any medical conditions that

may affect any treatment or product you recommend.

The role of cough medicine is to ease symptoms while the body heals. There are many brands of OTC cough medicines. But there are only three basic types:

**Expectorants** help thin mucus, making it easier to cough up. The ingredient is guaifenesin.

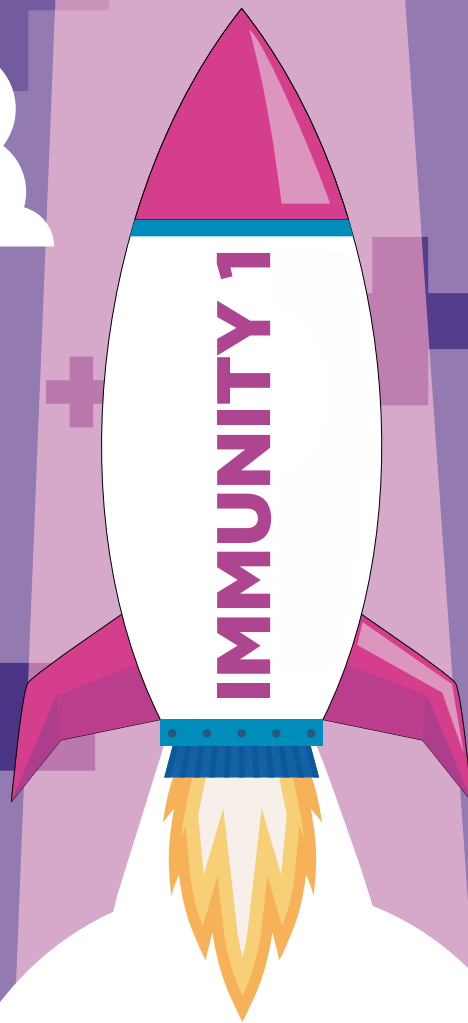
**Suppressants** help cut the number of times someone coughs. The active ingredient listed is usually dextromethorphan (DM). Other cough suppressants include camphor, eucalyptus oil, and menthol.

### Combination cough

**products** have more than one active ingredient. They have both guaifenesin and dextromethorphan. Cough medicines may also contain ingredients to help coat and soothe the throat.

Combination products may have medicines to ease other symptoms, that may include decongestants for stuffy nose, antihistamines for allergies or a runny nose, or painkillers.

**Cough drops** can also help relieve a cough and may ease a sore throat.



# BOOST YOUR IMMUNE SYSTEM



For more information contact your Valeo Healthcare rep:

Fintan Byrne: 087 647 0764  
fintan.byrne@valeofoods.ie

Julie Webster 086 462 1723  
julie.webster@valeofoods.ie

Eamonn Connolly 087 238 5648  
eamonn.connolly@valeofoods.ie

## Six in Ten Concerned about Flu

New research conducted on behalf of Boots Ireland has revealed 6 in 10 adults (60%) claim that they are concerned about contracting the flu since the arrival of Covid-19. While levels of concern are quite consistent across age groups, almost 3 in 10 (28%) adults claim that they are *more* concerned now than they were before Covid-19 about contracting the flu.



Caoimhe McCauley, Chief Pharmacist, Boots Ireland

to receiving both the flu and Covid-19 vaccine at the same time if needed. This rises to 69% in adults aged 55-64.

Meanwhile, two thirds (67%) of adults claim that they are likely to get the flu vaccine this year. Those aged 65 and older, are more likely to claim that they are likely to get the flu vaccine this year (84%), with those aged 18-44 significantly less likely to claim that they are very likely to get the flu vaccine this year.

Almost 6 in 10 (57%) adults claim that they would be open

Commenting at the launch of the service, Caoimhe McCauley, Chief Pharmacist at Boots said, "The seasonal flu vaccine is considered the best protection against the flu, the complications that can arise from it and further spread of the virus in the community. Annual vaccination is recommended because the virus is constantly changing and it is the best way to reduce your chance of contracting the flu year to year. Our Winter Flu Vaccination Service at Boots is a simple and convenient way to help protect against the flu."

## Sore Throat vs Strep Throat

Sore throat (also called pharyngitis) is typically caused by a viral or bacterial infection. An estimated 200 to 300 different strains of virus cause colds and sore throat.

In up to 90% of cases, sore throat is caused by viruses linked to the common cold or flu. The other 10% of cases result from bacterial infections or some other medical condition. The bacteria that most commonly cause sore throat are streptococci. Infection with streptococcal bacteria is commonly called strep throat.

Those white spots are pus pockets. In addition, some patients may exhibit swollen, tender lymph nodes in the neck and some with fever above about 101-102 F. The signs and symptoms are the same for both children and adults.

Although these signs may indicate strep, a visit to their

GP is necessary to make a full determination. A full diagnosis is impossible by visual signs alone.

Adults are less likely to have this disease than children. For school-age children, their odds of a sore throat being strep are about 20% to 30%. For adults, the odds are more like 5% to 15%.

Sore throats are often caused by viruses, making them difficult to cure. They can also be caused by

- dry air,
- irritants like pollution,
- smoke, including cigarette smoke, and
- allergies.

The following are some of the most common sore throat causes:

- **Strep throat:** The bacteria group A Streptococcus is the most common cause of strep throat.
- **Sore throat (viral pharyngitis):** Viruses are the most common cause of sore throat, including rhinoviruses or a respiratory syncytial virus. These viruses can cause other symptoms, such as:
  - o a cold
  - o earache
  - o bronchitis
  - o sinus infection

Some of the signs of strep throat will be visible. They may include

- white patches on the tonsils or throat,
- dark red splotches or spots on the roof of the mouth, and
- a skin rash.

Condition	Symptoms	Throat Appearance
Healthy Throat	A healthy throat should not cause pain or difficulty swallowing	A healthy throat is usually consistently pink and shiny. Some people may have noticeable pink tissue on either side of the back of their throat, which is usually the tonsils.
Sore Throat	Cough, runny nose, or hoarseness that changes the sound of a person's voice. Some people may also have conjunctivitis or pink eye symptoms. Most people's symptoms subside within a week or two, but are usually mild and not accompanied by a high fever.	Redness or mild swelling.
Strep Throat	Fast onset with pain when swallowing, fever greater than 101°F (38°C), swollen tonsils, and swollen lymph nodes.	Swollen, very red tonsils and/or white, patchy areas on the tonsils or in the back of the throat. Sometimes, the throat may be red with moderate swelling.



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# Becton Dickinson (BD) Tackle Epic Charity Cycle

The Mizzen Head to Malin Head challenge is well known among cyclists, usually taking several days to complete.

However, Peter Ferguson from BD decided to attempt to complete it in just 24 hours. Peter, who lives in Northern Ireland, has family members with Type 1 diabetes and he currently works for medical device company, Becton Dickinson (BD), where he is the diabetes care account manager for the UK and Ireland.

Currently, 97% of its insulin pens that are distributed worldwide are manufactured in Ireland. Last year was the 50th anniversary of when BD started manufacturing in Ireland, while this year is the 100-year anniversary of the discovery of insulin. Peter wanted to undertake some sort of challenge to mark these two events. He also wanted to do it for health reasons.

"This time 18 months ago, I was 17 stone. I was driving around Ireland for my job, eating the wrong things and doing no exercise and then lockdown happened. I started worrying that I would get Type 2 diabetes. I decided to use that four to five hours that I would have

been spending in a car and do a bit of exercise and within about six months, I had lost most of the weight," he explains.

Peter is an ex-professional rugby referee, so he had been fit previously. However, he had never cycled seriously before. This did not stop him from deciding to do a charity cycle for BD's nominated UK charity, which involved cycling 30 miles every day over a onemonth period. He had always wanted to do something with Diabetes Ireland so he decided to set himself a new charity challenge.

While he would have liked to cycle around Europe, this was not possible as a result of the pandemic, so he decided to do the Mizzen to Malin Head cycle, but with a twist – he hoped to complete it in 24 hours. He reached out to work colleagues in Ireland to see if anyone else would like to take part and in the end, 12 cyclists decided to give it a go.

Including the support team, almost 30 people were involved. "We completely overengineered what was going to happen on the cycle and what was going to happen with the support team. We had to consider details like how long we were going to stop for, what type of clothes to bring and what we were going to eat. As long as there is food in the body, it will keep going. The problem a lot of people have is that they just don't eat enough," he notes.

However, the one thing you cannot engineer is the weather. At the last minute, due to a change in the direction of the wind, the team decided to cycle from Malin to Mizzen Head instead. Peter says he didn't really struggle with the lack of sleep, but the hardest thing for him was the cold.

"It got down to one degree and I personally wasn't prepared for it. I was prepared for everything else, but that cold really saps your energy. It didn't really start to get warm for us until about 10am

the next morning as it was quite a misty and damp morning," he recalls. While the cyclists fell just outside the 24 hours altogether, when just cycling time was taken into account (excluding food stops etc), they managed complete the cycle in 21.5 hours – a huge achievement.

"In the few days after the cycle, I was living on adrenaline, but as the week wore on I became more tired, but it wasn't a physical tiredness it was an emotional tiredness. Some of the emotions that came out after the race were unbelievable. I was delighted that people were happy afterwards," he says. At the time of going to press, the cyclists had already raised over €25,000 for Diabetes Ireland.

If you would like to donate, visit: <https://www.justgiving.com/team/bddiabetesirelandcycle>

\*This article first appeared in Diabetes Ireland Autumn 2021 issue.

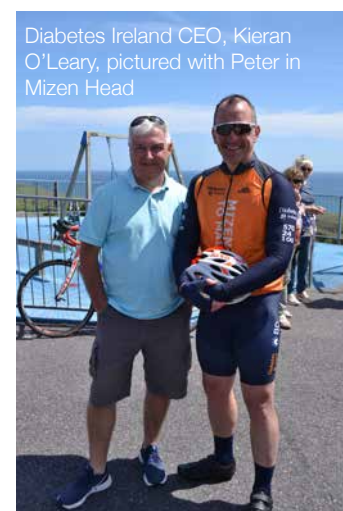
Peter Ferguson, BD



Members of the Mizzen to Malin challenge team



Diabetes Ireland CEO, Kieran O'Leary, pictured with Peter in Mizzen Head



Diabetes Ireland CEO, Kieran O'Leary, pictured with Peter in Mizzen Head

Peter Ferguson (left) and other members of the Mizzen to Malin challenge team pictured at Malin Head celebrating their achievement



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Medicinal product not subject to medical prescription. Supply through general sales.

**References:** 1. NTDs (neural tube defects). 2. Leading sales brand in pharmacy - IOVIA, IRLP audit, units, MAT Jan 20.  
Date prepared July 2020. 2020/ADV/CLO/048H

# Managing Men's Mental Health

Over the past two years, the Covid-19 pandemic has brought added attention to mental health and mental illness. Both the pandemic itself and the public health restrictions it necessitated have had a significant impact on psychological wellbeing. This article focuses on men's psychological wellbeing and mental health, as well as common mental illnesses, such as depression, and suicide. These were important issues before the pandemic, but the past two years have brought added challenges that require us to pay increased attention to mental health.



Written by Professor Brendan Kelly, Professor of Psychiatry, Trinity College Dublin

Photo: Ruth Medjber

## The difference between unhappiness, stress and mental illness

It is useful to start by noting the difference between the understandable stresses of life on the one hand, and mental illness on the other. Pharmacists who are familiar with their customers will often identify when a customer is stressed, unhappy, or distressed. During the pandemic, virtually everybody's wellbeing came under pressure at various points, as family members fell ill, tests results were awaited, or public health restrictions were tightened. Most people were stressed, upset or anxious for periods of time. Many sought informal support from family, friends and professionals with whom they were familiar: GPs, counsellors, pharmacists and others.

Many of these problems are largely understandable, especially during a pandemic. Most of these issues are best addressed by changing our lifestyles as best we can, watching our diets, getting more exercise, reaching out to family and friends, and finding activities that absorb us, like running, gardening, reading or knitting. Reflective pursuits such as mindfulness, meditation and

yoga can be especially beneficial. For many people, these activities will help them through the difficult times that we have all faced over the past two years.

These stressful experiences in our day-to-day lives are, however, different to mental illness. Mental illness occurs when our distress exceeds our personal and family resources, when we are disabled to a significant degree by our symptoms, and when we need to reach beyond our immediate circle for assistance and support. Depression is one example of a mental illness that commonly exceeds our usual ability to cope, and requires additional treatment.

## Features of depression

Depression is one of the most common mental illnesses among both men and women. The symptoms of depression vary significantly between individuals. The symptoms and signs depend on the person's general character, their life situation, any stresses triggering their depression, and various other factors.

For most people, key symptoms of depression include low mood or feeling down; loss of interest and enjoyment in usual activities; reduced energy, with fatigability and diminished activity; notable tiredness after slight effort; reduced concentration and attention; diminished self-confidence and self-esteem; thoughts of guilt and unworthiness; bleak, pessimistic views about the future; feelings of helplessness and hopelessness; ideas or acts of self-harm; disturbed sleep, and changes to appetite.

For a diagnosis of depression, rather than stress or unhappiness, these symptoms should, for

the most part, be present for two weeks, but shorter periods are reasonable if the symptoms are of rapid onset or unusually severe. Everybody is different, but this is the most common picture of depression: low mood, hopelessness, and various physical disturbances, such as loss of appetite, poor sleep, and diminished libido.

Women are diagnosed with depression more often than men. There are likely to be many reasons for this, but it is relevant that men are less likely to seek help for depression, stress and substance misuse. The reasons for this include prevailing perceptions of social norms for men, reluctance to talk openly, and a tendency for men to downplay symptoms. It is useful to bear these factors in mind if you feel that someone is depressed and might be reluctant to confide. This is particularly important owing to one of the most concerning consequences of depression: self-harm and suicide.

## Self-harm and suicide in men

Deliberate self-harm is the intentional infliction of non-fatal harm on oneself. It includes methods such as self-cutting and overdosing. Suicide is intentional self-killing and it features in every society for which there is recorded history. Non-fatal deliberate self-harm is more common among women compared to men, but completed suicide is more common among men.

Risk factors for non-fatal self-harm, in addition to female gender, include younger age, poor social support, major life events, poverty, being unemployed, being divorced, mental illness and previous deliberate self-harm. Risk factors for suicide, in addition to male gender, include poor social support, major life events, chronic painful illness, family history of suicide, and previous deliberate self-harm. Suicide is also associated with major depression (long-term risk of suicide: 10-15%), bipolar affective disorder (10-20%), schizophrenia (10%) and alcohol dependence syndrome (15%).

For both deliberate self-harm and suicide, availability of means is significant (e.g. availability of tablets to take overdoses).

How common is suicide, and what are the rates in men and women? The 2019 Annual Report of the HSE National Office for Suicide Prevention (NOSP) indicates that there were 421 completed suicides in Ireland in 2019, yielding a rate of 8.6 per 100,000 population per year. The 2019 data are, however, provisional and subject to change. Official data for 2016, including late registrations, indicate that there were 506 suicides in 2016, yielding a rate of 10.7 per 100,000 population per year.

The NOSP report points out that "it is not easy to compare suicide rates among European counterparts because of the variations in registration and reporting systems in different jurisdictions. Nevertheless, Eurostat provides comparisons using standardised death rates". In 2017, "the overall rate of suicide in Ireland was the 9th lowest rate of 33 countries". However, "the rate of suicide of age 15-19 year olds in Ireland was the 13th highest rate of 31 countries".

The ratio of male to female suicide in Ireland is 3:1, according to the provisional 2019 data, with 317 male suicides compared to 104 female suicides. Official data for 2016 also show a substantial male excess, with 403 male suicides compared to 103 female suicides. Men who are at particular risk likely include those who have experienced trauma, employment problems, marital breakdown, financial problems, substance misuse or mental illness.

## Treating depression

Individuals with depression commonly require assistance and support in order to deal with their symptoms, enter recovery, and maintain wellness into the future. In the first instance, it is important that the individual with depression is able to talk openly about their symptoms, without fear of criticism or judgment.

It is also important that any issues relating to alcohol or other drugs are identified at the outset and, if possible, resolved: treatment of depression is rendered extremely difficult in the presence of alcohol or drug misuse. These problems occur in both men and women, but are more common among men.

Treatment of depression is based on a bio-psycho-social approach to management; i.e. there are “biological” treatments (such as medication), psychological treatments, and social interventions.

Cognitive-behaviour therapy (CBT) focuses on the use of cognitive strategies (i.e. strategies related to thinking patterns and habits) and behavioural strategies (i.e. strategies related to actions and behavioural habits), in an effort to re-frame depressive thoughts, enhance coping strategies, reduce symptoms, and promote recovery. CBT is effective in the management of depression, generalised anxiety disorder, panic disorder, social phobia and post-traumatic stress disorder.

Biological treatments for depression include administration of medications and treatment of co-existing medical or substance-related disorders. Most guidelines now recommend newer antidepressants (such as selective-serotonin re-uptake inhibitors) as first-line treatments for depression, ahead of older ones (such as tricyclic antidepressants). Newer agents are safer and have fewer side effects, although adverse effects can occur and should be discussed beforehand.

Approximately two-thirds of patients with moderate or severe depression respond to the first antidepressant prescribed. In these patients, the medication should be continued for six to nine months after recovery from a single

depressive episode. For individuals who have experienced multiple depressive episodes, there is evidence to support continuation of treatment for up to two years.

If there is no or insufficient response to the first antidepressant prescribed after several weeks, it is recommended to either increase the dose, switch to a different antidepressant, or engage in a broader re-consideration of options. In the event of poor response after a second antidepressant, alternative treatment strategies may be required, possibly involving specialist mental health services.

For everyone with depression, a consideration of the social environment and social re-engagement is an essential step on the road to recovery. Self-help groups and organisations such as Aware ([www.aware.ie](http://www.aware.ie)) are very helpful. For men, in particular, Men’s Sheds offer psychological support and social outlets, and can be accessed through the Irish Men’s Sheds Association (<https://menssheds.ie>).

#### **Alcohol and other substance misuse in men**

Alcohol and other substance misuse are substantial problems among both men and women, but are more common among men. The Healthy Ireland Survey 2018 found that “male drinkers (54%) are more likely than female drinkers (19%) to binge drink on a typical occasion”. In addition, “out of men who drink, 67% of those aged 15-24 and 64% of those aged 25-34 binge drink on a typical occasion”.

This problem is not confined to alcohol: men are also more likely than women to enter specialised treatment for cannabis, cocaine, heroin and amphetamine misuse. Therefore, while alcohol and substance misuse present

problems for both men and women, they likely make a particular contribution to the higher rate of suicide among men.

Treatment for alcohol misuse or dependence is provided through local addiction services which can be accessed following referral by a GP, psychiatrist or other health professional, as well as through self-referral in certain circumstances. Abstinence is the usual and most sensible goal of treatment. The precise supports offered depend on the stage of the person’s addiction, their readiness for change, their general life circumstances, and their previous experiences of treatment.

For acute detoxification from alcohol, hospital admission is considered if there is a high risk of delirium tremens or seizures, or if the person is otherwise vulnerable (e.g. a child, cognitively impaired, or severely lacking social support). For many people, however, detoxification is just as effective if it occurs as an outpatient, using reducing doses of a medication such as chlordiazepoxide (for symptoms of acute alcohol withdrawal), appropriate medical supervision, and psycho-social or family support.

Treatments for drugs other than alcohol depend on the drug in question, but often include CBT, motivational interviewing and self-help groups, as well as specialist clinics and residential care. The precise strategies vary according to the substance in question, the person’s history, and the social and family circumstances in which the problem developed and is sustained.

#### **Conclusion: minding men’s mental health**

Men experience a broad range of mental health problems ranging from stress and unhappiness to severe depression and

schizophrenia. This article highlights some of the more common issues: depression, suicide and substance misuse.

Taking a broader perspective, it is useful to remember that maintaining good mental health involves not only preventing and treating mental illness and substance misuse, but also taking positive steps towards wellness. Exercise, diet and social connection all matter. Men experience particular difficulty speaking about emotional and psychological problems, and seeking assistance when needed. This is a pity and it highlights the need for pro-active strategies to improve men’s mental health.

*Brendan Kelly is Professor of Psychiatry at Trinity College Dublin and author of “The Science of Happiness: The Six Principles of a Happy Life and the Seven Strategies For Achieving It” (Gill Books, 2021).*

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# Skin Health for Men - What Pharmacists Need to Know

*Not long ago any man concerned about the appearance of his skin would be considered unusual – but that has all changed.*



*Written by Dr John Ashworth,  
Consultant Dermatologist  
M.B. Ch.B. (1979) M.R.C.P. (1983)  
M.D. (1988)*

*[www.dermatologist.ie](http://www.dermatologist.ie)*

**S**kin health for men can be broadly divided into two areas – 1 **skin cancer concerns** – and 2 **looking good**.

So let us consider these separately and the first thing to discuss is sunshine damage and skin cancer.

**THE NUMBERS are LARGE:** as we all live longer and longer and as we all spend more and more time outdoors in the sunshine then so do the numbers of sufferers multiply and increase exponentially.

The most serious of all skin cancers is melanoma from which people die on a regular basis but I will return to this problem a little later. The overwhelming majority of referrals by doctors to dermatology specialist these days concerns “non-melanoma skin cancer”. This means irregular patches of skin developing, almost always, in sunshine exposed areas on the body for example the crown of the scalp, the forehead, the backs of the hands and forearms, the upper shoulders and back.

This particular problem is a huge burden to health services because many men have multiple lesions and need to return to treatment many times throughout their lives – the commonest diagnoses lying in this area are as follows – **BASAL CELL CARCINOMA, SQUAMOUS CELL CARCINOMA, ACTINIC KERATOSIS** and a condition which can closely mimic all of the above called **SEBORRHOEIC PAPILOMA** please research these individually as we do not have the opportunity here to discuss these individually

If we did not get any sunshine damage to our skin, then most skin cancer would probably not occur – the evidence for this is about skin location – by that I mean it is highly unusual to get any kind of skin cancer

on nonexposed skin for example under the armpit or in the groin

Therefore sensible management revolves around two areas – first, **minimising sunshine exposure** – second, **careful self observation** and early intervention when something unusual appears on the skin – almost all skin cancer can be successfully eradicated if it is treated early enough, therefore an early alarm system is critical

**SELF OBSERVATION:** everyone has a smart phone which can take an excellent photograph – using a smart phone and a willing friend/family member to take a reasonably good photographic record of what your skin looks like is imperative.

Do not go too close because getting out of focus is a problem – taking a photo from about 1 metre away is the correct thing to do – it is also worth taking pictures of your entire back and back of legs even though you feel there is nothing much to see – because you cannot predict where something might occur in the future. So 4 pictures to cover your entire back – upper left and right, lower left and right – and then a couple of extra shots showing the back of the thighs and the back of the calves.

Armed with a decent set of about 12 or 15 photographs you then get a family member to check your skin approximately once every three months and if something is changing – see a specialist about it sooner rather than later.

Skin changes to look out for – my advice is not to go too “techie” on exactly what changes might be suspicious or might not be – is entirely appropriate to take the view that if something has changed for longer than six weeks and you are intuitively worried about it then please seek a medical opinion.

Having said that, it is of course entirely appropriate to familiarise yourself on the Internet with a variety of pictures about what irregular lesions look like. I use the six week rule because innocent skin changes for example an infected insect bite reaction will normally settle down using a bit of antiseptic cream over a six week period

**MELANOMA:** this is the most serious of skin cancers – and usually manifests as an unusual pigmented lesion on the skin, often very darkly purple or black – but beware because approximately 3% of melanomas are pink I have very little pigment within them – and irregularly shaped skin mark with more than one colour within it for example pale brown and dark purple, should raise the question of possible melanoma.

**LOOKING GOOD:** no one wants unsightly brown blemishes and unnecessary wrinkling/ageing changes on the skin and once again we are back to sunshine avoidance – the modern world views a tan as “healthy” and in my opinion this will not change for at least two further generations – therefore we have to live with the fact that many people like their skin colour to be somewhere between light tan and dark orange depending upon their preference.

Of course this can be achieved artificially but most men would not go down that route – therefore they will continue to expose themselves to sunshine.

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**SUNSHINE EFFECTS:** an excellent way of checking how sunshine affects your skin is to put your hand across onto your opposite shoulder and look at the difference between the skin on your outer forearm compared with the skin on the inner aspect of your opposite upper/inner arm (which of course sees very little sunshine) most patients show a dramatic difference. This dramatic difference is evident despite the fact that of course, the skin is precisely the same age, the only difference is the amount of sunshine exposure which has occurred to the two different areas.

**SOLAR LENTIGOS:** these are the flat or very slightly elevated brown patches ranging in size from small to several centimetres in diameter, often located extending across your cheeks and forehead as you get older – some patients are dramatically covered in these and look very unusual. Eradicating these lesions once established is difficult but liquid nitrogen spray gun applied gently and a variety of creams including those with RETINOL actions can sometimes be beneficial.

**MINOR WRINKLES:** By minor I refer to the very fine skin surface texture changes that slowly occur throughout life (as opposed to more major wrinkling (for example your frown lines on the forehead) – these fine wrinkles, as with most skin changes are mainly due to sunshine exposure. You don't see much change on the skin which is not exposed to the elements. RETINOL type treatments when used for a prolonged period can probably slightly reduce and improve the appearance of these changes.

This type of minor texture change is the change which can be approved by "laser resurfacing" which effectively tightens the skin and slightly stretches it by creating a very controlled tiny burn into the skin surface.

**ACTINIC KERATOSIS CHANGES:** these are often the first signs of skin sunshine damage – areas of quite hard, dry, scaly skin often on a pink base, sometimes a more pigmented base – occasionally they can disappear and re-occur – sometimes they persist and slowly get bigger. EFUDIX and some other prescription surface creams can eradicate these lesions but all the treatments have in common the possibility of burning and irritation therefore judicious applications are usually advised rather than the full protocol exposures (described on the official instructions) which will often create a lot of irritation.

**MAJOR WRINKLING:** By this I refer to the deep permanent wrinkles for example frown lines, horizontal forehead lines, and other deep facial wrinkles – these cannot be altered by external cream or superficial laser therapy – These can only be changed by either surgical methods for example facelifts and various types – or by injecting filler which is a glycoprotein jelly similar to the body's own connective tissue. Your natural spongy connective tissue slowly fades away as you get older.



Multiple areas of actinic keratosis change/sunshine damage



A typical BASAL CELL carcinoma

**INTERMEDIATE WRINKLING:** I mean partly visible wrinkles which can be exaggerated and made more obvious by muscular activity for example raising your eyebrows to exaggerate the forehead wrinkles or drawing your eyebrows together into a frown to exaggerate the frown lines – these intermediate wrinkles can be significantly suppressed by reducing the muscular activity by injecting a toxin (botulinum toxin) to paralyse these muscles which then have less effect on the overlying skin and reduce wrinkling.

The effects of toxin injections last between four and eight months then the treatment needs repeating.

**HAIR:** a reasonable head of hair is something that is unfortunately dictated by your genetics – and trying to fight genetics is often a fruitless task – however there are a couple of things worth considering – first, the important indices for hair growth include the following – iron, zinc, B12, folate and vitamin D. There is no harm in taking a reasonable daily supplement of these on a regular basis if you feel that hair support is needed.

REGAINE lotion at the highest licensed percentage concentration applied once per day for about nine months can help reduce natural hair loss but the benefit probably only lasts as long as you are using it – therefore prolonged use is usually needed.

Other options such as PROPECIA need a very careful medical assessment and should not be embarked upon without full medical support.

**IDENTIFY MALIGNANT MELANOMA EARLY:** from about 1 m distance get someone at home to take 4 photographs of your back – upper left and right, lower left and right – and once every three months get someone to check your back against your photographs – familiarise yourself by searching online information / photos and be aware of what irregular moles and suspicious skin lesions look like – anything

which changes in a suspicious way or which appears from otherwise normal skin and starts to grow should be checked by a doctor/specialist.

**IDENTIFY BASAL CELL CARCINOMA EARLY:** BCC tends to appear very quietly initially – is often thought to be nothing more than an insect bite or spot – but some months later it is still present and slowly growing. The common sites are around the "face mask" area of the face that is to say across the forehead around the sides of the nose cheeks and eyes – but they can appear virtually anywhere across sunshine exposed skin – please apply the "six week rule" I mentioned above.

**PROMINENT SKIN PORES:** these are usually most evident around the nose where they can develop into visible blackheads – Retinol containing products can be helpful in reducing the physical size but not by much – there is no very effective treatment at dealing with this because some people are just prone genetically to having larger pores than other people. Granular abrasive skin cleansers – that is to say skin cleansers with small particles in the suspension can be helpful for keeping these pores spotlessly clean and therefore reducing the appearance in that way. Techniques to stimulate the connective tissue of the body can sometimes be used to minimise pore appearance – for example intense pulsed light (IPL) can be used by experts in this way.

**GENERAL SKIN CARE:** oil deficiency in the outer layers of skin is almost universal above the age of about 40 and progressively becomes more important with advancing years. Stripping the skin of oil by using conventional soaps, common sweaty performance exercise, a wide variety of skin disease in particular eczema, dusty or dirty skin exposures, and other problems can all contribute. Therefore a reasonable cleansing programme together with replacing oil using appropriate moisturisers will give good long-term results. A good time to apply moisturiser is about one hour before going to bed.



# New Treatments for Cancer are Transforming Patient Outcome

The outcome for patients with certain types of cancer has been transformed in recent years. This transformation has been brought about, not by the traditional therapies such as chemotherapy and endocrine therapy but by 2 new forms of treatment known as targeted therapy and immunotherapy.

Targeted therapy uses drugs that specifically inhibit genes that are responsible for driving the growth of a particular cancer. A good example of targeted therapy is the use of Herceptin for the treatment of breast cancer. Herceptin is a monoclonal antibody which binds to the protein product of the cancer-driver gene HER2 and blocks it from functioning. The HER2 gene is amplified (i.e., no of copies is greatly increased) in 15-20% of breast cancers which in turn results in massively increased levels of the HER2 protein. This increased production of the HER2 protein causes normal breast cells to proliferate rapidly, ultimately leading to breast cancer. Administration of Herceptin then prevents HER2 from functioning which can lead to blockage of cancer cell proliferation, cancer cell death and tumor regression.

The availability of Herceptin has resulted in a major improvement in outcome for patients with HER2-positive breast cancer in recent years. Prior to the approval of Herceptin, the prognosis for patients with HER2-positive disease was poor and considerably worse than that of patients with HER2-negative disease. However, with the widespread availability of Herceptin, the outcome for patients with HER2-positive disease is currently at least as good if not better than that for patients with HER2-negative disease. Remarkable, approximately 10-15% of patients with HER2-positive metastatic breast cancer undergoing treatment with Herceptin have long-term remission (> 10 years) and indeed possible cure of metastatic disease.

While Herceptin was the first anti-HER2 drug to enter clinical use,

several other such drugs are now available for targeting HER2 such as pertuzumab, lapatinib, neratinib, tucatinib as well as conjugates of Herceptin and cytotoxic agents (eg., TDM-1). These newer drugs can either be combined with Herceptin to enhance efficacy or used in patients that develop acquired resistance to Herceptin. While anti-HER2 therapy was first introduced for patients with breast cancer, this therapy is also now approved for patients with gastro-esophageal cancer and is currently undergoing trials in patients with colorectal and to non-small cell lung cancer (NSCLC).

Other examples of successful targeted therapies include erlotinib and gefitinib for patients with NSCLC containing EGFR mutations, dabrafenib and vemurafenib for patients with melanoma expressing BRAF mutations, olaparib for patients with breast cancer possessing BRCA1/2 mutations and cetuximab or panitumumab in patients with colorectal cancers containing wild-type (i.e., normal) RAS.

In contrast to targeted therapy and indeed other forms of systemic therapy, immunotherapy does not target cancer cells directly. Rather, immunotherapy enhances the immune system (CD8+ lymphocytes) to attack and destroy cancer cells. Examples of immunotherapy include the so-called checkpoint inhibitors, pembrolizumab, nivolumab and atezolizumab. Immunotherapy with checkpoint inhibitors has been shown to be particularly effective in some cancers that were previously difficult to treat such as non small cell lung cancer, melanoma, renal cancer, and bladder cancer. As with Herceptin, immunotherapy

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can induce durable remission in some patients with advanced cancer. Thus, results from a recent phase III randomized clinical trial showed that treatment with pembrolizumab more than doubled the median and the 5-year overall of patients with NSCLC compared with standard chemotherapy.

Other examples of immunotherapy currently in use include the administration of cytokines such as interleukin 2 (IL2) and interferon alpha to treat renal cancer and the BCG vaccine to treat bladder cancer. With the recent developments in vaccine production technology for treating the COVID-19 virus, it is likely that before long, several new vaccines will become available to treat different types of cancer.

Although targeted therapy and immunotherapy have transformed the outcome for patients with certain types of cancer, a limitation of these therapies is that only a proportion of patients with a specific type of malignancy benefit. To identify patients likely to benefit, and spare those who are unlikely to respond, predictive biomarkers (companion diagnostics) are usually measured upfront. Thus, as mentioned

above, the HER2 status of breast cancers is used to determine women with breast cancer who might be eligible for treatment with anti-HER2 therapy. Measurement of PD-L1 is the biomarker most widely measured for predicting response to immunotherapy using checkpoint inhibitors.

In conclusion, the outcome for patients with specific types of cancer never was as good. Importantly, for the first time the possibility of cure of metastatic disease is on the horizon. In the authors view, long-term survival and possible cure is likely to be best achieved by the appropriate combination of different form of therapy (e.g., targeted therapy + immunotherapy ± chemotherapy).

Acknowledgement: The authors work was supported by the Cancer Clinical Research Trust



# Pharmacy Management of Prostate Cancer

About 3,890 men are diagnosed with prostate cancer each year in Ireland. This means that 1 in 7 men will be diagnosed with prostate cancer during their lifetime.

Prostate cancer can be treated with active surveillance, external beam radiotherapy, hormone therapy, brachytherapy, surgery, chemotherapy and watchful waiting. In 2018, 1,276,106 new cases of prostate cancer were registered worldwide, representing 7.1% of all cancers in men and 358,989 deaths representing 3.8% of all male cancer deaths.<sup>1</sup> 3,890 men are diagnosed with prostate cancer each year in Ireland indicating that 1 in 7 men in Ireland will be diagnosed with prostate cancer during their lifetime.<sup>1,2</sup>

We recently spoke to Theresa Lowry Lehnen (GPN, RNP, PhD) Clinical Nurse Specialist and Associate Lecturer at Institute of Technology Carlow to find out more about current advances in this field.

The prostate is part of the male reproductive system, which includes the penis, prostate, seminal vesicles, and testicles. The prostate gland is located just below the bladder and in front of the rectum. It surrounds the urethra and produces fluid that makes up a part of semen.<sup>3</sup> The prostate gland is a conglomerate of tubular or sac-like glands that secrete fluids into the urethra and ejaculatory ducts. The secretory ducts and glands are lined with a moist, folded mucous membrane. Beneath the mucous membrane lies connective tissue composed of a thick network of elastic fibres and blood vessels. The interstitial tissue surrounding the secretory ducts and glands contains muscle, elastic fibres, and collagen fibres that give the prostate gland support and firmness. The capsule enclosing the prostate is also composed of interstitial tissue.<sup>1,6</sup>

Theresa, who is a member of the Irish General Practice Nurses Educational Association says, "Prostate cancer incidence rates are highly variable worldwide and the variations in incidence is likely to be attributed to PSA testing. In Europe, prostate cancer is the most frequently diagnosed cancer among men, accounting for 24% of all new cancers in 2018, with around 450,000 new prostate cancer cases detected in 2018.<sup>3</sup> Prostate cancer incidence increases with age."

## Risk factors

So what are the most common risk factors for prostate cancer? Theresa reflects that increasing age is one of them.

She adds, "It usually affects men over the age of 50 and almost two in every three prostate cancers are diagnosed in men over the age of 65. In Ireland, the majority of cases are detected in men aged 65-to-84 years, with

37 per cent detected in men under 65 years of age. Genetic factors play a role. Family history is associated with an increased risk and men with a father or brother diagnosed with prostate cancer at age 50 years have an approximately two-fold increased risk of prostate cancer.<sup>1</sup>

"Risk is higher in males with a relative who developed prostate cancer at a younger age and in males who have more than one relative with the disease. Two genes, BRCA1 (breast cancer type 1) and BRCA2 (breast cancer type 2), have been linked to prostate cancer. Like women, men can have mutations in the BRCA1 and BRCA2 genes."

The function of the BRCA genes is to repair cell damage and keep breast, ovarian, and other cells growing normally. "Men carrying mutations in BRCA2 gene have an increased risk of developing prostate cancer, and mutations in either gene can significantly reduce survival," she adds.

"Studies have revealed an association between hereditary susceptibility to prostate cancer and sequence variations in the RNASEL gene (ribonuclease L), which plays a role in maintaining immunity against viral infections.

"A common RNASEL variant involves a mutation resulting in decreased activity of the encoded ribonuclease L protein, reducing the immune defence against viruses. Men who inherit this mutation have a significant increased risk of developing prostate cancer.<sup>7</sup> It is estimated that about 20% of patients with prostate cancer report a family history, which may develop not only because of shared genes, but also for a similar pattern of exposure to certain environmental carcinogens and common lifestyle habits.<sup>9</sup>

"Afro-Caribbean men have the highest incidence of prostate cancer of any group (231.9 per 100,000) while Asian men have the lowest risk. Obesity and physical inactivity has been associated with higher-grade prostate cancers and studies have shown increased risk associated with various dietary intakes, including high levels of high-saturated fats and red meats and reduced intake of fish, fruit and vegetables.<sup>1,2,9</sup> Research is ongoing into the links between diet and prostate cancer and there is some evidence that a diet high in calcium is also linked to an increased risk of developing prostate cancer.<sup>8</sup>

"Although there are no studies that can sufficiently demonstrate the direct correlation between diet and nutrition with risk or prevention of prostate cancer development, many preclinical studies that look at links between certain eating behaviours and cancer suggest there may be a connection," says Theresa.



*Interview with Theresa Lowry Lehnen (GPN, RNP, PhD)*

*Clinical Nurse Specialist and Associate Lecturer at Institute of Technology Carlow.*

*Member of the Irish General Practice Nurses Educational Association (IGPNEA)*

## Unknown Factors

The aetiology of prostate cancer is the subject of numerous studies and remains largely unknown compared to other common cancers.

She continues, "While the exact causes of prostate cancer are not fully understood many cases do appear to be related to aberrant cell signalling that involves male androgen hormones, particularly testosterone and its metabolites.

"Within certain tissues, testosterone may be converted into one of two active compounds, oestradiol or dihydrotestosterone. Oestradiol promotes the growth of prostate cancer cells and dihydrotestosterone inhibits apoptosis of those cells. Testosterone plays a central role in maintaining prostate cells and stimulating apoptosis when abnormal cells arise. However, the mechanism by which testosterone and its active derivatives contribute to the development of prostate cancer is not entirely understood.<sup>7</sup>

"During the process of malignant transformation, cells gradually evolve from the benign to malignant phenotype. High-grade prostatic intraepithelial neoplasia (PIN) is the histological entity widely considered to be the most likely precursor of invasive prostatic cancer. It is characterised by cellular proliferation within pre-existing ducts and glands with cytological changes.<sup>2</sup>

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References: 1. Qvaril S, Mellino M, Lee J, et al. Triple therapy with olmesartan medoxomil, amlodipine besylate and hydrochlorothiazide in adult patients with hypertension: the TRINITY multicenter, randomized, double-blind, 12-week, parallel-group study. *Clin Ther* 2010 Jul; 32(7):1252-69. 2. Summary of Product Characteristics (SmPC) Olmesartan/Amlodipine/Hydrochlorothiazide Krka. 3. European Directorate for the Quality of Medicines, Strasbourg, [Internet]. [cited 01/2021]. Available at: <http://www.edqm.eu> 4. Source: CEGEDIM, ePharma Market, HmK, Intellit, IQVIA, MEDICUBE, PharmaZoom, PHARMSTANDARD, SOFIDENT 1-9/2020.

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Our innovation and knowledge are dedicated to health. Therefore, our determination, persistence and experience work together for a single purpose – to develop effective and safe products of the highest quality.

“Although other prostate lesions may be associated with even higher rates of carcinoma, PIN has been identified as the most likely progenitor of the majority of prostatic adenocarcinomas.”<sup>9</sup>

### Symptoms and Diagnosis

When the prostate gland becomes cancerous, it can put pressure on the urethra, causing dysuria, a burning sensation and frequency of micturition. It can also cause hesitancy, a weak and intermittent flow, nocturia, haematuria and impotence or sexual dysfunction. Theresa continues, “Other symptoms include swollen lymph nodes in the groin and pain in the pelvis, hips, back, or ribs. More advanced stage of the disease may present with urinary retention and back pain, as the axis skeleton is the most common site of bony metastatic disease. Prostate cancer should not be confused with benign prostate hyperplasia, which has similar symptoms and often occurs in older men but is not a type of cancer.”<sup>7</sup>

Prostate cancers usually grow very slowly, and symptoms may not occur for some time. She adds, “If the prostate is enlarged, a preliminary diagnosis can be made by rectal examination or transrectal ultrasound (TRUS). A PSA blood test for prostate-specific antigen is used to detect prostate tumours in their earliest stages in high-risk individuals.

“Although originally introduced as a tumour marker for the detection of cancer recurrence, PSA testing became widely adopted as a screening tool for prostate cancer. However, it is not prostate cancer-specific and other prostate conditions, such as benign prostatic hyperplasia (BPH) or prostatitis, can also affect PSA levels.<sup>2</sup> If prostate cancer is suspected a biopsy is done to confirm the diagnosis. When detected early, prostate cancer is treatable. A large majority of prostate cancers are diagnosed either before they have spread or when they have spread only locally. Survival rates in these cases are very high.”<sup>7</sup>

### Staging Systems

The TNM staging system refers to the size of the tumour (T), if the cancer has spread to the lymph nodes (N) and if the cancer has spread to other parts of the body- metastasis (M).<sup>1</sup>

#### Tumour (T) –Size of the tumour

**T1** The tumour is within the prostate gland. It is too small to be felt during a rectal exam.

**T2** The tumour is still within your prostate gland. It is large enough to be felt during a rectal exam.

**T3** The tumour can be felt throughout the prostate, and may have broken through the outer layer of the prostate.

**T4** The tumour has spread to organs outside the prostate gland.

#### Node (N) – Are the lymph nodes affected?

**N** Cancer is present in the lymph nodes.

**N0** No cancer in the lymph nodes.

**N1** Cancer has spread to 1 or more of the lymph nodes.

If diagnosed with early prostate cancer, **N0** signifies that the cancer has not spread outside the prostate.

#### Metastasis (M) – has it spread outside the prostate?

**M** The cancer has spread to lymph nodes and/or other organs, commonly bones

**M0** The cancer has not spread.

If diagnosed with early prostate cancer **M0** signifies that the cancer has not spread outside the prostate.

#### The Gleason Score

The Gleason Score is a grading system used to determine the aggressiveness of prostate cancer and can be used to choose appropriate treatment options. “The Gleason Score ranges from 1-5 and describes how much the cancer looks like healthy or abnormal tissue,” she notes.

“Most cancers score a grade 3 or higher. Since prostate tumours are often made up of cancerous cells that have different grades, two grades are assigned for each patient. A primary grade is given to describe the



# PROSTATE CANCER



cells that make up the largest area of the tumour and a secondary grade is given to describe the cells of the next largest area. If the Gleason Score is written as 3+4=7, it means most of the tumour is grade 3 and the next largest section of the tumour is grade 4. If the cancer is almost entirely made up of cells with the same score, the grade for that area is counted twice to calculate the total Gleason Score. Typical Gleason Scores range from 6-10. The higher the Gleason Score, the more likely that the cancer will grow and spread quickly. Scores of 6 or less describe cancer cells that look similar to normal cells and suggest that the cancer is likely to grow slowly. A score of 7 suggests an intermediate risk for aggressive cancer. Scoring a 7 means that the largest section of the tumour (primary score) scored a 3 or 4. Tumours with a primary score of 3 and a secondary score of 4 have a reasonably good outlook, whereas cancers with a primary Gleason Score of 4 and a secondary score of 3, are more likely to grow and spread. Scores of 8 or higher describe cancers that are likely to spread more rapidly and these cancers are often referred to as high grade or poorly differentiated.<sup>10</sup>

## Treatment Options

Treatment options for patients with prostate cancer depend on the stage and grade of the cancer and include active surveillance, watchful waiting, hormone therapy, radical prostatectomy, external beam radiotherapy, and brachytherapy.<sup>1</sup>



“Active surveillance is used to monitor the cancer closely. This involves a prostate-specific antigen (PSA) blood test every three months and a digital rectal exam (DRE) every six months for the first year followed by a PSA blood test every 6 months and a DRE at least once a year. Prostate biopsies and imaging tests may also be done every 1 to 3 years.<sup>12</sup> Because prostate cancers usually progress slowly, a “watchful waiting” approach rather than immediate treatment may be recommended.

“This is especially true for patients who are elderly or in otherwise poor health. In patients with intermediate or high-risk localised prostate cancer with a real prospect of long-term disease control and those with locally-advanced disease, radical prostatectomy or radical radiotherapy should be offered.<sup>2</sup>

“Hormone therapy is the primary treatment for metastatic prostate cancer, but is also used for patients with locally-advanced, non-metastatic disease. In patients with localised prostate cancer, the choice of treatment depends on whether the disease is low, intermediate, or high risk.<sup>2</sup> Hormone therapy also called androgen suppression or androgen deprivation therapy (ADT) attacks androgens that stimulate the growth of prostate cancer. A form of hormone therapy involves drugs called LHRH analogs, or LHRH agonists such as buserelin, goserelin, leuprorelin acetate or triptorelin that chemically block the production of androgens. Side effects of hormone therapy include reduced libido, sexual dysfunction, osteoporosis, gynaecomastia and hot flushes.<sup>2,7</sup>

“Brachytherapy is a form of radiation therapy used to treat prostate cancer. Prostate brachytherapy involves placing radioactive seeds in the prostate gland which destroys the cancer cells while causing less damage to healthy tissue nearby. Prostate brachytherapy procedures vary based on the type. High dose rate (HDR) brachytherapy is a temporary type of prostate brachytherapy that involves placing radioactive sources in the prostate gland and delivering a high dose of radiation over a few minutes before the sources are removed. Treatment may involve several sessions. Low dose rate (LDR) brachytherapy is permanent and involves placing radioactive seeds in the prostate gland permanently, where they slowly release radiation over several months. Brachytherapy may be the only treatment used for early-stage prostate cancer that is less likely to spread beyond the prostate. For larger prostate cancers or those that have a greater chance of spreading beyond the prostate, brachytherapy may be used along with other treatments, such as external beam radiation therapy (EBRT) or hormone therapy.<sup>1,11</sup>

“In external beam radiation therapy, beams of radiation are focused on the prostate gland from a machine outside the body. This type of radiation can be used to try to cure earlier stage cancers, or to help relieve symptoms such as bone pain if the cancer has spread to a specific area of bone.<sup>7,11</sup>

Surgery is usually only carried out if the cancer has not spread from the prostate, Theresa explains. “A radical prostatectomy may be considered if examination of the pelvic lymph nodes reveals that they are not cancerous. Surgical risks can include impotence and urinary incontinence.<sup>7</sup> Transurethral resection of the prostate (TURP) can be used to relieve symptoms but does not remove all of the cancer. TURP is often used in men who cannot have a radical prostatectomy because of advanced age or illness or in men who have a noncancerous enlargement of the prostate.

“In men who are unable to have traditional surgery, cryosurgery may also be used. In this procedure, a metal probe is inserted into the cancerous regions of the prostate; liquid nitrogen is then used to freeze the probe, killing the surrounding cells. If the cancer has spread from the prostate, radiation therapy may be used. Bi lateral orchidectomy should be offered to all

patients with metastatic prostate cancer as an alternative to continuous LHRH agonist treatment. Removal of the testicles cuts off the supply of testosterone to the tumour, which the prostate cancer needs in order to continue growing. It can delay or stop the tumour growth and eliminates the need for other hormone therapy. If surgery or hormone therapy fails, chemotherapy may be used. While chemotherapy can slow the growth of the tumour, it is not very effective in treating prostate cancer.<sup>7,7</sup>

## Prognosis and Outlook

The outlook for prostate cancer is generally good because, unlike many other types of cancer, it usually progresses very slowly. If treated early, prostate cancer can often be cured. She concludes, “The survival rate is over 90% and many men die with prostate cancer, rather than as a result of having it. Prostate cancer has one of the highest survival rates of any type of cancer. 92% of all prostate cancers are found when they are in the early stage, and almost 100% of men who have local or regional prostate cancer will survive more than five years after diagnosis. For most with local or regional prostate cancer, the relative 10-year survival rate is 98% and the relative 15-year survival rate is 96%. Once prostate cancer has spread beyond the prostate, however, survival rates fall and about 7% have more advanced prostate cancer at the time of diagnosis. For men with prostate cancer that has spread to other parts of the body, the 5-year survival rate is 30%.<sup>13,14</sup>

“Prostate cancer presents a number of challenges for primary care clinicians. Many men with prostate cancer are asymptomatic until the tumour has progressed, and common symptoms have significant crossover with benign conditions affecting the prostate. PSA-based testing of prostate cancer is very common but remains controversial. The value of screening remains uncertain because the PSA test does not distinguish between benign and malignant disease, and there has been no proof that early treatment leads to increased cure rates. Digital rectal examination alone is insufficient for screening as its positive predictive value is only 11%–26%. Current diagnostic tests have limitations in terms of significant false positive and false negative rates however research is ongoing into improved methods for diagnosing prostate cancer. Nanotechnology has shown initial success in prostate cancer disease diagnosis, imaging and treatment. A number of new tests and testing strategies are being trialled to improve the diagnosis of clinically significant prostate cancer and blood-based biomarkers for prostate cancer are also being extensively investigated.<sup>15,16</sup> Because the value of PSA-based testing of prostate cancer remains unclear, more genetic testing-based detection strategies are needed to identify individuals at high risk of prostate cancer and novel drugs need to be evaluated to substantially improve the clinical care of patients with prostate cancer. Continued clinical and translational research in prostate cancer is important and could be key to the treatment and management of prostate cancer through leading improvements in prostate cancer imaging and diagnosis.<sup>16</sup>

References available upon request

# Unlocking Your Best Tomorrow – with Me Today

The Me Today Range was recently launched at an event in the Dylan hotel, Dublin



From left to right, Lorraine Keane, Ally Garvey, Maeve Madden, Nichola Flood, Dr. Clodagh Campbell

As a direct result of the last 18 months there's been a global movement towards wellness; an holistic approach to beauty and being kind to yourself, so the arrival of Me Today's supplement and skincare range of products is great news for health-conscious people in Ireland.

Even if there's little time to go to the gym or practice yoga daily, everyone deserves to unlock a few minutes for themselves at the beginning and end of each day. By investing in yourself with your skincare and supplement routine you really can unlock your best tomorrow.

Based on a combination of science and tradition, the Me Today ethos revolves around people living their best lives and feeling good about

themselves on the inside, as well as the outside. It's not easy to reach your potential when life slows you down, but Me Today believes in stepping up; it's okay to want more from your life and from your body, which is why they created a range of products to help you unlock your best tomorrow.

Me Today is a New Zealand owned and operated, lifestyle and wellness company with a nurturing spirit. Its mission is to

encourage positive change in the lives of its consumers through simple yet effective, daily self-care. Based on science and tradition, Me Today's range of supplements and skincare is thoughtfully formulated in New Zealand using clean, high-quality ingredients. Created to help people put themselves first so that they are at their best to then look after the people around them. Unlocking your best tomorrow with Me Today.



The range includes a mix of **supplements**, which are based on scientific and traditional evidence to support overall wellbeing and to help consumers be on top of their game, naturally. All products are encapsulated in easy to swallow vegetable capsules and are packed in glass vessels for efficacy and environmental reasons.

Me Today skincare is enriched with essential botanicals, antioxidants and vitamins blended specially to hydrate, protect and

From left to right, Maeve Madden and Lorraine Keane



Maeve Madden

comfort your skin. The entire Me Today skincare range is vegan or vegetarian friendly and is made from 93%+ naturally derived ingredients, contains no parabens, sls/sles or phthalates.

Michael Kerr, along with Steve Sinclair and Grant Baker, launched Me Today in 2018 after Michael's wife, Nikki, was diagnosed with stage three breast cancer. Michael's immediate reaction was to stop working, stay at home and look after her. However, Nikki wanted Michael to carry on and ensure he was keeping himself healthy, both mentally and physically, so that he could be there to look after the whole family. So, Michael began to focus on nourishing his body from the inside out. It was through his and Nikki's search for a trustworthy supplement and skincare range that the concept for Me Today was born.

**Speaking about the launch, founder and CEO of Me Today, Michael Kerr** says, "We are very excited to see Me Today launch in Ireland with a new wellness routine. We want our Me Today fans to feel their best from the inside out and our natural range of skincare and supplements are specially formulated for this. We can't wait for people in Ireland to unlock their best tomorrow."

Me Today also confirmed it is working with a number of Brand Ambassadors in the Irish market including fitness queen Maeve Madden and businesswoman and broadcaster Lorraine Keane.

**Maeve Madden comments,** "Self-care is really important to me and something I believe we all need to focus on more in our daily lives. Slowing down isn't always an option but taking some time each day to indulge in little wellness rituals can be a great reset. I love the ethos of Me Today and I'm absolutely thrilled to be working with the brand. I'm using the products as part of my own daily routine and love how they make me feel."

**Lorraine Keane adds,** "There's so much pressure on women nowadays to look a certain way and follow trends, but it doesn't have to be complicated. I'm really passionate about empowering women of all ages to be the best version of themselves they can be, and this chimes with what Me Today is all about – a range of nurturing, quality products that can help you to feel good from the inside out. Their serums and oils have become a staple of my skincare routine since I started using them."

Me Today skincare products start from €19.99 and Me Today supplements are each priced at €24.99.

The Me Today supplement range was launched in November 2019 with eight core complex products to help with everything from general wellbeing to immune function, energy, mobility and relaxation. The range has since grown to 17 supplements including high dose, targeted formulas such as B12 50, Ashwagandha 3000, and Vitamin D3 1000.

**Me Today Brand Roadmap**

**Vision** – To be a global leader in the lifestyle and wellness spaces

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Louise Martin



# POWERED BY V REMISSION

## VENCLYXTO<sup>®</sup> REGIMENS: DEEP RESPONSE\*\* AND LONGER PFS WITH FIXED TREATMENT DURATION<sup>1,2</sup>

|| Remission as measured by CR/CRi: 1L VEN+O FTD 1 year<sup>1</sup>: CR/CRi(at 15 months): 50% (VEN+O) vs 23% (O+Clb) (P<0.0001<sup>1</sup>); 2L+: VEN+R FTD 2 years<sup>1</sup>: CR/CRi(at 9 months): 27% (VEN+R) vs 8% (BR)<sup>1</sup>; \*\* Deep response as measured by CR/CRi and MRD negativity (PB): 1L: VEN+O FTD 1 year<sup>1</sup>: MRD negativity (PB)(at 15 months) 76% (VEN+O) (95% CI: 69–81) vs 35% (O+Clb) (95% CI: 29–42) (P<0.0001<sup>1</sup>); 2L+ VEN+R FTD 2 years<sup>1</sup>: MRD negativity (PB)(at 9 months): 62% (VEN+R) (95% CI: 55.2–69.2) vs 13% (BR) (95% CI: 8.9–18.9)<sup>1</sup>. PFS 4-year estimates: 1L: VEN+O FTD 1 year<sup>1</sup>: 74% (VEN+O) vs 35% (O+Clb) (HR=0.33; 95% CI: 0.25–0.45)<sup>1</sup>; 2L+: VEN+R FTD 2 years<sup>1</sup>: 54 months median PFS<sup>1</sup> (95% CI: 48.4–57.0) (VEN+R) vs 17 months mPFS (95% CI: 15.5–21.7) (BR)<sup>1</sup>. ‡ Results are descriptive. PFS=progression free survival; CR(i)=complete remission (incomplete marrow recovery); 1L=1st Line; 2L+=2nd Line+; VEN=VENCLYXTO; O=Obinutuzumab; Clb=Chlorambucil; B=Bendamustine; MRD= Minimal Residual Disease; R=Rituximab; PB=peripheral blood; CI=Confidence Interval. FTD=Fixed Treatment Duration. **References:** 1. VENCLYXTO<sup>®</sup> SmPC available at [www.medicines.ie](http://www.medicines.ie). 2. Al Sawaf et al, *HemaSphere*, 2021;5(S2):27

**VENCLYXTO<sup>®</sup> (venetoclax) 10 mg/50 mg/100 mg film-coated tablets. PRESCRIBING INFORMATION. PRESENTATION:** Each film-coated tablet contains 10mg, 50mg or 100mg of venetoclax. Please refer to the Summary of Product Characteristics (SmPC) before prescribing. **INDICATION:** Venclyxto in combination with obinutuzumab is indicated for the treatment of adult patients with newly diagnosed chronic lymphocytic leukaemia (CLL) (see section 5.1). Venclyxto in combination with rituximab is indicated for the treatment of adult patients with CLL who have received at least one prior therapy\*. Venclyxto monotherapy is indicated for the treatment of CLL in the presence of 17p deletion or TP53 mutation in adult patients who are unsuitable for or have failed a B cell receptor pathway inhibitor or in the absence of 17p deletion or TP53 mutation in adult patients who have failed both chemoimmunotherapy and a B cell receptor pathway inhibitor\*. Venclyxto in combination with a hypomethylating agent is indicated for the treatment of adult patients with newly diagnosed acute myeloid leukaemia (AML) who are ineligible for intensive chemotherapy. **DOSE AND ADMINISTRATION:** Oral. Treatment to be initiated and monitored by a physician experienced in the use of anticancer medicinal products. Patients treated with venetoclax may develop tumour lysis syndrome (TLS). Refer to SmPC for specific details on TLS management by disease indication. See SmPC for full dosology. **Posology (CLL): Dose-titration schedule:** the starting dose is 20 mg of venetoclax once daily for 7 days. The dose must be gradually increased over a period of 5 weeks up to the daily dose of 400 mg. **Post-titration dose for venetoclax in combination with rituximab:** The recommended dose of venetoclax in combination with rituximab is 400 mg once daily. Administer Rituximab after the patient has completed the dose-titration schedule and has received the recommended daily dose of 400 mg venetoclax for 7 days. Venetoclax is taken for 24 months from Cycle 1 Day 1 of rituximab. **Venetoclax in combination with obinutuzumab:** Venetoclax is given for a total of 12 cycles, each cycle consisting of 28 days; 6 cycles in combination with obinutuzumab, followed by 6 cycles of venetoclax as a single agent. Administer obinutuzumab 100 mg on Cycle 1 Day 1, followed by 900 mg which may be administered on Day 1 or Day 2. Administer 1000 mg on Days 8 and 15 of Cycle 1 and on Day 1 of each subsequent 28-day cycle, for a total of 6 cycles. Start the 5-week venetoclax dose-titration schedule (see table 1) on Cycle 1 Day 22 and continue through Cycle 2 Day 28. After completing the dose-titration schedule, the recommended dose of venetoclax is 400 mg once daily from Cycle 3 Day 1 of obinutuzumab to the last day of Cycle 12. **Post-titration dose for venetoclax monotherapy:** the recommended dose of venetoclax is 400 mg once daily. Treatment should be continued until disease progression or no longer tolerated by the patient. **Posology (AML):** Day 1: 100mg; Day 2: 200mg; Day 3 (and beyond): 400mg. Azacitidine should be administered at 75 mg/m<sup>2</sup> either intravenously or subcutaneously on Days 1-7 of each 28-day cycle beginning on Cycle 1 Day 1. Decitabine should be administered at 20 mg/m<sup>2</sup> intravenously on Days 1-5 of each 28-day cycle beginning on Cycle 1 Day 1. Venetoclax dosing may be interrupted as needed for management of hematologic toxicities and blood count recovery. Venetoclax, in combination with a hypomethylating agent, should be continued until disease progression or unacceptable toxicity is observed. Patients should swallow the tablets whole with water at approximately the same time each day. The tablets should be taken with a meal. **Prevention of tumour lysis syndrome (TLS):** Prior to initiating venetoclax, tumour burden assessment, including radiographic evaluation must be performed for all patients. The following prophylaxis measures should be followed to minimise the risk of TLS and more intensive measures should be employed as overall risk increases: adequate hydration, administration of anti-hyperuricemic agents if necessary, blood chemistry monitoring and correction of abnormalities. Monitoring should be increased for patients at high risk of TLS. All patient comorbidities should be considered for risk appropriate prophylaxis and monitoring, either outpatient or in hospital. Dosing interruption and/or dose reduction for toxicities may be required. Dose modifications for TLS or other toxicities may need to be considered during treatment. See SmPC for full details of prophylaxis measures. **Special Populations: Elderly:** No dose adjustment required. **Renal impairment:** No dose adjustment is needed for patients with mild, moderate or severe renal impairment (CrCl ≥15 ml/min and <90 ml/min). Venclyxto should be administered to patients with severe renal impairment (CrCl ≥15 ml/min and <30 ml/min) only if the benefit outweighs the risk and patients should be monitored closely for signs of toxicity due to increased risk of TLS. Patients with reduced renal function may require more intensive prophylaxis to reduce the risk of TLS and closer monitoring. Safety in patients with severe renal impairment or on dialysis has not been established, and a recommended dose for these patients has not been determined. **Hepatic impairment:** No dose adjustment is recommended in patients with mild or moderate hepatic impairment. Patients with moderate hepatic impairment should be monitored more closely for signs of toxicity. A dose reduction of at least 50% throughout treatment is recommended for patients with severe hepatic impairment. These patients should be monitored more closely for signs of toxicity. **Paediatric Population:** The safety and efficacy of Venclyxto in children aged less than 18 years has not been established. **CONTRAINDICATIONS:** Hypersensitivity to any of the active substances or excipients. In patients with CLL, concomitant use of strong CYP3A inhibitors at initiation and during the dose-titration phase. In all patients, concomitant use of preparations containing St. John's wort. **SPECIAL WARNINGS AND PRECAUTIONS:** Tumour lysis syndrome (TLS) The risk of TLS is a continuum based on multiple factors, including comorbidities (particularly reduced renal function), tumour burden and splenomegaly. Reduced renal function (CrCl <80ml/min) further increases the risk. Assess patient-specific factors for level of risk of TLS and provide prophylactic hydration and anti-hyperuricemic to patients prior to first dose of venetoclax to reduce risk of TLS. Blood chemistry should be monitored and abnormalities managed promptly. Dosing should be interrupted if needed; when restarting venetoclax, dose modification guidance should be followed. More intensive measures should be employed as overall risk increases. **Neutropenia and**

**infections:** In patients with CLL, grade 3 or 4 neutropenia has been reported. In patients with AML, grade 3 or 4 neutropenia are common before starting treatment. The neutrophil counts can worsen with venetoclax in combination with a hypomethylating agent. Neutropenia can recur with subsequent cycles of therapy. Complete blood counts should be monitored throughout the treatment period. Dose interruptions or reductions are recommended for patients with severe neutropenia. Serious infections, including sepsis with fatal outcome, have been reported. Monitoring of any signs and symptoms of infection is required. Suspected infections are to receive prompt treatment, including antimicrobials and dose interruption or reduction as appropriate and the use of growth factors (e.g., G-CSF) as appropriate. **Immunisation:** Live vaccines should not be administered during treatment and thereafter until B-cell recovery as the safety and efficacy has not yet been established. **CYP3A inducers:** Co-administration of CYP3A4 inducers may lead to decreased Venclyxto exposure and consequently a risk for lack of efficacy. Concomitant use of Venclyxto with strong or moderate CYP3A4 inducers should be avoided. **Women of childbearing potential:** Women of childbearing potential must use a highly effective method of contraception while taking Venclyxto. **INTERACTIONS:** See SmPC for full details. Venetoclax is predominantly metabolised by CYP3A. **CYP3A inhibitors:** In patients with CLL, concomitant use of venetoclax with strong CYP3A inhibitors is contraindicated at initiation and during the dose-titration phase due to increased risk for TLS. Alternative treatments should be considered. In all patients, if a CYP3A inhibitor must be used, follow the recommendations for managing drug-drug interactions. If a moderate CYP3A inhibitor must be used, the doses must be reduced and patients should be monitored more closely. Refer to SmPC for full details. Grapefruit, Seville oranges and starfruit should be avoided during treatment. **P-gp and BCRP inhibitors:** Concomitant use of Venclyxto with P-gp and BCRP inhibitors at initiation and during the dose titration phase should be avoided; if a P-gp and BCRP inhibitor must be used, patients should be monitored closely for signs of toxicities. **CYP3A inducers:** For patients requiring concomitant use of Venclyxto with strong or moderate CYP3A inducers should be avoided. Preparations containing St. John's wort are contraindicated during treatment with venetoclax. **Bile acid sequestrants:** Co-administration of bile acid sequestrants with Venclyxto is not recommended as this may reduce the absorption of venetoclax. If a bile acid sequestrant is to be co-administered with Venclyxto, the SmPC for the bile acid sequestrant should be followed to reduce the risk for an interaction, and Venclyxto should be administered at least 4-6 hours after the sequestrant. **Warfarin:** It is recommended that the international normalised ratio be monitored closely in patients receiving warfarin. **Substrates of P-gp, BCRP and OATP1B1:** Co-administration of narrow therapeutic index P-gp, or BCRP substrates with Venclyxto should be avoided. If a narrow therapeutic index P-gp or BCRP substrate must be used, it should be used with caution. For an orally administered P-gp or BCRP substrate sensitive to inhibition in the gastrointestinal tract its administration should be separated from Venclyxto administration as much as possible to minimise a potential interaction. If a statin is used concomitantly with Venclyxto, close monitoring of statin related toxicity is recommended. **FERTILITY PREGNANCY AND LACTATION:** **Women of childbearing potential/Contraception in females:** Women should avoid becoming pregnant while taking Venclyxto and for at least 30 days after ending treatment. **Pregnancy:** Venclyxto is not recommended during pregnancy and in women of childbearing potential not using highly effective contraception. **Breast-feeding:** Breast-feeding should be discontinued during treatment with Venclyxto. **Fertility:** Before starting treatment, counselling on sperm storage may be considered in some male patients. **SIDE EFFECTS:** See SmPC for full details on side effects. In patients with CLL: **Very common side effects (≥1/10):** Pneumonia, upper respiratory tract infection, neutropenia, anaemia, lymphopenia, hyperphosphataemia, hyperkalaemia, hypocalcaemia, diarrhoea, vomiting, nausea, constipation and fatigue. **Common side effects (≥1/100 to <1/10):** Sepsis, urinary tract infection, febrile neutropenia, tumour lysis syndrome, hyperuricaemia, and blood creatinine increased. In patients with AML: **Very common side effects (≥1/10):** Pneumonia, sepsis, urinary tract infection, neutropenia, febrile neutropenia, anaemia, thrombocytopenia, hypokalaemia, decreased appetite, dizziness, headache, hypotension, haemorrhage, dyspnoea, nausea, diarrhoea, vomiting, stomatitis, abdominal pain, arthralgia, fatigue, asthenia, weight decreased and blood bilirubin increased. **Common side effects (≥1/100 to <1/10):** Tumour lysis syndrome and cholecystitis. Tumour lysis syndrome (TLS): TLS is an important identified risk when initiating Venclyxto.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions via HPPA Pharmacovigilance. Website: [www.hppa.ie](http://www.hppa.ie). Suspected adverse events should also be reported to AbbVie Limited on 01-4287900.

**LEGAL CATEGORY:** POM (S1A). **MARKETING AUTHORISATION NUMBERS/PRESENTATIONS:** 10mg film-coated tablet, 14 tablets, EU/1/16/1138/002; 50mg film-coated tablet, 7 tablets, EU/1/16/1138/004; 100mg film-coated tablet, 7 tablets, EU/1/16/1138/005; 100mg film-coated tablet, 14 tablets, EU/1/16/1138/006; 100mg film-coated tablet, 112 tablets, EU/1/16/1138/007. **MARKETING AUTHORISATION HOLDER:** AbbVie Deutschland GmbH & Co. KG, Knollstrasse, 67061 Ludwigshafen, Germany. Further information is available from AbbVie Limited, 14 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

† Indications are not reimbursed \* Indications are reimbursed

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Continuing Professional Development

# CPD

## 60 Second Summary

Cancer describes a group of illnesses caused by a rapid and uncontrolled growth of abnormal cells. These form a mass, leading to a growth or tumour, which can damage nearby organs or metastasise to invade distant organs.

The most common types of cancer in Ireland are prostate, colorectal and lung cancers for males; and breast, colorectal and lung cancers for females.

Systemic anti-cancer therapy (SACT) involves the systemic treatment of cancer, including, but not limited to, chemotherapy, targeted therapies and immunotherapies. Oral anti-cancer medicines (OAM) can be grouped into three categories: cytotoxic agents, targeted agents and hormonal agents. Targeted therapies are often cytostatic (i.e. they block tumour cell proliferation) whereas standard chemotherapy agents are cytotoxic (i.e. they kill tumour cells).

Systemic anticancer therapy (SACT) involves the administration of medication that often has a narrow therapeutic window and toxic side effects.

Recommendations about communication are also made that highlight the importance of, but current inconsistency in, communication from the hospital about OAM treatment with the patient's GP and community pharmacy. This is required for the safe management of patient care.

When reviewing an OAM prescription as recommended by the Oral Anti-Cancer Medicines Model of Care<sup>7</sup>, check the indication and drug dose. If possible, check the calculation for body surface area (BSA) or weight.

In addition to prescription review, it is important to talk to the patient about what information they have already received - the opportunity to talk and ask questions about medications may really be appreciated.

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Donna graduated with a BSc in Pharmacy from the Royal College of Surgeons in Ireland. She then returned to university to complete a MSc in Neuropharmacology. This led to a PhD investigating the genetics of schizophrenia, followed by a postdoctoral research position in the same area. Currently Donna works as a pharmacist in Galway, and as a clinical writer.



- 1. REFLECT** - Before reading this module, consider the following: Will this clinical area be relevant to my practice?
  - 2. IDENTIFY** - If the answer is no, I may still be interested in the area but the article may not contribute towards my continuing professional development (CPD). If the answer is yes, I should identify any knowledge gaps in the clinical area.
  - 3. PLAN** - If I have identified a knowledge gap - will this article satisfy those needs - or will more reading be required?
  - 4. EVALUATE** - Did this article meet my learning needs - and how has my practise changed as a result? Have I identified further learning needs?
  - 5. WHAT NEXT** - At this time you may like to record your learning for future use or assessment. Follow the 4 previous steps, log and record your findings.
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# Oral Chemotherapy Medications

## Introduction

Cancer describes a group of illnesses caused by a rapid and uncontrolled growth of abnormal cells. These form a mass, leading to a growth or tumour, which can damage nearby organs or metastasise to invade distant organs.<sup>1</sup> The National Cancer Registry Ireland (NCRI) collects, classifies, stores and analyses information about the incidence and prevalence of cancer in Ireland. In 2020, the NCRI estimated that, on average<sup>2</sup>, about 36,907 invasive cancers were diagnosed annually during the years 2018-2020 (24,793 cancers excluding the common but rarely fatal non-melanoma skin cancer). Cancer was responsible

for nearly 31% of deaths in 2017 and is the most common cause of death in Ireland. The most common types of cancer in Ireland are prostate, colorectal and lung cancers for males; and breast, colorectal and lung cancers for females (Table 1). Lung cancer accounted for the highest proportion of mortality in both sexes: 20% of cancer deaths in women and 22% in men. The risk of dying of cancer was about 33% higher for men than for women. Although the incidence of cancer is increasing, the survival rate is also increasing. Ireland ranked in the top half of countries surveyed for 14 out of 18 common cancers studied in the EU five-year net survival during 2010-2014.

The top risk factors for all cancers are<sup>4</sup>:

- Cigarette smoking and tobacco use
- Infections
- Radiation
- Immunosuppressive medication
- Diet
- Alcohol
- Physical activity
- Obesity
- Diabetes
- Environmental risk factors

The HSE National Cancer Control Programme (NCCP) was established in 2007.<sup>5</sup> It monitors the incidence, mortality and survival patterns of cancer in Ireland using data from bodies

Table 1. The most common types of cancer in Ireland<sup>3</sup>

Type of Cancer	Average Annual Diagnoses
Skin	13,311
Prostate	3,890
Breast	3,704
Bowel	2,819
Lung	2753



Full prescribing information is available on [www.medicines.ie](http://www.medicines.ie)  
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like the NCRI, and also aims to monitor and improve the quality of cancer care. National chemotherapy regimens have been developed by healthcare professionals with the NCCP to support safe, evidence-based and cost-effective cancer treatment for all Irish cancer patients.

#### Treatment

Systemic anti-cancer therapy (SACT) involves the systemic treatment of cancer, including, but not limited to, chemotherapy, targeted therapies and immunotherapies.<sup>6</sup> Oral anti-cancer medicines (OAM) can be grouped into three categories: cytotoxic agents, targeted agents and hormonal agents. Targeted therapies are often cytostatic (i.e. they block tumour cell proliferation) whereas standard chemotherapy agents are cytotoxic (i.e. they kill tumour cells).

- *Cytotoxic chemotherapy* slows the process of cancer cells growing or multiplying. They can be cell cycle phase-specific or cell cycle phase non-specific. These drugs interfere with growth and division of all cells with no discrimination: all rapidly dividing cells in the body are targeted, which gives rise to the side effects commonly associated with chemotherapy.
- *Targeted therapy* (biological therapies) are aimed at specific molecular targets on the cell surface or within the cell that are specifically present in the cancer cells, and not present in healthy cells.
- *Hormonal therapy* works on

the hormones that increase cell proliferation in certain types of cancer, i.e. breast, thyroid, prostate and uterine. With these diseases, the action of hormones or hormone antagonists depends on the presence of hormone receptors in the tumours themselves (e.g., oestrogen receptors in breast cancers).

Many treatment regimens use a combination of these categories. Neoadjuvant therapy may be necessary in some cases. This refers to all treatments that are administered before the primary cancer treatment. If the cancer is e.g. too large, in an awkward location, or obstructing an organ, neoadjuvant therapy can be used to shrink the tumour to allow e.g. surgical treatment. Adjuvant therapy refers to regimens administered after the primary treatment. Chemotherapy is often administered to destroy any micrometastases.

Prescribing of OAM in Ireland is usually based on one of the HSE National Cancer Control Programme (NCCP) chemotherapy regimens. A comprehensive list of NCCP OAM regimens is available on the NCCP website.<sup>5</sup>

#### Dispensing Oral Chemotherapy

Systemic anticancer therapy (SACT) involves the administration of medication that often has a narrow therapeutic window and toxic side effects.<sup>7</sup> OAM have the same potential for risk as parenteral SACT in terms of side effects, toxicities and serious medication errors. Defined quality and safety policies are in place

for parenteral SACT in Ireland, but such policies are less well defined for OAM. Treating patients using OAM is a multidisciplinary process that has multiple steps, such as the decision to treat, the prescribing, dispensing and management of a patient. OAM has significant differences to that of parenteral SACT. OAM are dispensed in the community and self-administered at home, while parenteral SACT is dispensed and usually administered in hospitals. The advantages of OAM include the convenience – as it is administered at home, there is no waiting for hospital administration. OAM can also lead to an increased sense of control for the patient.

As new and potentially more complex OAM regimens are developed additional safety challenges are likely to emerge, and it is envisaged that the provision of national guidance through a model of care will help standardise and overcome these. The 2014 NCCP Oncology Medication Safety Review identified the need for a national guideline for the management of the prescribing and dispensing of oral chemotherapy under the following topics:

- Safe prescribing
- Prescription checking
- Prescription format
- Administration
- Service models for dispensing and supply
- Communication system between primary care and secondary care

In response to this, the NCCP published the Oral Anti-Cancer Medicines Model of Care Recommendations in 2018.<sup>7</sup> The main recommendations relevant to community pharmacists in this report that are the following:

- All OAM prescriptions should be verified prior to dispensing and administration by an oncology pharmacist. Currently there is variation in the practice for the verification of OAM prescriptions. Some prescriptions, but not all, are verified by an oncology pharmacist prior to being given to the patient.
- Community pharmacists should have access to the recommended information (potentially including training and education programmes), where relevant, to allow prescription review prior to dispensing, as OAM are mostly dispensed by community pharmacists.
- Only one cycle of an OAM should be dispensed at a time. The quantity dispensed should not exceed the number of doses required to complete the cycle to reduce the risk of the patient overmedicating.

Recommendations about communication are also made that highlight the importance of, but current inconsistency in, communication from the hospital about OAM treatment with the patient's GP and community pharmacy. This is required for the safe management of patient care. A recommendation was also made that all prescriptions for OAM should include the recommended information either as a standard OAM prescription template, current prescription formats plus a treatment information document, or current prescription formats with the recommended information included as free text. (The NCCP plan to engage with the PCRS with regard to the current format of the High Tech prescription form).

#### Oral Chemotherapy Medications

Dosing of OAMS can be continuous (the same dose every day) or pulsed dosing. One "pulse" refers to one chemotherapy cycle e.g. "q21d" is every 21 days. Pulsed dosing allows the immune system to recover somewhat between cycles.

Women of childbearing potential or their male partners must use a highly effective method of contraception while taking OAMS.

Drug	Mechanism of Action	Administration	Indication	Dose	Side effects	Interactions
Capecitabine	Prodrug of fluorouracil, antimetabolite inhibiting DNA/RNA synthesis	30 mins after food	Breast, colorectal, gastric	1,250mg/m <sup>2</sup> bd for 14 days, followed by 7 days off treatment	Hand-foot syndrome. (palmar-plantar erythrodysesthesia)	CYP2C9 substrates (warfarin, phenytoin)
Abiraterone	CYP17 inhibitor (reduces androgen synthesis)	Empty stomach (food increases absorption and risk of ADRs)	Metastatic castration resistant prostate cancer (Used in combo with LH agonists, or with orchidectomy)	1000mg od	Should always be disp with prednisolone (This reduces mineralocorticoid side effects)	Strong inducers of CYP3A4 (phenytoin, carbamazepine) Avoid spironolactone: binds to androgen receptor, may cause disease progression
Enzalutamide	Androgen receptor inhibitor	With or without food	Metastatic castration resistant prostate cancer	160mg od	Many patients require treatment for hypertension which occurs in ~7%. Use with caution if previous seizure history	Strong CYP2C8 inhibitors, (gemfibrozil). Induces CYP2B6, CYP3A4, CYP2C9, CYP2C19, UGT1A1 - can lead to increased clearance of drugs.
Palbociclib	Reversible inhibitor cyclin-dependent kinases 4 and 6 inhibitor (involved in cell cycle regulation)	Swallowed whole with food	Hormone receptor (HR) - positive, HER2 - negative breast cancer	125mg od for 21 days followed by 7 days off treatment	Interstitial lung disease (report any respiratory issues)	CYP3A4 inhibitors/inducers
Lenalidomide	Binds to cereblon (receptor of the cullin 4-RING E3 ligase complex), inhibiting proliferation/enhancing apoptosis	Swallow whole with water	Multiple myeloma	Usual starting dose 25 mg od for 21 days, followed by 7 days off treatment	PE, DVT. The conditions of the Pregnancy Prevention Programme must be fulfilled.	Digoxin, statins, P-gp inhibitors
Tamoxifen	Primarily an oestrogen receptor antagonist	With or without food	Breast cancer	20-40mg daily	VTE, optic neuropathy. Any abnormal gynaecological symptoms should be investigated.	CYP2D6 inhibitors (e.g. paroxetine, fluoxetine)

Table 2. Commonly prescribed OAMs in Ireland<sup>8-13</sup>

on BSA in cancer care. If the calculated BSA is within 10% of that specified on the prescription, that is generally thought to be acceptable. Rounding usually occurs during calculation of BSA and medication dose to account for the available strengths of tablets. Rounding of OAM doses of 5%<sup>14</sup> is generally accepted. If the prescription is not rounded, contact should be made with the hospital to see if the prescriber prefers to round up or down.

When a query arises from performing an OAM prescription check, useful sources of information include the prescriber, the hospital pharmacy (especially the oncology/haematology pharmacists), liaison nurses, the oncology/haematology day ward/clinic, hospital treatment protocols, the SPCs for each medication, and the NCCP protocols.

The patient should be made aware that if they have any medication left for disposal they should bring back to the hospital to place in the cytotoxic bins.

The NCCP have multiple leaflets/booklets also available online that provide important information for cancer patients with one of the most important being about infection prevention. The Irish Cancer Society website is also a great source of information for patients. A UK website called Chemocare is useful for both patients and pharmacists: it provides information about treatments, patient counselling, and managing side effects in a patient-friendly way.

**General ADRs**

Nausea and vomiting is one of the most frequent side effects experienced by patients undergoing SACT.<sup>15</sup> It is often a distressing side effect, and anxiety about the recurrence of such symptoms from future cycles may become a cause of anticipatory nausea and vomiting. The NCCP has developed a guideline on SACT related nausea and vomiting, setting out the classification of emetogenic risk of SACT drugs, and antiemetics to prevent and treat SACT induced nausea and vomiting. SACT drugs are classified into four levels of emetogenicity (high, moderate, low and minimal). The emetogenic potential of the

**Patient Care**

When reviewing an OAM prescription as recommended by the Oral Anti-Cancer Medicines Model of Care<sup>7</sup>, check the indication and drug dose. If possible, check the calculation for body surface area (BSA) or weight. For BSA, both height and weight are needed. Multiple formulae are available to calculate BSA: the two main ones are Mosteller (which

can be performed using your own calculator), and Dubois & Dubois (the most commonly used). Online calculator tools are available to use (e.g. www.halls.md website). There are several limitations to calculating drug dosages based on BSA:

- BSA is estimated, not measured
- BSA formulae take no account of obesity or weight loss

- There is no precise correlation between drug clearance and BSA
- Different BSA formulae give different results
- The most popular nomogram for BSA calculation is DuBois which is based on only 9 subjects

Despite these limitations, drug doses are very frequently based

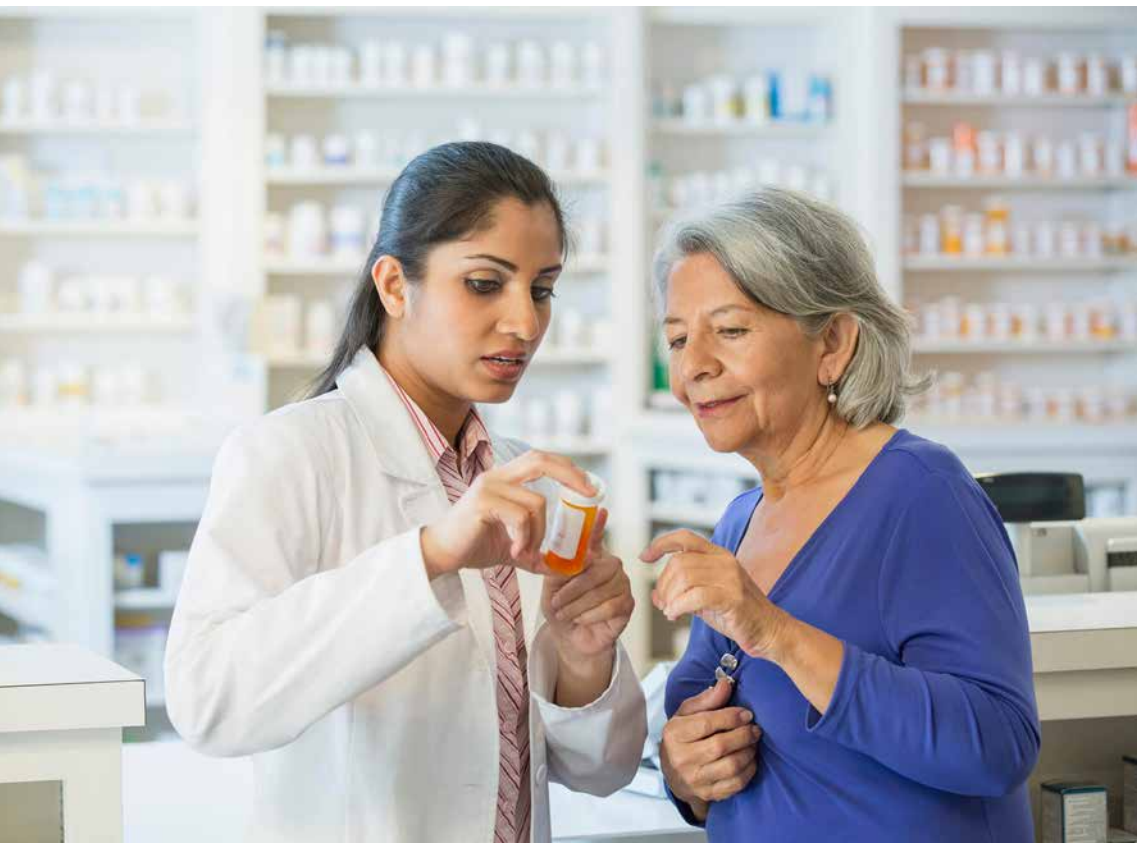


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SACT must be considered when deciding which antiemetics to prescribe. When antiemetics are prescribed for patients receiving SACT drugs, the goal of antiemetic therapy is prevention of nausea/vomiting. Prophylaxis is better than treatment. If prophylaxis treatment is not fully effective, escalation to a stronger treatment is required immediately. In general, for moderate to high emetogenic drugs, ondansetron should be offered. For low to minimal emetogenic drugs, the recommended options are metoclopramide, prochlorperazine, or ondansetron, with a PPI to also be considered for all.

The type of emesis experienced influences the choice of drug:

- Acute: Nausea and vomiting experienced usually within a few minutes to several hours after drug administration and which commonly resolves within the first 24 hours
- Delayed-onset: Nausea and vomiting developing more than 24 hours after SACT administration and which may last for up to 6 - 7 days
- Breakthrough: Development of nausea and vomiting,

despite prophylactic treatment and/or requires rescue with antiemetic agents

- Anticipatory: Nausea and vomiting that occurs prior to the beginning of a new cycle of SACT. It is primarily considered a conditioned response and typically occurs after a negative past experience with SACT
- Refractory: Nausea and/or vomiting that occur during subsequent treatment cycles when antiemetic prophylaxis and/or rescue have not been effective in earlier cycles.

If the patient has poorly controlled nausea, check their compliance and understanding of their regimen: are they taking regular antiemetics, at the right time? Refer the patient to the hospital if the symptoms are poorly controlled despite compliance.

Diarrhoea is generally treated with loperamide. If it is not responding adequately (e.g. 4-6 runny stools a day), the patient should contact the team in hospital.

Immunosuppression is common with the older cytotoxic medications which often cause a reduction in white blood cells and

also platelets. Refer the patient to the hospital if their temperature reaches over 38 degrees or if there are any feelings of unwellness, e.g. sore throat, coughing. Any unexplained bleeding should also be reported. Paracetamol may mask a temperature and should never be used to reduce a temperature without reporting the high temperature to the hospital first. Hand hygiene practices are important. The patient should also try and avoid contact with anyone who has an infection such as chickenpox or the flu.

Stomatitis (in the mouth) and mucositis (in the GI tract) are also very common side effects. To help reduce irritation in the mouth, patients can be advised to use a soft toothbrush, and a bland mouthwash, such as salty water. Spicy, sharp foods and alcohol should be avoided (16). BMX mouthwash can be prescribed if required. Chlorhexidine mouthwash is not usually recommended as it can sting, and stain teeth.

Neuropathy (numbness and tingling in fingers and toes peripheral nerves) is more common with the cytotoxic agents. If it is not treated, it can

become irreversible. Symptoms of neuropathy need to be reported to the hospital by the patient as soon as possible. The hands and feet should be kept warm, and care should be taken with e.g. hot drinks.

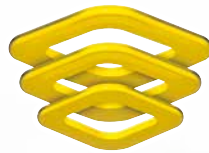
Fatigue can be caused by both the cancer itself and the chemotherapy. The patient should be encouraged to rest, but if appropriate, also encouraged to implement a rest/activity cycle that includes some very light exercise. There is also evidence to suggest that American ginseng<sup>17</sup> is beneficial for reduction of fatigue, as long as there are no drug interactions. Anaemia can also contribute to feelings of tiredness.<sup>16</sup>

Capecitabine in particular is associated with hand-foot syndrome (palmar-plantar erythrodysesthesia) where the palms of the hands and the soles of the feet become dry and red, feeling numb or tingling, and the skin becomes flaky. This is common at start of treatment, but also seen later on. To help with this, tight fitting shoes should be avoided. It is also very important to regularly moisturise with an emollient.

#### The Role of the Pharmacist

In addition to prescription review, it is important to talk to the patient about what information they have already received - the opportunity to talk and ask questions about medications may really be appreciated. Patient education is one of the most important ways to support medication adherence, which is crucial for good treatment outcomes. Check that the patient is aware of their dosing schedule and the need for them to report any high temperature and any feeling unwell (e.g. Sore throat, cough). Pharmacists can support patients in identifying and treating some of the ADRs and toxicities associated with SACTs, and recognise serious symptoms that require referral to the patient's treatment centre. The patient should be advised to follow their management plan in order to prevent, minimise and handle ADRs. If any side effects are getting worse, early referral to hospital is advised. Blood checks need to be performed to the patients commencing a new cycle of treatment.

References available on request



# Betmiga™

mirabegron 50mgs once daily

## 50mgs once daily

Her 10th shopping trip since the day she started BETMIGA<sup>1</sup>



**Prescribing Information:** Please read the Summary of Product Characteristics (SPC) before prescribing. **Presentation:** Prolonged-release tablet, containing mirabegron 25mg/50mg. **Indication:** Symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adult patients with overactive bladder (OAB) syndrome. **Posology and method of administration:** The recommended dose is 50 mg once daily. A lower dose of 25mg is recommended for specific patient populations (renal and hepatic impairment) as well as in specific patient populations in combination with strong CYP3A4 inhibitors such as itraconazole, ketoconazole, ritonavir and diltiazem. **Renal impairment:** End stage renal disease (GFR < 15 mL/min/1.73 m<sup>2</sup> or patients requiring haemodialysis): Not recommended. **Severe renal impairment (GFR 15 to 29 mL/min/1.73 m<sup>2</sup>):** Reduce dose to 25 mg. **Severe renal impairment and concomitant strong CYP3A4 inhibitors:** Not recommended. **Moderate renal impairment (Child-Pugh B):** Reduce dose to 25 mg. **Moderate hepatic impairment and concomitant strong CYP3A4 inhibitors:** Not recommended. **Mild renal impairment (GFR 30 to 59 mL/min/1.73 m<sup>2</sup>):** 50 mg. **Moderate renal impairment and concomitant strong CYP3A4 inhibitors:** Reduce dose to 25 mg. **Mild renal impairment (GFR 60 to 89 mL/min/1.73 m<sup>2</sup>):** 50 mg. **Mild renal impairment and concomitant strong CYP3A4 inhibitors:** Reduce dose to 25 mg. **Hepatic impairment:** Severe hepatic impairment (Child-Pugh Class C): Not recommended. **Moderate hepatic impairment (Child-Pugh B):** Reduce dose to 25 mg. **Moderate hepatic impairment and concomitant strong CYP3A4 inhibitors:** Not recommended. **Mild hepatic impairment (Child-Pugh A):** 50 mg. **Mild hepatic impairment and concomitant strong CYP3A4 inhibitors:** Reduce dose to 25 mg. The tablet is to be taken once daily, with liquids, swallowed whole and is not to be chewed, divided, or crushed. It may be taken with or without food. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients (see the SPC for a list of excipients). Severe uncontrolled hypertension defined as systolic blood pressure  $\geq 180$  mm Hg and/or diastolic blood pressure  $\geq 110$  mm Hg. **Special warnings and precautions for use:** **Renal impairment:** Betmiga has not been studied in patients with end stage renal disease (GFR < 15 mL/min/1.73 m<sup>2</sup> or patients requiring haemodialysis) and, therefore, it is not recommended for use in this patient population. Data are limited in patients with severe renal impairment (GFR 15 to 29 mL/min/1.73 m<sup>2</sup>); based on a pharmacokinetic study a dose reduction to 25 mg is recommended in this population. This medicinal product is not recommended for use in patients with severe renal impairment (GFR 15 to 29 mL/min/1.73 m<sup>2</sup>) concomitantly receiving strong CYP3A4 inhibitors. **Hepatic impairment:** Betmiga has not been studied in patients with severe hepatic impairment (Child-Pugh Class C) and, therefore, it is not recommended for use in this patient population. This medicinal product is not recommended for use in patients with moderate hepatic impairment (Child-Pugh B) concomitantly receiving

strong CYP3A4 inhibitors. **Hypertension:** Mirabegron can increase blood pressure. Blood pressure should be measured at baseline and periodically during treatment with mirabegron, especially in hypertensive patients. Data are limited in patients with stage 2 hypertension (systolic blood pressure  $\geq 160$  mm Hg or diastolic blood pressure  $\geq 100$  mm Hg). Patients with congenital or acquired QT prolongation: Betmiga, at therapeutic doses, has not demonstrated clinically relevant QT prolongation in clinical studies. However, since patients with a known history of QT prolongation or patients who are taking medicinal products known to prolong the QT interval were not included in these studies, the effects of mirabegron in these patients is unknown. Caution should be exercised when administering mirabegron in these patients. Patients with bladder outlet obstruction and patients taking antimuscarinic medicinal products for OAB: Urinary retention in patients with bladder outlet obstruction (BOO) and in patients taking antimuscarinic medicinal products for the treatment of OAB has been reported in postmarketing experience in patients taking mirabegron. A controlled clinical safety study in patients with BOO did not demonstrate increased urinary retention in patients treated with Betmiga; however, Betmiga should be administered with caution to patients with clinically significant BOO. Betmiga should also be administered with caution to patients taking antimuscarinic medicinal products for the treatment of OAB. **Interactions:** **Pharmacokinetic interactions:** Mirabegron is a substrate for CYP3A4, CYP2D6, butyrylcholinesterase, uridine diphosphate-glucuronosyltransferases (UGT), the efflux transporter P-glycoprotein (P-gp) and the influx organic cation transporters (OCT) OCT1, OCT2, and OCT3. **Pharmacokinetic interactions involving the potential for other medicinal products to affect mirabegron exposure:** Increases in mirabegron exposure due to drug-drug interactions may be associated with increases in pulse rate. **Strong CYP3A4 inhibitors:** See Posology and administration above for dose adjustments recommended during concomitant use of strong CYP3A4 inhibitors in patients with renal or hepatic impairment. Mirabegron exposure (AUC) was increased 1.8-fold in the presence of the strong inhibitor of CYP3A4/P-gp ketoconazole. **CYP2D6 inhibitors:** No dose adjustment is needed for mirabegron when administered with CYP2D6 inhibitors (or in patients who are CYP2D6 poor metabolisers). **Inducers:** Inducers of CYP3A4 (such as rifampicin) or P-gp may decrease the plasma concentrations of mirabegron. No dose adjustment of mirabegron is required as this effect is not expected to be clinically relevant. **Pharmacokinetic interactions involving the potential for mirabegron to affect exposures to other medicinal products:** **Inhibition of CYP2D6:** Moderate and time dependent inhibition of CYP2D6 by mirabegron may result in clinically relevant drug interactions. CYP2D6 activity recovers within 15 days after discontinuation of mirabegron. Caution is advised if mirabegron is co-administered with medicinal

products metabolized by CYP2D6 with a narrow therapeutic index such as thioridazine, Type 1C antiarrhythmics (e.g. flecainide, propafenone) and tricyclic antidepressants (e.g., imipramine, desipramine). Caution is also advised if mirabegron is co-administered with CYP2D6 substrates that are individually dose titrated. **Inhibition of P-gp:** Mirabegron is a weak inhibitor of P-gp. For patients who are initiating a combination of Betmiga and digoxin, the lowest dose for digoxin should be prescribed initially. Serum digoxin concentrations should be monitored and used for titration of the digoxin dose to obtain the desired clinical effect. The potential for inhibition of P-gp by mirabegron should be considered when Betmiga is combined with sensitive P-gp substrates e.g. dabigatran. **Fertility, pregnancy and lactation:** The effect of mirabegron on human fertility has not been established. Betmiga is not recommended during pregnancy and in women of child-bearing potential not using contraception. Mirabegron should not be administered during breast feeding. Refer to SPC for full guidance. **Driving and use of machines:** Betmiga has no or negligible influence on the ability to drive and use machines. **Undesirable effects:** Summary of the Safety Profile: the safety of Betmiga was evaluated in 8433 patients with OAB, of which 5648 received at least one dose of mirabegron in the phase 2/3 clinical program, and 622 patients received Betmiga for at least 1 year (365 days). In the three 12-week phase 3 double blind, placebo controlled studies, 88% of the patients completed treatment with this medicinal product, and 4% of the patients discontinued due to adverse events. Most adverse reactions were mild to moderate in severity. The most common adverse reactions reported for patients treated with Betmiga 50 mg during the three 12-week phase 3 double blind, placebo controlled studies are tachycardia and urinary tract infections. The frequency of tachycardia was 1.2% in patients receiving Betmiga 50 mg. Tachycardia led to discontinuation in 0.1% patients receiving Betmiga 50 mg. The frequency of urinary tract infections was 2.9% in patients receiving Betmiga 50 mg. Urinary tract infections led to discontinuation in none of the patients receiving Betmiga 50 mg. Serious adverse reactions included atrial fibrillation (0.2%). Adverse reactions observed during the 1-year (long term) active controlled (muscarinic antagonist) study were similar in type and severity to those observed in the three 12-week phase 3 double blind, placebo controlled studies. The following adverse reactions were observed with mirabegron in the three 12-week phase 3 double blind, placebo controlled studies. The frequency of adverse reactions is defined as follows: very common ( $\geq 1/10$ ); common ( $\geq 1/100$  to  $< 1/10$ ); uncommon ( $\geq 1/1,000$  to  $< 1/100$ ); rare ( $\geq 1/10,000$  to  $< 1/1,000$ ); very rare ( $< 1/10,000$ ); not known (cannot be established from the available data). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness. The adverse events

are grouped by MedDRA system organ class. **Infections and infestations:** Common: urinary tract infection **Uncommon:** vaginal infection, cystitis **Psychiatric disorders:** Not known: Insomnia\*, confusional state\* **Nervous system disorders:** Common: headache\*, dizziness\* **Eye disorders:** Rare: eyelid oedema **Cardiac disorders:** Common: tachycardia **Uncommon:** palpitation, atrial fibrillation **Vascular disorders:** Very rare: Hypertensive crisis\* **Gastrointestinal disorders:** Common: nausea\*, constipation\*, diarrhoea\* **Uncommon:** dyspepsia, gastritis **Rare:** lip oedema **Skin and subcutaneous tissue disorders:** **Uncommon:** urticaria, rash, rash macular, rash papular, pruritus **Rare:** leukocytoclastic vasculitis, purpura, angioedema **Musculoskeletal and connective tissue disorders:** **Uncommon:** joint swelling **Renal and urinary disorders:** **Uncommon:** urinary retention\* **Reproductive system and breast disorders:** **Uncommon:** vulvovaginal pruritus **Investigations:** **Uncommon:** blood pressure increased, GGT increased, AST increased, ALT increased (\*observed during post-marketing experience). **Reporting of suspected adverse reactions:** see below. **Legal category:** POM (S1B) **Marketing Authorisation number:** EU/1/12/809/003 - 25mg EU/1/12/809/010 - 50mg. **Marketing Authorisation holder:** Astellas Pharma Europe B.V. Sylviusweg 62, 2333 BE Leiden, The Netherlands. **Further information is available from:** Astellas Pharma Co., Ltd, 5 Waterside, Citywest Business Campus, Dublin 24. Phone: +3531 467 1555. Summary of Product Characteristics with full prescribing information available upon request. **Job number:** BET\_2019\_0002\_IE **Date of preparation of API:** 27 May 2019.

**Reporting of suspected adverse reactions:**  
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via:

HPRA Pharmacovigilance  
Earlsfort Terrace, IRL - Dublin 2  
Tel: +353 1 6764971  
Fax: +353 1 6762517  
Website: www.hpra.ie  
E-mail: mdsafely@hpra.ie

Astellas Pharma Co. Ltd  
Earlsfort Terrace, IRL - Dublin 2  
Tel: +353 1 467 1555  
E-mail: Irishdrugsafety@astellas.com



# Oral Health and Healthy Ageing

Written by Etain Kett, Dylan Masterson,  
The Dental Health Foundation Ireland

**G**rowing old can be as tough on your mouth as it is on your body, but it doesn't have to be.

Oral health is an essential part of healthy and active ageing, it enhances quality of life and maintains our confidence as we age and is now recognised for its importance to global public health.

The World Health Organisation (WHO) recently noted a shocking and little-known fact, that for the last three decades, the combined global prevalence of tooth decay, gum disease and tooth loss has remained unchanged at 45%, which is higher than the prevalence of any other non-communicable disease (NCD).

In Ireland, research from the Irish Longitudinal Study on Ageing 2017 found that the prevalence of tooth loss increases with age, with 40% of those aged 75 years and over having no natural teeth compared to 7% of those aged 54 to 64 years, it's a significant increase in just 10 short years. This can affect quality of life in many ways, including a lack of confidence and low self-esteem.

The WHO describes oral health as 'the well-being of the mouth, encompassing many essential functions, including breathing, eating, speaking, smiling and socialising. Experiencing good oral health, comfortably and confidently, enables an individual to achieve their full capacity and participation in society. Oral health is integral to overall health, well-being and quality of life, from birth to old age'.

There are over 700,000 people aged 70+ years in Ireland, and this figure is growing (OECD 2020).

It's commonplace to have oral health issues at this age. For example, unsuitable

or ill-fitting dentures can affect a person's ability eat and speak properly. Maintaining healthy, and functional teeth contributes to healthier longer life in older adults by reducing the risk of suffering from NCD's such as diabetes, and cardiovascular heart disease.

Covid-19 highlighted the challenges that the elderly in our society face with and without support structures. Older people in long-term care facilities are at particular risk of complications from poor oral health. Risk factors, such as poor general health and frailty, and perhaps an increased dependence on others for their personal care can affect their wellbeing.

As 18% of adults aged 54 years and over in Ireland has no natural teeth (although most have dentures in place of teeth), the Dental Health Foundation would like Pharmacists to join with us in raising awareness amongst older adults, and carers, as to how good oral hygiene habits can have a positive effect on overall health. Together, we can empower patients (and others) to take good care of their oral health daily.

Look after your oral health and wellbeing by following the 3P's

**Protect** Your Mouth – with fluoride toothpaste.

**Prevent** Decay – Reduce the number of sugary foods and drinks you consume

**Healthy Ageing**

- Be wise about your oral health. Good oral health is essential for your overall wellbeing and a healthy mouth will improve your quality of life.
- It has never been more important to take care of your teeth and gums, because of links between gum disease, diabetes, cancer and heart disease.
- Small diet and lifestyle changes can make a big difference to your oral and general health. Eat more fruit and vegetables and take regular exercise.

**DHF**  
Dental Health Foundation Ireland  
Charity No. 6200

[www.dentalhealth.ie](http://www.dentalhealth.ie) | [info@dentalhealth.ie](mailto:info@dentalhealth.ie)

daily. Eat healthy snacks like fruit and veg. Water and milk are the most tooth friendly drinks.

**Practice** Good Oral Care – brush your teeth twice a day and floss daily. Visit your dentist at least once a year.

It's vitally important that adults visit their dental team once a year, even if they no longer have teeth of their own. Regular check-ups can help to detect mouth cancer

at an early and treatable stage while also helping to treat gum disease, tooth decay and bad breath.

### Tooth Tips for Good Oral Hygiene

- Brush twice daily for 2-3 minutes before bed and one other time. Use a soft/medium toothbrush using a fluoride toothpaste (1450 ppm) to keep teeth strong and help prevent tooth decay.
- Change your brush when the bristles are worn or every 3 months.
- Gently brush your tongue to remove bacteria.
- Spit, don't rinse after brushing.
- Floss daily to reduce plaque build-up or use interdental brushes. Ask your dental team for advice on technique.
- Clean dentures/plate daily and use a soft toothbrush to clean your tongue and roof of your mouth. Remove dentures before sleeping to give the gums a chance to rest.

### Diet Tips for Good Oral Hygiene

- Eat lots of fresh fruit and vegetables and choose healthy snacks between meals like low-fat dairy, limit sugary snacks to mealtimes. Dried fruits and honey are high in sugars that cause tooth decay.
- Keep hydrated, water and low-fat milk are the best drinks, sugary/fizzy drinks may cause tooth decay. Avoid adding sugar to tea or coffee.
- Limit fruit juice or smoothies to one small glass daily, with a meal and choose unsweetened.
- Read food labels for sugar content (less than 5g per 100g is low sugar).
- Other things to consider for good oral health are, choosing sugar free medicines when available. Medications and dry mouth, sweetened diet and sweetened fortification drinks as well as poor oral hygiene/mouth care are risk factors for tooth decay in older adults.

### Xerostomia (Dry Mouth)

The feeling of a dry mouth is a particularly uncomfortable one and often gives rise to difficulty in speaking and eating and can have a major negative impact on the quality of life. Saliva does more than keep the mouth wet. It is the best natural defence against decay as acid produced from bacteria in the mouth can be neutralised by saliva.

- It helps digest food.
- It protects teeth from decay.
- It prevents infection by controlling bacteria and fungi in the mouth.
- It makes it possible to chew and swallow food.

Reduced saliva flow (dry mouth) can also give rise to an increased incidence of gum disease and an increase in oral infection, such as candida albicans.

There are many causes of dry mouth, and it is very common in older adults. However, if a person suffers with a constant dry mouth, it is important to refer them to the dentist or doctor to find the cause.

### Causes might include:

- A side effect of many medications is reduced flow of saliva, e.g., those used to control high blood pressure, anti-Parkinson drugs and anti-anxiety agents.
- Excessive intake of caffeine. Caffeine is found in coffee, tea, chocolate, and cola drinks. It draws fluid from the body and reduces saliva.
- Working in a dry environment and not rehydrating often enough.
- Some specific diseases or conditions such as Sjogren's syndrome, diabetes.
- Radiotherapy treatment for head and neck cancer (salivary flow can stop altogether either long term or for periods of up to three months).

The following advice can be given to patients in the management of dry mouth:

- Determination of the cause by dentist/doctor
- Management of the problem involves making the person comfortable by providing saliva substitutes and preventing disease using fluoride mouth rinses and mouth rinses to control plaque.
- Saliva substitutes can be useful if used just before eating, at night if a person wakes because of dry mouth, or first thing in the morning.
- Be careful not to suck sweets regularly e.g., mints, boiled sweets. Although this may give temporary relief it will cause severe dental caries in the absence of saliva.
- Frequent consumption of drinks sweetened with sugar e.g., soft drinks, is also to be avoided.
- Sip water (fluoridated tap water will help to prevent tooth decay) or sugarless drinks or during meals. This will make chewing and swallowing easier. It may also improve the taste of food.
- Avoid drinks with caffeine such as tea or coffee, caffeine can dry out the mouth.
- Tobacco and alcohol dry out the mouth.
- Chewing sugar-free gum.

### Oral Health and General Health

Research shows a link between oral health and diabetes and with oral health and pneumonia.

If diabetes is not well controlled a person with the disease has higher risk of developing oral health problems such as gum disease, dry mouth, and oral infections. Diabetes is more common among toothless adults aged 64 to 75

years which has implications for ongoing management of their health.

Gum disease can also make it more difficult to control diabetes. An important message to share with diabetic patients is that a good oral hygiene routine, controlling blood glucose levels and visiting the dental team every 6-12 months for advice and a check-up will help reduce the risk. Be aware that those with diabetes also have a higher risk of oral infections such as Thrush, signs of which include white patches or redness in the mouth.

Poor oral health is also a risk factor for aspiration pneumonia. This is because oral bacteria can be easily aspirated into the respiratory tract and encourage the development of diseases like pneumonia. Good oral hygiene management is especially important for those older adults in long-term care. Daily oral hygiene should be considered an essential need, along with grooming and bathing, and must not be neglected. Oral health education, information and advice has the potential to help nursing homes enhance the quality of care for residents.

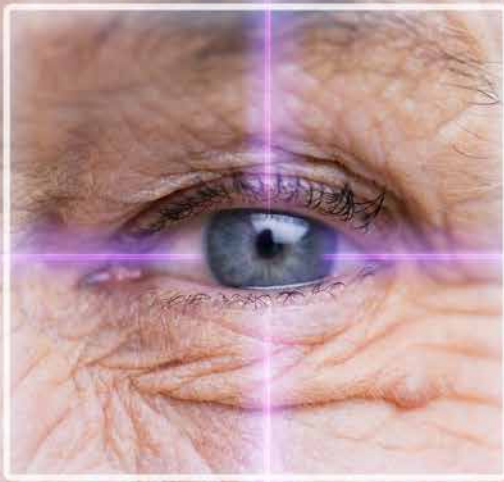
The discipline of health promotion at the National University of Galway offers a 1-year Specialist Certificate in Health Promotion – Oral Health delivered in partnership with the Dental Health Foundation and the Health Service Executive. It's particularly aimed at oral health professionals and those in a position to promote oral health, including pharmacists, who can spread the message that oral health is much more than having a nice smile and that mouth care is important in later life too.

All Health Care Professionals can adopt a holistic approach to oral health by paying attention to the underlying causes of oral health problems and asking patients/ giving advice about lifestyle, health, and wellbeing issues. For example, pharmacists can refer patients to smoking cessation services and give information about the links between alcohol and health risks, smoking and alcohol are both risk factors for mouth cancer and gum disease. Regular exercise may help relieve stress which is a risk factor for gum disease and may also cause tooth wear.

In a nutshell, we need to increase and strengthen the message of good oral health amongst older adults. Further information and advice are available at [www.dentalhealth.ie](http://www.dentalhealth.ie) to find out what individuals can do to improve their oral health, because keeping the mouth, teeth, and gums healthy is important for both oral health and all body health across the life course.

We need to aspire to help this generation keep their natural teeth, to let them keep eating the food they like and smiling with confidence.

# Elderly Care: Ophthalmology



Written by Mr Frank Kinsella  
MRCPI, FRCS, (Glasg), FRCOphth  
Consultant Ophthalmic Surgeon



**O**phthalmology has the three most frequently carried out surgical procedures worldwide: Cataract, Laser Eye Surgery and Anti-VEGF injections.

## Cataract

Cataract is opacification of the crystalline lens, and surgery involves removal and replacement with either a monofocal lens giving good distance vision or the newer multifocal implants giving distance, intermediate and reading vision.

In order to be suitable for a multifocal implant patients need good corneal tomography (CT scan looking for subclinical irregularities in the cornea), and as the multifocal design has a series of rings patients may experience halos driving at night. Furthermore as 50% of the multifocal lens energy is used for distance, 20% for intermediate and 30% for close patients frequently find that although they can see up close without glasses they need a good bright light to read. The multifocal implants are typically suitable for people who are longsighted (needing glasses for both distance and near) and tend not to be suitable for emmetropes (people needing merely reading glasses) or myopes (where the close vision is good without glasses and they simply need glasses for distance).

## Laser Eye Surgery

Laser eye surgery is the most common surgical procedure carried out worldwide. In the early days it was almost exclusively reserved for young people with poor distance vision but now days 30% of patients undergoing this treatment are older people who have become presbyopic (needing reading glasses) and monovision is achieved by lasering the dominant eye to achieve good distance vision and the non-dominant eye to achieve good close vision. 80% of patients tolerate this imbalance and this is tested for prior to treatment by contact lens trialling to ensure the patients

visual cortex can tolerate the imbalance between both eyes.

The most common procedure is Lasik (whereby a flap is made) and patients are merely on drops for one week. Some patients whose corneas are too thin undergo surface laser where the vision takes up to one week to improve, it can be painful (necessitating local anaesthetics eye drops for several days together with a bandage contact lens) and need antibiotic drops for one week and mild topical steroid drop for six weeks.

The main complication from laser eye surgery is ectasia (steepening on the cornea due to loss of tensile strength) resulting in worsening of vision over the years, and one of the main goals in accessing patients prior to laser is to screen for any risk factors that which might lead to this complication.

## Glaucoma

It is a common condition affecting 5% of patients over 70 years of age.

Glaucoma is loss of vision due to progressive optic neuropathy related to the intraocular pressure. Although formally it had been thought that most patients had high intraocular pressure we now know with earlier diagnostic methods that 85% patients at diagnosis have normal intraocular pressure. The main screening tool for early glaucoma detection is nerve fibre layer analysis, whereas the main method of monitoring glaucoma progression is visual field analysis.

Although topical anti-glaucoma drops have been the mainstay treatment of many years, selective laser trabeculoplasty (whereby the trabecular meshwork receives a number low energy burns) is now the first line of treatment in newly diagnosed glaucoma patients.

Newer treatments that have emerged over recent years are trabecular meshwork stents (the smallest stents available in

medicine nowadays at merely 70 microns in diameter). This can give significantly lower intraocular pressure where drops or laser have not worked sufficiently well and avoid the need for more invasive surgery such as trabeculectomy (whereby a fistula is made from behind the pupil to the sub-conjunctival space).

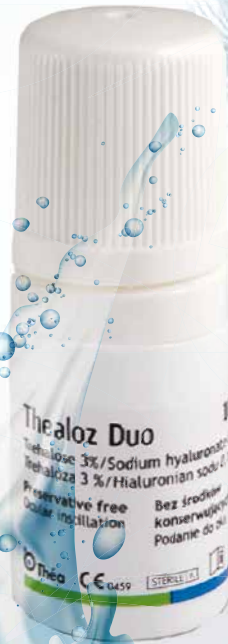
## Age Related Macular Degeneration (AMD)

Longitudinal studies have shown that patients with dry AMD (macular wear and tear) greatly reduce their progression to more severe dry AMD as well as conversion to wet AMD (development of fluid or blood) by long-term use of lutein supplements. There is a strong case to be made for placing family members of patients with significant AMD on these lutein supplements.

Both dry and wet AMD can cause distortion on amsler grid testing, but the key message for patients with dry AMD who self monitor for progression to wet AMD is that the change in vision / distortion changes quickly over a few weeks, and are advised to present immediately as patients who receive their first anti-VEGF injection within two weeks of wet AMD occurring tend to do much better.

The modern trend with managing wet AMD is "treat and extend" whereby a series of injections is carried to induce regression, and to then continuing injecting when the disease is in remission, and to inject at an ever-increasing interval in order to identify the longest interval between injections to keep the macula dry. 50% of patients maintain vision of 6/12 (adequate to drive and to function nowadays with anti-VEGF treatment).





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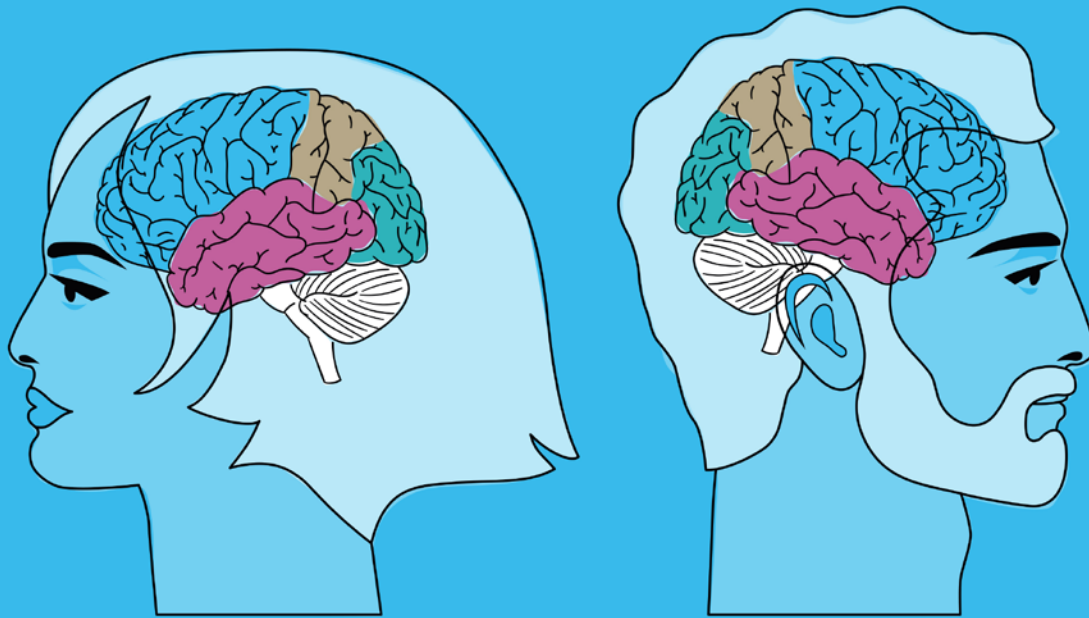


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# Perceptions of Dementia

**A** new survey by the Dementia: Understand Together campaign has found improving public perceptions and attitudes towards people with dementia since the last time similar questions were asked.

The focus of the survey reflects an ongoing commitment by the Dementia: Understand Together campaign, which is led by the HSE in partnership with The Alzheimer Society of Ireland, Age Friendly Ireland, Age and Opportunity, and the Dementia Services Information and Development Centre, to help create communities that actively embrace and include those living with dementia and their families.

There are many forms of dementia – the four most common being Alzheimer’s disease, vascular dementia, mixed Alzheimer’s Disease and vascular dementia, and Lewy body disease – and approximately 64,000 people live with dementia in Ireland today. This number is expected to more than double to over 150,000 by 2045.

The nationally representative survey of over 1,200 people undertaken by Behaviour & Attitudes in July of this year found:

- **Welcoming society:** when asked about the attitudes of others, 67% of respondents believe most people would accept a person with dementia as a close friend and a similar number (68%) believe most would treat a person with dementia as they would anyone. Both of these results are up from 56% in 2016, showing a significant positive shift in public inclusivity and empathy towards people with dementia
- **Good company:** seven in ten (71%) people are happy to spend time with a person with dementia, up from 66% in 2018, and a similar number (72%) are happy to be in a social group in the company of a person with dementia, up from 68% in 2018. When asked if they wouldn’t bother to visit a person with dementia because “they won’t remember” three in four people (76%) rejected this, up from 73% in 2018

- **Active citizens:** in a new survey question asked in 2021, more than nine in ten who responded (92%) believe that people with dementia have the right to be active citizens in their communities
- **Businesses:** in another question not previously asked, more than eight in ten (81%) believe that there are things businesses and service providers can do to make their services accessible to people with dementia
- **Circle of friends:** demonstrating how dementia touches the lives of so many people, almost half of those surveyed (48%) said that they know (or have known) at least one person with dementia, up from 44% in 2018
- **Understanding:** a third of adults (33%) feel that they have a reasonable understanding of dementia while almost nine in ten adults (88%) know something about dementia – just 12% say they know nothing at all. These figures have remained consistent with those reported in the previous survey in 2018, notwithstanding the public discourse being understandably dominated by information on COVID-19 over the past 18 months
- **Early diagnosis:** more than nine in ten (91%) agreed that getting diagnosed at an early stage is good because it allows the person more of an opportunity to make decisions about their care – up from 78% in 2018
- **Seeking attention:** a further additional question for 2021 found that almost six in ten (58%) would react immediately if they felt they were becoming forgetful and were concerned that it might be a sign of

early dementia. Three in ten (31%) would probably delay a couple of months and “keep checking myself”. One in ten (9%) say they would be anxious about such a diagnosis and would probably try and cover it up for a while.

For Professor Suzanne Timmons, Consultant Geriatrician and Clinical Lead of the HSE’s National Dementia Office, it is important that we convert our understanding of the importance of early diagnosis into seeking support.

“An interesting finding from the survey is that most of us agree that early diagnosis is good in principle but that, if push comes to shove, a significant number of us would delay seeking help,” she says.

“It is a very positive indicator that people understand that early diagnosis is a good thing, but equally it is important that people understand the benefits of seeking support in a timely way. It may not be dementia in the end, but the assessment may indicate certain risk factors for future dementia that could be tackled now. In the event that it is dementia, for many people, there are medications and cognitive therapies that aim to support the person to carry on their normal daily life despite the dementia. For everyone, getting a diagnosis enables us to make decisions about our future, and it means we can get the right information, advice and support at the right time. All of this gives us the best chance for having the best possible quality of life, regardless of the diagnosis.”

## Community Supports

For more information on dementia, including details of local services and HSE Memory Technology Resource Rooms in each county, visit [www.understandtogether.ie](http://www.understandtogether.ie). Members of the public can also contact The Alzheimer Society of Ireland Helpline for support and details of their local Dementia Adviser on Freephone 1800 341 341 (Monday to Friday 10am to 5pm, Saturday 10am to 4pm).

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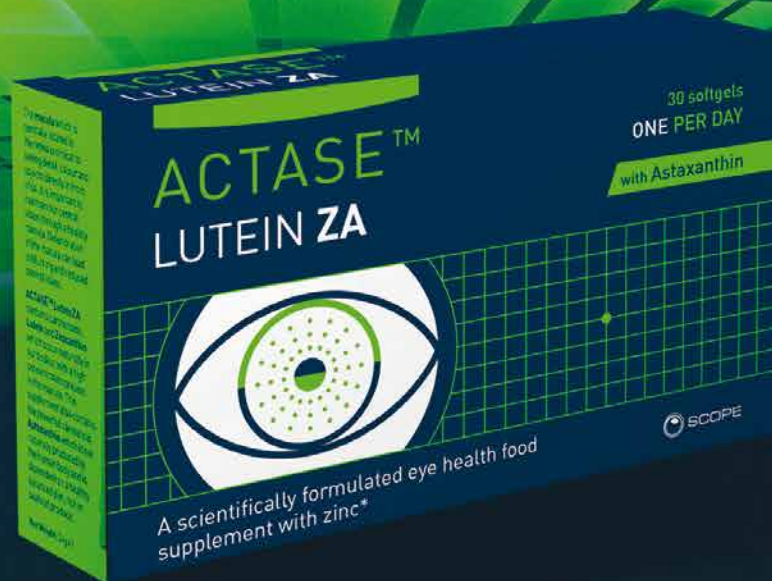
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## Is your Pharmacy Age Friendly?

Age Friendly Ireland has, during this year, awarded Age Friendly Charters to eight leading business groups who have appointed an Age Friendly Champion in their branches, completed training and achieved an Age Friendly Charter. Some of these include community pharmacies.

The Age Friendly Business Recognition programme is available to all businesses which are prepared to put in place a few low cost or no cost changes to make their businesses more welcoming and accessible to the older consumer.

Age Friendly Ireland is currently offering training for businesses all over Ireland to help them understand the needs and requirements of older consumers

and to develop a response that signals to older people that their business is valued and appreciated.

"Post Covid, older people are regaining their confidence and slowly beginning to move out again after more than a year at home" said Catherine McGuigan, Chief Officer of Age Friendly Ireland. "We really want business to encourage and support older customers to enjoy the live consumer experience once again, so that they can

continue using the products and services they need and enjoy."

Businesses that successfully take part in the Recognition Programme receive Charters, a listing in the Age Friendly Business directory at [agefriendlyireland.ie](http://agefriendlyireland.ie) and the opportunity to go forward to the National Age Friendly Awards.

Visit [www.agefriendlyireland.ie](http://www.agefriendlyireland.ie) for further details on how your pharmacy can get involved.

## Break the Obesity Stigma

The HSE has hosted a free virtual event Overweight and Obesity... Lets Talk! to share the science behind obesity and give practical information to help people to manage and understand behaviours related to weight.

It also continued to break the stigma of obesity through sharing lived experiences and explored conversations about weight and health in healthcare settings.

The event, a collaboration between the HSE Obesity Management Clinical Programme, the Association for the Study of Obesity in Ireland (ASOI) and the Irish Coalition for People Living with Obesity (ICPO) saw over 1,200 participants joining different seminars over the duration of the event.

Currently 60% of adults and 20% children have overweight and obesity in Ireland.

Speaking about the event, Susie Birney, Executive Director ICPO, Patient Representative ASOI said, "I am delighted to see the continuation of a patient centred approach with the involvement of the Irish Coalition for People Living with Obesity in planning this event. It is clear that hearing the lived experience of those who live with obesity, combined with the science and the research, is an impactful approach for discussing health and weight and also towards addressing the stigma which comes with this disease."

Professor Donal O'Shea, HSE National Clinical Lead for Obesity explains, "Obesity is a complex chronic disease for which there are a lot of different causes. Many people believe that obesity is a lifestyle choice which is due to poor self-discipline and lack of motivation, but that is just not the case. The reality is that your body tries to protect its fat stores to maintain your highest weight - meaning that managing obesity is a lifelong process. Genetics are increasingly recognised to be a major contributor to body weight."

Recall - Please note: A placed Athena Pharmaceuticals Advert appearing on page 67 of the printed issue of IPN November had to be recalled due to a compliance issue and replaced within the digital issue. This advert was compliant at the time of going to press.



### Pharma Managers Series – HSE Briefing Date: 4th November, 2021

The Pharmaceutical Managers' Institute is delighted to welcome HSE CEO, Paul Reid back to the PMI to give members an update on where the HSE, the rollout of the vaccination programme and the impact of the pandemic on the healthcare budget.

This event is proudly sponsored by AXIS Consulting.

Visit [www.thepmi.com](http://www.thepmi.com) for more details.

## Heart of our City

Pictured at the launch of Heart of our City, a new pilot population health project by the Irish Heart Foundation, Smart D8 and Novartis are (left to right): Roisin Ryder, Social Prescribing Coordinator, F2 Family Resource Centre; Dr Angie Brown, Medical Director, Irish Heart Foundation, Audrey Derveloy, General Manager, Novartis Ireland and Orla Veale, Project Lead, Smart D8.



The project aims to improve the cardiovascular health of people living in Dublin 8 by connecting them with information, supports and social prescribing, or non-medical initiatives in the community. Heart disease and stroke have a devastating impact on families across Ireland and we know that 80% of this is preventable. Find out more about the Heart of our City project at [www.irisheart.ie/heartofourcity](http://www.irisheart.ie/heartofourcity).



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# Sharing a Vision of Value and Innovation

## PCO Manufacturing celebrated its 35th year in business last month (October).

Established in 1986, PCO Manufacturing Ltd is the market leading parallel importer of pharmaceutical products into Ireland, specialising in sourcing the highest quality pharmaceutical products from a network of authorised pharmaceutical wholesalers both domestically and across the European Union.

*Irish Pharmacy News* recently spoke to John Lanigan, PCO Manufacturing's Commercial Director to hear more about how the company is expanding in scale, and innovation.



PCO Manufacturing was established in order to give pharmacists an additional supply channel to the traditional wholesalers. Over the years, the company has grown to become the largest parallel importer of medicines in Ireland.

John explains that the company has a vision for expansion coupled with offering cost effective solutions across the pharmacy market.

“Our vision in the early years was to offer a value proposition to both pharmacists with lower supply costs and to the State through lower reimbursement costs for medicines,” he says. “Whilst pharmaceutical parallel import companies were already

established in some other EU countries the concept was new for Irish pharmacies but as the supply benefits became clear the business started to grow quickly.

“Today PCO employs 140 staff at our facility in Ashbourne and we have a wide supply network across 18 countries in the EU where we source ambient and cold chain medicinal and diagnostic products. Our product range has continued to grow and we now offer a wide range of ambient, cold chain, controlled drugs, high tech lines, OTC and exempt medicinal products.”

### Leading the Market

So what sets PCO apart from their competitors? Creating a difference

and maintaining an edge are key, he reflects.

“Our business model is structured in a different manner to our competitors in that we have all of our business functions and support services – Regulatory Affairs, Quality, Purchasing, Sales, Dispatch and IT located within our facility in Ashbourne in the Republic of Ireland and this gives us complete control over all aspects of our business. We don't outsource any aspect of our operation other than courier services for some deliveries.

“Our facility in Ashbourne ships over 1,500 orders each day including cold chain deliveries to community pharmacies and hospitals throughout Ireland and we offer a same day delivery service to many of our customers and a next day service to all others. We work with all of the main buying platforms and also operate a web ordering system which many of our customers find very useful for checking stock availability, pricing and stock ordering.

“As the market leader we have invested significantly in product licenses and currently hold over



John Lanigan Commercial Director

600 licenses from the EMA and HPRA to parallel import products into Ireland, Northern Ireland and the UK.”

### Addressing Challenges

Like every business, the team at PCO Manufacturing had to adapt their work practices during Covid, to ensure that they could maintain supplies of medicines to pharmacies.

He adds, “Whilst some of our colleagues could work remotely from home many of our teams in Quality, Production and Dispatch had to continue to work in our Ashbourne facility and our primary objective here was to ensure that we provided a safe working environment for them.

“This involved significant changes to shift patterns to avoid large numbers of staff arriving and leaving at the same time and our teams showed great flexibility in ensuring that we continued to maintain product supply and we actually grew our volumes during this period.”

Product shortages and out of stocks in the market have become a growing challenge for the industry in recent years. This in turn has led to increased demand for parallel import products.

“We were well placed to be able to react quickly to these situations. As we identified product supply shortages we worked closely with our suppliers across the EU to source additional stocks to ensure pharmacies could still access these medicines for their patients. Initially this was a very reactive process where we increased supply after identifying a potential shortage but as the

“As we identified product supply shortages we worked closely with our suppliers across the EU to source additional stocks to ensure pharmacies could still access these medicines for their patients. Initially this was a very reactive process where we increased supply after identifying a potential shortage but as the year progressed we were also being advised by some local manufacturers of potential future supply shortages to see if we could assist with increased supply”

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“Our new products team have also been busy identifying potential new lines for our community pharmacy customers and we have a strong pipeline of new license applications in process which will deliver a wider product range to our customers into 2022”

year progressed we were also being advised by some local manufacturers of potential future supply shortages to see if we could assist with increased supply.

“This approach worked well and it was great to see originator and parallel suppliers working together to ensure that full market supply volumes were being maintained for patients.”

#### Working with Partners

Brexit remains high on the political agenda, despite the Covid-19 pandemic diverting attention. Has it impacted on PCO Manufacturing in the same way as many other importers?

“On the supply side Brexit has removed the UK as a potential supply country for us although in our preparations for Brexit we had already moved these UK sourced lines to other EU supply countries,” John told us.

“Transport from the EU to Ireland has been a major area for us as we use temperature controlled vehicles to transport all of our incoming stock and we worked closely with our transport partners to switch over to direct ferry routes from Europe to Ireland to avoid using the UK land bridge in order to reduce the risk of delays to supplies.

“Brexit has also presented us with new opportunities as we operate a sister company in Northern Ireland – NIP Pharma Ltd who sell into Northern Ireland and the UK markets. Following Brexit some UK based suppliers have withdrawn from the Northern Ireland market and there are ongoing supply challenges in that market which are driving increased demand and

we are working closely with our customers to see how best we can assist them.

“We are also working with some manufacturers who envisage supply challenges in these markets as a result of Brexit and our ability to supply stock from Ireland to these markets may help to alleviate some supply challenges.”

The past year has been particularly busy for PCO’s product team, who have been focused on identifying potential new lines for community pharmacy customers.

John continues, “Over the past year we have significantly increased our range of High Tech Medicines, Controlled Drugs, Cold Chain lines and OTC products and we have started to supply a number of hospital pharmacies.

“Parallel import supply is a relatively new area for hospitals in Ireland and our new products team are working closely with a number of hospital customers to identify opportunities where we can bring our experience in the community sector to hospital pharmacy supply. Our new products team have also been busy identifying potential new lines for our community pharmacy customers and we have a strong pipeline of new license applications in process which will deliver a wider product range to our customers into 2022. We have also increased our range of Exempt Medicinal Products and see this as a major growth area for PCO in the coming year as we already have an extensive network of suppliers across Europe from whom we can source these products and we can react quickly to market demands for EMPs.”

#### Supporting Pharmacy

Product shortages look to be an ongoing issue for community pharmacy in Ireland, which will take some time to correct. “We have been increasing our stock holding on some lines which have had intermittent supply issues. Another major challenge for pharmacists will be the new IPHA agreement which is being negotiated with the state and this may impact community pharmacies through further price re-alignment,” he adds.

In looking to the future, John says many plans for development are in the pipeline.

“We have a strong pipeline of new license applications in process and PCO have recently received planning permission for a major extension to the Ashbourne site to provide additional repackaging and warehousing capacity to meet our increased demand.



#### PCO Manufacturing Ltd

01 8356700  
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# Diabetes Self-Management Support: Key Role of Pharmacists

The role of community pharmacists has expanded beyond a singular focus on medication dispensing to a more patient-centred model of care. The pharmacists interviewed in this study described the availability of pharmacists, and their relationship with patients, as key contributors to this expanded role.



Written by Eva Cooney, PhD candidate NUIG, Consultant at S3 Connected Health  
This article is based on a semi-structured qualitative interview study with community pharmacists in Ireland. Further insights and a comprehensive report of the findings of the study can be found in 'Pharmacists' perceived role in supporting diabetes education and self-management in Ireland: a qualitative study' (Cooney, O'Riordan & McSharry, 2021) published in HRB Open Research. Thank you to all the pharmacists who gave their time to participate in this study, and to the co-authors Mr David O'Riordan and Dr Jenny McSharry

This expanded role may be particularly important for people with chronic illnesses, such as diabetes, who are frequent visitors to pharmacies. As described by one pharmacist in our study; "A pharmacist has more touch points with a diabetic patient than any other member of the healthcare system and it'd be very common that the patient would be more honest with the pharmacist than their doctor or endocrinologist or diabetic nurse". This places pharmacists in a unique position to support people with diabetes in their self-management behaviours.

Diabetes is a condition which requires considerable life change for the patient, something that cannot be solely treated with medication. As such, people with diabetes require support in the wider elements of self-management such as diet, exercise, foot, and eye care. Through speaking with pharmacists, it became evident that there is potential for a greater role in diabetes support, given their expertise, accessibility and the aforementioned patient relationship, but there are also barriers which should not be overlooked.

Firstly, the patients' perception of the pharmacist role is key. Pharmacists said that their involvement varies by patient, with some actively seeking engagement in their care, while others "don't want to hear from you, they just want to talk to

a doctor". Similar variability was noted in the pharmacists' perception of their own roles. While the majority engaged in the provision of wider patient self-management support, the extent of this involvement varied from setting up a diabetes specific information day, to patient-initiated contact, or for one pharmacist, no involvement at all. Furthermore, there was a disparity noted in the pharmacists' current and potential roles in diabetes care. Several pharmacists suggested that they are currently underutilised, particularly when comparing themselves to counterparts in other countries. Pharmacists suggested that if given the opportunity to assume more responsibility in adjusting types and doses of medication, they could enhance the care received by people with diabetes and reduce the burden on other healthcare services.

Perhaps the greatest barrier of all however, was with regards to resources. Dispensing medication is a time intensive task and there are challenges in balancing consultation with supervising prescription sales. At times pharmacists felt a need to be in two places at once. Having another pharmacist on site may appear to be the obvious solution but the cost of this cannot be sustained by most pharmacies, owing to the reimbursement structure - "numbers of prescriptions doesn't constitute enough for a second pharmacist".

Whether pharmacists can take on a greater role in the support of people with diabetes' self-management remains to be seen. While it is evident that there is potential, it seems that a review of the overall structure may be required at a higher level, given that at present the extended services offered are at the discretion of individual practices.

One opportunity for pharmacist engagement was identified in the study, which also explored pharmacists' knowledge of structured diabetes education programmes. Structured diabetes education programmes were developed to equip people with diabetes with the skills, knowledge and support to self-manage their condition. Attendance at such courses has been linked to improvements across clinical, lifestyle and psychosocial outcomes (Steinsbekk et al., 2012) but a considerable challenge exists in poor uptake and attendance. While the reasons for non-attendance are diverse, communication about the programmes from healthcare professionals has been identified as an influential factor (McSharry et al., 2019).

From speaking to pharmacists, it was evident that there was little to no awareness of these programmes. The pharmacists interviewed strongly emphasised the importance of education for patients, describing the issues that arise when knowledge on diabetes is insufficient. As such, pharmacists could offer further support to patients by signposting to diabetes structured education programmes. This would add a

minimal burden to pharmacists' workload but could benefit patients immensely.

As with many aspects of healthcare, the delivery of these programmes has changed over the past year to remote delivery online. Such developments have opened the programmes up to patients who may have previously been unable to access them due to time or travel constraints (MacKenzie et al., 2020). More investigation is required to understand the process of such adaptations and to explore how outcomes compare, but overall, the growth of digital health solutions offers great opportunities for improved self-management support. Digital tools can be used to reduce burden on healthcare professionals while enhancing patient monitoring and patient-HCP communication (Kruse, Bolton & Freriks, 2015). Speciality pharmacy medications present a prime example and opportunity to provide patient support programmes and medication therapy management, due to the complexity of handling and dispensing the medications. Tech-enabled management of these services is becoming more prevalent, providing improved patient access to education about condition, treatment, dosing and other adherence supports while automating processes and reducing pharmacy operational costs (Wilco Source, 2021). Digital health is an area that will continue to grow over the coming years and may offer solutions to expand the role of community pharmacists in the self-management support of people with diabetes.

References available on request





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# The Role of the Pharmacists in Recognising Type 1 Diabetes

The Covid-19 pandemic has affected the access to health-care providers, such as general practitioners, or hospital-based specialist teams. In diabetes care, most consultations are provided remotely, and before seeing a GP, each patient must be sure they have no Covid-19 symptoms (any), and if they do, they must get the negative PCR test to be able to see the GP team. In such circumstances, the role of pharmacists in recognizing symptoms and providing medical advice must have increased.



Written by Dr Kate Gajewska,  
Clinical Manager for Advocacy and  
Research, Diabetes Ireland

One of the conditions, in which pharmacists can play a significant role when it comes to early recognition, is type 1 diabetes.

## Know what it stands for

**TYPE 1 DIABETES** is one of the most prevalent chronic conditions in children and adolescents, but it can be diagnosed at any age. Recent evidence suggests, that almost a half of newly diagnosed type 1 diabetes cases are in adults over 30. In the paediatric population it is crucial to recognise the symptoms and react quickly, as deterioration is very quick, and the risk of Diabetes

Ketoacidosis (DKA) is higher than in adults. But early recognition of symptoms in adults lowers the risk of severe and long-term complications also. Therefore it is extremely important to know what to look for and TEST.

The TEST campaign was recently launched to raise awareness of the symptoms of Type 1 diabetes. We believe that this simple acronym will help the public: adults and children, parents, grandparents, co-workers and teachers, and health professionals in community and hospital care, as well as the pharmacists, to more easily remember, and

recognise the symptoms of Type 1 diabetes and take action when these are noticed.

## Recognise the symptoms of Type 1 diabetes

TEST represents the following: **Thirst (increased), Energy (reduced), Sudden (weight change) and Toilet (trips increased)**. These symptoms are key indications that a person might have Type 1 diabetes and a simple fingerprick blood glucose TEST is required urgently.

Professor Edna Roche, University of Dublin, Trinity College and Consultant Paediatric Endocrinologist, CHI at Tallaght University Hospital developed and leads the Irish Childhood Diabetes National Register (ICDNR): **“We all need to know the symptoms of Type 1 diabetes so we can recognise them early and take action.** These TEST symptoms are the key indicators a child might have Type 1 diabetes. Delays in diagnosis can happen because the symptoms of Type 1 diabetes are subtle. If you see the symptoms talk to the parents and recommend, they go to their GP for a TEST”.

The sooner we act, the better - **a delay in the diagnosis of Type 1 diabetes can quickly lead to a life-threatening complication - DKA.** “On average, 25 children are

diagnosed with Type 1 diabetes in Ireland each month. In 2020, **over 40% of new admissions with diabetes had DKA.**” – she said. This is an increase from 31.6% % in the period 2011-2015 and has increased steadily from 2016. As there is no other national diabetes register in Ireland, we don’t know how the incidence of type 1 diabetes and DKA presents in adults.

Professor Hilary Hoey, Chairperson of Diabetes Ireland said: “Delays in the diagnosis of Type 1 diabetes is an ongoing problem in Ireland, and COVID-19 pandemic made it even worse. Acting fast is so important and has great benefits – **early recognition of symptoms will enable earlier diagnosis and treatment, preventing the development of DKA.** Avoiding DKA can make the initial treatment much easier and has short- and long-term benefits”.

## Take action

What action to take when you recognize the symptoms? **A simple finger-prick blood glucose TEST** can inform whether a person with the TEST symptoms needs to be seen by an emergency or diabetes team immediately. If a client comes to the pharmacy and mentions Thirst, Exhaustion, Sudden weight change and Toilet visits (meaning frequent urination), a pharmacist should suggest (and perform, if possible) a blood glucose check, even by a finger prick. If the result is above the range (i.e. above 8-10 mmol/L), this person should be advised to see a GP soon, and if it is much higher – this person should contact the hospital emergency team. TEST is the key to diagnose Type 1 diabetes and lower the risk and prevalence of DKA.

Check our website to check how to help a person with newly diagnosed diabetes. Further information is available on [www.diabetes.ie](http://www.diabetes.ie). The campaign is supported by the Irish Childhood Diabetes National Register (ICDNR), Diabetes Ireland and Novo Nordisk Ltd.

<b>T</b>	<b>THIRST INCREASED</b>		<b>Being extremely thirsty but unable to quench the thirst</b>
<b>E</b>	<b>ENERGY REDUCED</b>		<b>Lack of energy and feeling very tired or weak</b>
<b>S</b>	<b>SUDDEN WEIGHT CHANGE</b>		<b>Rapid, unexplained weight-loss over a short period of time</b>
<b>T</b>	<b>TOILET TRIPS INCREASED</b>		<b>Frequent urination, particularly late at night</b>

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## Benefits of Magnesium and Sleep

In recent years, magnesium has been shown to have beneficial properties when it comes to aiding better sleep. Magnesium plays a large role in sleep regulation and current research shows that additional magnesium can help the body relax and even improve symptoms of insomnia.

Magnesium is an essential mineral needed for over 300 chemical reactions in the body, including regulating blood sugar levels and pumping the heart. It's also a vital co-factor nutrient for other minerals (helping them to do their job) including chromium and calcium. Without magnesium, these other minerals do not work efficiently.

According to the College of Naturopathic Medicine, the Recommended Daily Allowance (RDA) of magnesium varies per person, dependent on sex, age and special requirements such as in pregnancy or chronic conditions.

A guideline is as follows:

- Men (aged 19+): 400 – 420mg per day
- Women (aged 19+): 320 – 360mg per day
- Children (aged 1 – 18 years): 85 – 300mg per day, dependent on age

- Pregnant/ breastfeeding women: 350 – 400mg per day

Insomnia is a common sleep disorder whereby sufferers have difficulty falling asleep, staying asleep, or both. People with insomnia experience a lack of energy and don't feel refreshed in the morning. They may also struggle with excessive daytime sleepiness, irritability, anxiety, or depression.

Research shows that magnesium may help improve insomnia symptoms. In a study of elderly patients with insomnia, taking 500 mg of magnesium daily for eight weeks improved many subjective and objective measures of insomnia. The patients:

- Fell asleep faster and slept longer
- Increased their sleep efficiency, meaning they spent more time sleeping while they were in bed

- Woke up later and reduced early morning awakening
- Experienced increased concentrations of melatonin, a sleep hormone, and serum renin which plays a role in regulating blood pressure
- Experienced decreased concentrations of serum cortisol, the "stress hormone"

Other studies have produced similar results. Patients given a combination supplement of magnesium, melatonin, and vitamin B for three months also experienced significant benefits in the management of their insomnia. The combination reduced insomnia symptoms and side effects, leading to a better quality of life.

### 10 signs of Magnesium Deficiency:

1. Tiredness
2. Twitching eyes, muscle spasms, restless feet and leg cramps (including at night)
3. Sugar or chocolate cravings (cacao beans are high in magnesium)
4. Constipation
5. Pre-Menstrual Tension (PMT) and spasmodic period pain
6. Recurring headaches or migraines
7. Depression or low mood
8. Feeling edgy, tense or anxious
9. Sleep issues especially falling asleep
10. Cardiovascular issues such as high blood pressure or irregular heartbeat

## Further Evidence on Vitamin D Effects

New research from Trinity College Dublin and University of Edinburgh has examined the association between vitamin D and Covid-19, and found that ambient ultraviolet B (UVB) radiation (which is key for vitamin D production in the skin) at an individual's place of residence in the weeks before Covid-19 infection, was strongly protective against severe disease and death.

Professor Evropi Theodoratou, Professor of Cancer Epidemiology and Global Health, University of Edinburgh

confounded and in fact a result of other factors, such as obesity, older age or chronic illness which are also linked with low vitamin D.

To overcome this, researchers were able to calculate "genetically-predicted" vitamin D level, that is not confounded by other demographic, health and lifestyle factors, by using the information from over one hundred genes that determine vitamin D status.

Researchers, for the first time, looked jointly at genetically-predicted and UVB-predicted vitamin D level. Almost half a million individuals in the UK took part in the study, and ambient

UVB radiation before Covid-19 infection was individually assessed for each participant. When comparing the two variables, researchers found that correlation with measured vitamin D concentration in the circulation was three-fold stronger for UVB-predicted vitamin D level, compared to genetically-predicted.

Researchers found that ambient UVB radiation at an individual's place of residence preceding Covid-19 infection was strongly and inversely associated with hospitalisation and death. This suggests that vitamin D may protect against severe Covid-19 disease and death.

Professor Lina Zgaga, Associate Professor in Epidemiology, School of Medicine, Trinity College and senior researcher on the study said, "Our study adds further evidence that vitamin D might protect against severe Covid-19

infection. Conducting a properly designed Covid-19 randomised controlled trial of vitamin D supplementation is critical. Until then, given that vitamin D supplements are safe and cheap, it is definitely advisable to take supplements and protect against vitamin D deficiency, particularly with winter on the horizon."

Professor Evropi Theodoratou, Professor of Cancer Epidemiology and Global Health, University of Edinburgh and senior researcher on the study added, "Given the lack of highly effective therapies against Covid-19, we think it is important to remain open-minded to emerging results from rigorously conducted studies of vitamin D."

The paper: [An observational and Mendelian randomisation study on vitamin D and COVID-19 risk in UK Biobank](#) can be read here:

<https://www.nature.com/articles/s41598-021-97679-5> [2]



Previous studies have linked vitamin D deficiency with an increased susceptibility to viral and bacterial respiratory infections. Similarly, several observational studies found a strong correlation between vitamin D deficiency and Covid-19, but it could be that these effects are

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## Future-Proofing and Connecting Community Pharmacy

The PharmacyConnect platform is proving to be a popular choice for Irish pharmacies; ensuring customer satisfaction whilst saving valuable time in pharmacy and reducing the risk of dispensing errors.



Cormac McKenna  
(PharmacyConnect) and David Dodd  
(David Dodd Pharmacy Greystones)

“As an effective way to communicate with my customers and they with the pharmacy, PharmacyConnect is building up to be a real timesaver on the pharmacy side.”

in August 2021 and are very pleased with it so far,” he told Irish Pharmacy News.

“We’re seeing customers naturally gravitating to use it and the user experience at both the customer and pharmacy ends is really great. As an effective way to communicate with my customers and they with the pharmacy, it’s building up to be a real timesaver on the pharmacy side,” he adds.

“A further benefit is that the platform serves as a record of what the customer ordered thus reducing the potential for errors or omissions on both sides. Customers are happy too.”

### Future Developments

The pandemic has shown us how quickly things can change and how technology can suddenly go from a nice-to-have to a must-have for businesses.

With an eye moving beyond customer orders and payments and to facilitating local deliveries, the PharmacyConnect team is working with several pharmacies on how this might work.

“We’re very much focussed on how to help pharmacies at a platform level to delight their customers and enhance their local brand. We see lots of potential to work with pharmacies to do this and the signs are very encouraging that customers will respond,” Cormac concludes.

For more information see [PharmacyConnect.ie](http://PharmacyConnect.ie) or email [hello@pharmacyconnect.ie](mailto:hello@pharmacyconnect.ie)

Since early 2020, Irish pharmacies – like many businesses – have been grappling with changes and demands stemming from the pandemic. Many pharmacy managers are now looking ahead and examining ways that they can improve the efficiency of their operations while also improving the way they serve their customers. Inevitably this means looking at how they can make more effectively use of technology.

### Improving Efficiency

The PharmacyConnect platform was conceived and developed specifically to provide a grounding for Irish pharmacies to serve their customers better while also improving the efficiency of their business. Developed by the team behind VillagePod – an app platform based on local gift cards for local communities – it enables pharmacies to deploy their own branded smartphone apps which facilitate the customer ordering journey.

“When we talked to local community pharmacies, they expressed a need for having a platform that would deliver the great user experience that customers are now used to from other industries” comments Cormac McKenna, VillagePod and PharmacyConnect founder.

Allied to the desire to serve customers better is the looming threat of new providers with different business models entering the market and encroaching on

the share of the market currently served by community pharmacies.

While Ireland may not have the imminent threat of Amazon entering the market as may exist in other geographies, there are notable examples of providers already operating in the Irish market – with ambitious expansion plans - who are innovating at pace.

Fundamental to the PharmacyConnect platform is that each pharmacy’s brand is front and centre with the customer; having its own branded presence within the Apple and Google app stores. “Adopting technology shouldn’t mean diluting your brand and that’s why we went down the route of delivering branded apps for each pharmacy client” said Siobhan Kennedy, Partner Manager with PharmacyConnect. “Customers must be given a context to ensure that they know that they are dealing with their local, trusted community pharmacy and not an anonymous aggregator.”

### Healthmail

Key to the platform is how the pharmacy can use it to flexibly deal with inbound prescriptions from the HSE’s Healthmail system.

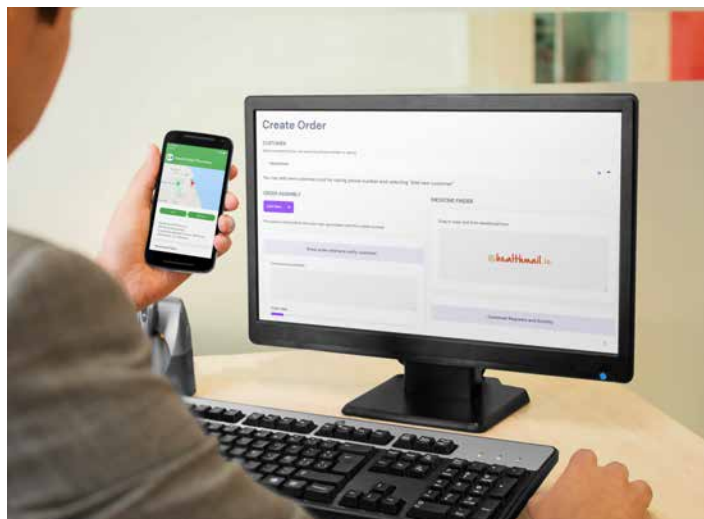
Cormac adds, “When we looked at the changes that had come about over the last couple of years in Irish pharmacies, the biggest single area was around the way most prescriptions were coming directly from the doctor to the pharmacy. While this improved security around prescriptions,

it also created an information vacuum for both the pharmacy and the customer as the customer had not sighted the prescription and the pharmacy often didn’t know what to dispense. Pharmacies were handling this in different ways, and so it was important to develop a flexible tool which enabled all pharmacies to handle it the way they wanted and to give them options to move more strategically when they were ready.”

### Pilot Project

A key early supporter of the initiative was David Dodd of David Dodd Pharmacy Greystones, who reports very encouraging results.

“We launched our apps on the PharmacyConnect platform



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Further information is available on request or in the Summary of Product Characteristics (SmPC) at [www.medicines.ie](http://www.medicines.ie).

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IE-AMB-0821-00003. Date of preparation: August 2021.

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#### References:

1. BVBM Amgevita Product Information Sheet. <https://www.hse.ie/eng/about/who/cspd/ncps/medicines-management/best-valuebiologicalmedicines/bvb-medicine-amgevita-product-informationsheetpdf> Accessed Aug 2021.

2. Medicines Management Programme Best-Value Biological Medicines: Adalimumab 20 mg solution for injection. <https://www.hse.ie/eng/about/who/cspd/ncps/medicines-management/best-value-biological-medicines/mmp-report-bvbmedicine-adalimumab-20mg-march-2021.pdf> Accessed Aug 2021.

#### Adult

- Rheumatoid arthritis
- Ankylosing spondylitis (AS)
- Axial spondyloarthritis without radiographic evidence of AS
- Psoriatic arthritis
- Crohn's disease
- Ulcerative colitis
- Psoriasis
- Hidradenitis suppurativa
- Uveitis

#### Paediatric

- Polyarticular juvenile idiopathic arthritis (JIA) (from 2 years of age)
- Enthesitis-related arthritis (from 6 years of age)
- Crohn's disease (from 6 years of age)
- Ulcerative Colitis (from 6 years of age)
- Plaque psoriasis (from 4 years of age)
- Adolescent hidradenitis suppurativa (acne inversa) (from 12 years of age)
- Uveitis (from 2 years of age)

# Topic Team Training – Emergency Contraception

A community pharmacy environment that fosters teamwork ensures high levels of consumer satisfaction. This series of articles is designed for you to use as guide to assist your team in focusing on meeting ongoing CPD targets and to identify any training needs in order to keep the knowledge and skills of you and your team up to date.



The below information, considerations and checklist provides support to enable you to run a team training session and identify opportunities for learning within the topic of Emergency contraception.

Emergency contraception is an effective and responsible method of preventing pregnancy when regular contraception has failed, no contraception was used. For those who act quickly, emergency contraception will usually prevent pregnancy. ellaOne is the most effective morning after pill and it can be effective for up to 5 days (120 hours) after unprotected sex. However, like all morning after pills, it is more effective the sooner you take it.

Emergency contraception will not prevent someone from getting a sexually transmitted infection (STI).

It is important for pharmacy teams to understand that many

customers will often find it embarrassing to talk about sexual health and would prefer to do this in an informal, but confidential and private manner, with someone they trust.

It is also best not to assume anything about the patient when they approach the pharmacy for advice on sexual health. A person who is asking for information may not be sexually active and just want to be better informed. A person may not already know all the facts. Be prepared to go back to basics. Giving information in stages ensures you give a patient time to ask questions about what you have said and clarify any areas of misunderstanding.

It can be hard to reduce a whole conversation about sexual health into a 30-second-over-the-counter chat. It is much more beneficial if consultations can take place in an appropriately confidential

space if possible. This helps to build up a trusting relationship with the patient as confidentiality is a priority when accessing sexual health services in any setting.

From July 2017, medical card holders are able to get emergency contraception directly from their local pharmacist free of charge. Up until 2011, anyone who needed emergency contraception had to attend a doctor in order to get a prescription before they could go to a pharmacy to buy it.

Just recently, the Irish Pharmacy Union has reiterated its call for women to be allowed access to contraception directly from pharmacies, without prescription and free of charge.

In its 2019 submission to the Department of Health on the subject, the IPU pointed to HSE research that almost half of women in Ireland would prefer to access contraception through their pharmacy.

## How to take the Morning After Pill

For maximum effectiveness, emergency contraception should be started as soon as possible after unprotected intercourse. The sooner it is taken after sex, the more effective it will be.

The morning after pill can be taken more than once in a menstrual cycle. However, it's important to advise customers to remember that it should not be used as a form of regular contraception.

ellaOne contains ulipristal acetate, which changes the way the body responds to the hormone progesterone. Ulipristal acetate is thought to work mainly by preventing or delaying ovulation, depending on which stage of the menstrual cycle a customer is at.

Advise customers not to have sex until they start another method of birth control. The morning-after pill doesn't offer lasting protection from pregnancy.

Refer to their GP, anyone who is sick within 3 hours of taking the morning after pill. Also refer anyone who has severe lower abdominal pain three to five weeks after taking the morning after pill or those with bleeding or spotting that lasts longer than a week.

Using the morning-after pill may delay a period by up to one week. For those who don't get their period within three to four weeks of taking the morning-after pill, advise they take a pregnancy test.

## Discussing Emergency Contraception

- Reassure them they have done the right thing
- Offer them the use of a private consultation room, so that they may talk more freely
- Talk to them in consumer language, for example mention 'morning-after pill' rather than EHC
- Be professional but have a warm and approaching manner

## Key Points:

Check your pharmacy team are aware and understand the following key points:

- The pharmacy team knows and can explain the difference in the emergency contraception options available
- The team can recognise safeguarding issues when supplying emergency contraception
- Ensure the team is trained in understanding research regarding sexual health and fertility
- My pharmacy assistants can meet the points in this training checklist.

## Actions:

- Ensure efficient sign posting to discreet consultation areas within the pharmacy for further help and advice
- Ensure that the pharmacy team is confident and sensitive when dealing with customers who may be unsure they are making the right decision
- Ensure they can offer these women re-assurance and information on effective self-help measures
- Train my pharmacy assistants to ensure that they can meet the points in this training checklist.

## Consider:

- Am I/are my team, able to explain the emergency contraception options available to customers?
- Do we as a pharmacy team understand the most up-to-date guidelines and guidance?
- Are we aware of the aims of having a contraception service in the pharmacy?
- Are we trained to be able to navigate sensitive issues when dealing with sexual health and contraception?
- When to refer customers to the pharmacist.



# IT'S HER MORNING AFTER



Be her support and ensure she's making an informed choice.  
No other emergency hormonal contraception (EHC) is more  
effective than ellaOne®.<sup>1</sup>

REFERENCES:

1. Glasier A et al. Lancet 2010; 375 (9714): 555-62

PRODUCT INFORMATION ellaOne® 30 mg film-coated tablet (ulipristal acetate). Refer to the SmPC for further information. INDICATION: Emergency contraception (EC) within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure. DOSAGE: one 30mg tablet taken orally as soon as possible, but no later than 120 hours (5 days) after unprotected intercourse or contraceptive failure. Another tablet should be taken if vomiting occurs within 3 hours of intake. Can be taken at any time during the menstrual cycle. Not recommended for women with severe hepatic impairment. CONTRAINDICATIONS: Hypersensitivity to the active substance or excipients. SPECIAL WARNINGS AND PRECAUTIONS: Occasional use only. Use reliable barrier method after use until next menstrual period. If next menstrual period is delayed >7 days or is abnormal or suggestive symptoms occur then perform pregnancy test. Consider ectopic pregnancy. If pregnancy confirmed, woman should contact their doctor. Concomitant use with EC containing levonorgestrel not recommended. Does not contraindicate the continued use of regular hormonal contraception but reliable barrier method should be used until next menstrual period. Not recommended in severe asthma treated by oral corticosteroids. Concomitant use of CYP3A4 inducers [e.g. barbiturates (including primidone and phenobarbital), phenytoin, fosphenytoin, carbamazepine, oxcarbazepine, herbal medicines containing Hypericum perforatum (St. John's wort), rifampicin, rifabutin, griseofulvin, efavirenz, nevirapine] not recommended (may decrease efficacy of ellaOne). Long term use of ritonavir not recommended. Not recommended for women who have used enzyme-inducing drugs in the past 4 weeks. Non-hormonal emergency contraception (i.e. a copper intrauterine device (Cu-IUD)) should be considered. Contains lactose. FERTILITY, PREGNANCY AND LACTATION: Not intended for use during existing or suspected pregnancy. Limited human data does not suggest safety concern. Does not interrupt existing pregnancy. No teratogenic potential was observed; animal data insufficient with regard to reproduction toxicity. Marketing Authorisation Holder maintains a pregnancy registry ([www.hra-pregnancy-registry.com](http://www.hra-pregnancy-registry.com)) to monitor outcomes of pregnancy in women exposed to ellaOne®. Patients and health care providers are encouraged to report any exposure. Ulipristal acetate is excreted in human breast milk; breastfeeding is not recommended for one week after intake. Breast milk should be expressed and discarded. A rapid return of fertility is likely following ellaOne use; regular contraception should be continued or initiated as soon as possible; subsequent acts of intercourse should be protected by reliable barrier method until next menstrual period. UNDESIRABLE EFFECTS: Always consult the SmPC before prescribing. Only the most common side effects and those which are rare but may be serious are listed below. Most commonly reported adverse reactions: headache, nausea, abdominal pain and dysmenorrhea. Common (≥1/100 to <1/10): mood disorders, dizziness, vomiting, abdominal discomfort, myalgia, back pain, pelvic pain, breast tenderness and fatigue. Rare (≥1/10,000 to <1/1,000): ruptured ovarian cyst. RETAIL PRICE: ellaOne 30 mg single film-coated tablet blister pack; € 35.

MARKETING AUTHORISATION HOLDER Laboratoire HRA Pharma, 200 avenue de Paris, 92329 Châtillon, France. Marketed in Ireland by: HRA Pharma UK & Ireland Limited, Haines House, 21 John Street, Bloomsbury, London, WC1N 2BF MARKETING AUTHORISATION NUMBER(S): EU/1/09/522/003. LEGAL CATEGORY: Medicinal product not subject to medical prescription.

Date of last revision of text: May 2019 Unique ID: IE/ELLA/0112

**ellaOne®** 30 mg  
film-coated tablet Ulipristal acetate

Adverse events should be reported. Reporting forms can be found at [www.hpra.ie](http://www.hpra.ie) or email: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).  
Adverse events should also be reported to HRA Pharma UK & Ireland limited on Freephone: 1800 812 984  
or email [med.info.ie@hra-pharma.com](mailto:med.info.ie@hra-pharma.com)

IE/ELLA/0200 Date of preparation: November 2020

## Indications that Asthma ‘Not under Control’

The Asthma Society of Ireland has revealed data-based research, commissioned to establish the level of Oral Corticosteroid (OCS) usage by people with asthma in Ireland, covering the period from November 2018 to October 2020.

The research revealed that from the estimated 380,000 people with asthma in Ireland, almost 27% (101,997) filled a prescription for Oral Corticosteroids from a retail pharmacy in 2020, with 82,500 people with asthma collecting up to two OCS prescriptions over a 12-month period – an indication that they may not have their asthma under control. This research was supported by AstraZeneca.

Oral Corticosteroids can be associated with significant harmful side effects as a result of long-term use. Research now indicates that even occasional short courses of OCS can be associated with increased health risks.

The continual need to prescribe steroid tablets for a patient with mild to moderate asthma should signify that they need a review by their GP. The person with asthma may not be taking their “controller” inhaler every day or they may not be using it properly.

The data also revealed, while the total number of people requiring steroid tablets for their asthma increased by 5,728 in 2019 from the previous year, the numbers decreased in 2020 by over 25,000 – a drop of 21%. Reassuringly, the figures indicate Oral Corticosteroid use amongst children fell by almost a third from 2018 to 2020 by 31% compared to 10% among adults during the same period.

Of particular concern from the findings, 18.46% of all people with asthma prescribed steroid tablets are using the medication three or more times per year, leaving them at significant risk of immediate side effects as well as cumulative health risks associated with OCS use into the future.

Despite the overall drop in OCS usage, there has been an alarming increase in Oral Corticosteroid use among a small but vulnerable group of people (4,212) whose numbers have increased between 2019 and 2020 by a staggering 26%. These are patients who have collected OCS prescriptions three months or more in a row and are being prescribed consistent dosages over those months.

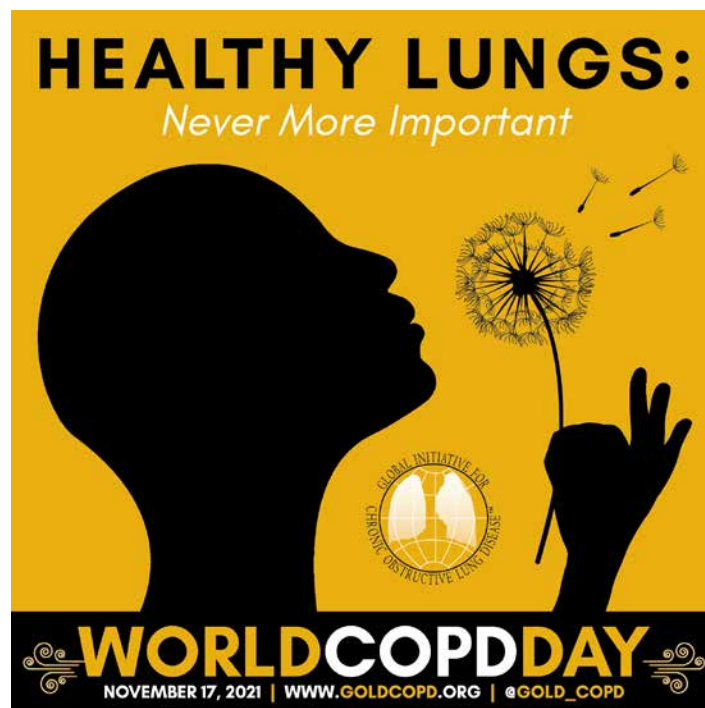
## Burden of COPD ‘Remains’

World COPD Day takes place this month (November 17th) with the key aim of highlighting that the burden of COPD remains, in spite of the ongoing Covid pandemic.

In 2016 Ireland was noted as having the highest hospitalisation rates per 100,000 head of population in the OECD in relation to COPD. It is estimated that 380,000 people are living with COPD yet only 110,000 are diagnosed. It is particularly prevalent in the more vulnerable in society including people from areas with high social deprivation.

World COPD Day is organized by the Global Initiative for Chronic Obstructive Lung Disease (GOLD) in collaboration with health care professionals and COPD patient groups throughout the world. Its aim is to raise awareness, share knowledge, and discuss ways to reduce the burden of COPD worldwide.

Each year GOLD chooses a theme and co-ordinates preparation and distribution of World COPD Day materials and resources. World COPD Day activities are organized in each country by health care professionals, educators, and



members of the public who want to help make an impact locally and worldwide.

The 2021 theme for World COPD Day will be “Healthy Lungs – Never More Important.” Even in light of Covid, COPD remains a leading cause of death worldwide – there is never a more important time to focus on lung health!

Keeping lungs healthy can include avoiding cigarettes, air pollution or occupational exposures, as well as staying active either through regular physical activity or pulmonary rehab. In addition, receiving important vaccines, keeping medical appointments and taking medications correctly can help keep lungs healthy.

## Transplantation and Organ Donor Decline

Patient groups involved in the Irish Donor Network (IDN) have expressed their deep concern about the marked decline in the rates of organ donation and transplantation in Ireland between 2019 and 2020, a period that includes the onset of the Covid-19 pandemic.

The IDN further expressed deep concern that Ireland is struggling in respect of organ donation and transplantation compared with other EU28 countries\*, slipping from 14th place in 2019 to 18th place in 2020 in respect of transplantation and being in 17th place for organ donation.

The IDN comprises nine patient groups concerned with organ donation and transplants in Ireland including, for example: Cystic Fibrosis Ireland; COPD Support Ireland; Cystinosis Ireland; the Irish Lung Fibrosis Association; the Irish Thoracic Society; the Irish Heart and Lung Transplant Association; and the Alpha-1 Foundation Ireland.

The network is calling on Government to undertake a range of measures to revive organ donation and transplantation in Ireland including: developing an ambitious plan to bring Ireland into the Top 10 EU countries for transplantation and organ donation; increasing investment in facilities and staffing; and enacting the Human Tissue Bill to introduce soft opt-out organ donation.

IDN analysis of the figures shows:

- There was a 32.1% decline in solid organ transplantation in Ireland in 2020 compared with 2019
- There was a 27.1% decline in deceased organ donations in Ireland in 2020 compared with 2019
- The most impacted transplant programmes in Ireland in 2020 are:
  - All lung transplants down 58.2% in 2020 compared with 2019
  - All heart transplants down 42% in 2020 compared with 2019
  - All liver transplants down 44.9% in 2020 compared with 2019
  - All kidney transplants, from both living and deceased donors, are down 21.3% compared with 2019

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**Refer to Summary of Product Characteristics (SmPC) before prescribing, and for full prescribing information.**

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**Indication:** Jyseleca is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease modifying anti-rheumatic drugs (DMARDs). Jyseleca may be used as monotherapy or in combination with methotrexate (MTX). **Dosage:** Adults: 200 mg once daily. Taken orally with/without food. It is recommended that tablets are swallowed whole. **Laboratory Monitoring:** Refer to the SmPC for information regarding laboratory monitoring and dose initiation or interruption. **Elderly:** A starting dose of 100 mg once daily is recommended for patients aged 75 years and older as clinical experience is limited. **Renal impairment:** No dose adjustment required in patients with estimated creatinine clearance (CrCl)  $\geq$  60 mL/min. A dose of 100 mg of filgotinib once daily is recommended for patients with moderate or severe renal impairment (CrCl 15 to < 60 mL/min). Not recommended in patients with CrCl < 15 mL/min. **Hepatic impairment:** Mild/moderate hepatic impairment: no dose adjustment required. Severe hepatic impairment: not recommended. **Children (< 18 years):** Safety and efficacy not yet established. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Active tuberculosis (TB) or active serious infections. **Pregnancy.** **Warnings/Precautions:** See SmPC for full

information. **Immunosuppression:** Combination use, with immunosuppressants e.g. azathioprine, ciclosporin, tacrolimus, or biologic DMARDs (bDMARDs) or other Janus kinase (JAK) inhibitors is not recommended as a risk of additive immunosuppression cannot be excluded. **Infections:** Infections, including serious infections such as; pneumonia and opportunistic infections e.g. tuberculosis (TB), oesophageal candidiasis, and cryptococcosis have been reported. In some cases, treatment should be temporarily interrupted. There is a higher incidence of serious infections in the elderly aged 75 years and older, caution should be used when treating this population. Treatment should be interrupted if a patient develops a serious infection until the infection is controlled. Patients should be closely monitored for the development of signs and symptoms of infections during and after filgotinib treatment. **Tuberculosis:** Patients should be screened for TB before initiating filgotinib, and filgotinib should not be administered to patients with active TB. **Viral reactivation:** Cases of herpes virus reactivation (e.g., herpes zoster), were reported in clinical studies (see SmPC). If a patient develops herpes zoster, filgotinib treatment should be temporarily interrupted until the episode resolves. Screening for viral hepatitis and monitoring for reactivation should be performed. **Malignancy:** Immunomodulatory medicinal products may increase the risk of malignancies. Malignancies were observed in clinical studies (see SmPC). **Fertility:** In animal studies, decreased fertility, impaired spermatogenesis, and histopathological effects on male reproductive organs were observed (see SmPC). The potential effect of filgotinib on sperm production

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- ACR20 response seen by **Week 2** in **37%** of JYSELECA patients (n=475) vs. 15% of those in the placebo group (n=475; p<0.001)<sup>2</sup>
- By **Week 52**, **44%** of JYSELECA patients had achieved ACR70 response (n=475)<sup>2</sup>
- **Similar** observed rates of serious infections, VTEs and Herpes Zoster vs. adalimumab<sup>2,3</sup>

\* Based on AE rates observed as 'Uncommon' (<1% and ≥0.1%) or of lower frequency in the JYSELECA clinical trials.<sup>1,3</sup>

† JAK inhibitor-associated adverse events defined as VTEs, Herpes Zoster reactivation and serious infections.<sup>4</sup>

## Visit [strengthofbalance.co.uk](http://strengthofbalance.co.uk) to learn more

and male fertility in humans is currently unknown. **Haematological abnormalities:** Do not start therapy, or temporarily stop, if Absolute Neutrophil Count (ANC) <1 × 10<sup>9</sup> cells/L, ALC <0.5 × 10<sup>9</sup> cells/L or haemoglobin <8 g/dL. Temporarily stop therapy if these values are observed during routine patient management. **Vaccinations:** Use of live vaccines during, or immediately prior to, filgotinib treatment is not recommended. **Lipids:** Treatment with filgotinib was associated with dose dependent increases in lipid parameters, including total cholesterol, and high-density lipoprotein (HDL) levels, while low density lipoprotein (LDL) levels were slightly increased (see SmPC). **Cardiovascular risk:** Rheumatoid arthritis patients have an increased risk for cardiovascular disorders. Patients should have risk factors (e.g., hypertension, hyperlipidaemia) managed as part of usual standard of care. **Venous thromboembolism:** Events of deep venous thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients receiving JAK inhibitors including filgotinib. Caution should be used in patients with risk factors for DVT/PE, such as older age, obesity, a medical history of DVT/PE, or patients undergoing surgery, and prolonged immobilisation. **Lactose content:** Contains lactose; patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take filgotinib. **Interactions:** Co-administration with sensitive OATP1B1 or OATP1B3 substrates (e.g., valsartan, statins) is not recommended. See SmPC for full list. **Pregnancy/Lactation:** Filgotinib is contraindicated in pregnancy. Filgotinib should not be used during breast-feeding. Women of childbearing

potential must use effective contraception during and for at least 1 week after cessation of treatment. **Driving/Using machinery:** No or negligible influence, however dizziness has been reported. **Side effects:** See SmPC for full information. **Common** (≥1/100 to <1/10): nausea, upper respiratory tract infection, urinary tract infection and dizziness. **Uncommon** (≥1/1000 to <1/100): herpes zoster, pneumonia, neutropenia and blood creatine phosphokinase increase. **Serious side effects:** See SmPC for full information. **Legal category:** POM **Pack:** 30 film-coated tablets/ bottle **Price:** Ireland: POA **Marketing authorisation number(s):** Ireland & United Kingdom (Northern Ireland): EU/1/20/1480/001, EU/1/20/1480/003 **Further information:** Gilead Sciences Ltd, 280 High Holborn, London, WC1V 7EE, Great Britain & Northern Ireland: +44 (0) 8000 113700; Ireland: +353 214825999. [ukmedinfo@gilead.com](mailto:ukmedinfo@gilead.com). Jyseleca® is a trade mark. **Date of Preparation:** July 2021 UK-RA-JY-202107-00014

▼ Additional monitoring required

### Adverse events should be reported.

For Ireland, reporting forms and information can be found at [www.hpra.ie](http://www.hpra.ie) and can be reported to HPRA on +353 1 6764971.

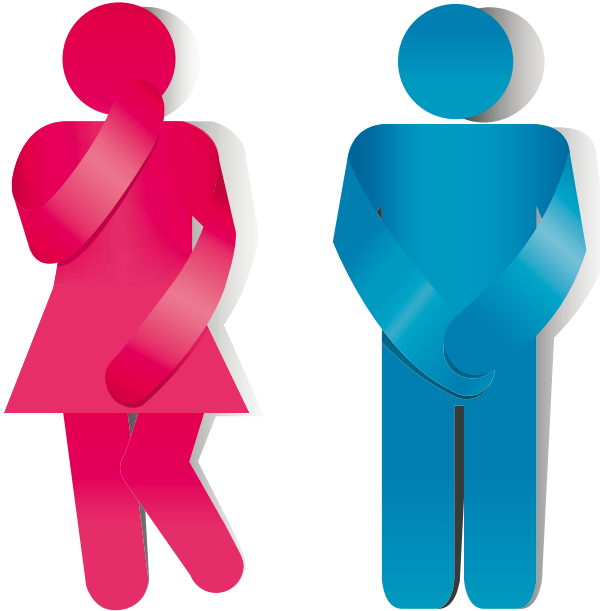
Adverse events should also be reported to Gilead to [safety\\_FC@gilead.com](mailto:safety_FC@gilead.com) or +44 (0) 1223 897500.

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# Topic Team Training – Incontinence

A community pharmacy environment that fosters teamwork ensured high levels of consumer satisfaction. This series of articles is designed for you to use as guide to assist your team in focusing on meeting ongoing CPD targets and to identify any training needs in order to keep the knowledge and skills of you and your team up to date.



The below information, considerations and checklist provides support to enable you to run a team training session and identify opportunities for learning within the topic of Incontinence.

Incontinence is a condition that most people are too embarrassed to talk about, yet one that affects one in three women and one in nine men, and costs the HSE €100 million every year.

Urinary Incontinence (UI) can have a hugely negative impact on a person's quality of life, mood and confidence with some sufferers becoming virtual prisoners in their own homes.

Prevalence increases with age, with an estimated 46% of women and 34% of men aged 80-plus affected. What's more concerning is that up to 80% of sufferers have never sought medical advice and 35% view it as simply part of the ageing process. In most cases

these conditions can be easily treated or significantly improved via straightforward interventions.

## Types of Incontinence

Urinary incontinence is loss of control of the bladder. It can affect anyone, regardless of age. It is a condition which ranges from mild to uncontrollable and embarrassing wetting. Incontinence can often be caused by an illness, such as a urinary tract infection, and often when the infection gets better the incontinence improves.

Bladder control problems have a significant effect on the quality of life of sufferers on a physical, emotional and social level. Continence is a necessity for comfortable social adjustment and conversely, urinary incontinence frequently causes profound psychological and social consequences and restricts social activities.

Urinary incontinence can occur when the normal process of storing and passing urine is disrupted. This can happen for a number of reasons, with certain factors increasing the likelihood of incontinence developing; advancing age is the biggest risk factor.

Stress incontinence occurs when the pressure inside the bladder as it fills becomes greater than the strength of the urethra to stay closed. Additional pressure to the bladder such as laughing or sneezing can then cause urine to leak. Weak or damaged pelvic floor muscles or an inadequate urethral sphincter can result in the urethra opening when it shouldn't.

Urge incontinence is the urgent and frequent need to pass urine, which can be caused by a problem with the detrusor muscles in the walls of the bladder. These muscles relax to allow the bladder to fill with urine and contract when going to the toilet to let urine out. If these muscles contract too often then this creates an urgent need to go to the toilet – this is known as an overactive bladder.

Urinary incontinence can result in significant suffering, including psychological problems and social isolation, sexual issues, lack of sleep due to nocturia, constipation from limiting fluid intake and falls and fractures in older people who have to rush to the toilet.

Since urinary incontinence is a very common problem, pharmacists and their teams have many opportunities to support and help their customers.

## Consider:

- Moving to the consultation room starting any conversation with “we have a more private area for consultations, would this be preferable?”
- Are we as a pharmacy team aware of how to ask open questions to allow the patient to tell us more about what is happening and how they feel?
- Is every member of the pharmacy team confident in talking about bladder weakness?
- Do I know of medicines that can cause urinary frequency and hence increase the risk of urinary incontinence?
- Do we stock an appropriate range of incontinence products, including bladder weakness products? Can my staff explain how these products should be used?

## Further Resources:

[www.continence.ie](http://www.continence.ie) - The Continence Foundation of Ireland (CFI)

[www.oab.ie](http://www.oab.ie) – Overactive Bladder Support

## Key Points:

Check your pharmacy team are aware and understand the following key points:

- Bladder weakness tends to be a taboo subject, which should be dealt with sensitively and discretely
- The possible causes of bladder weakness and therefore those customers who could experience it
- There are several types of bladder weakness (i.e. stress incontinence, urge incontinence and overflow incontinence)
- The importance of pelvic floor exercises and bladder training

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- The importance of pelvic floor exercises and bladder training

## Actions:

- Ensure efficient sign posting to discreet consultation areas within the pharmacy for further help and advice
- Ensure your knowledge of medication associated with urinary frequency is up to date
- Find and research guidance on urinary incontinence
- You can raise awareness of this condition in the pharmacy by displaying appropriate leaflets and literature
- Train all pharmacy assistants to ensure that they can meet the points in this training checklist



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Does your bladder leak pads need to be thick to protect? **Always Discreet** doesn't. It has a unique core with *RapidDry™ layers* that turn liquid to gel, for strong protection in a pad you barely feel.

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## 'Tis The Season to Get Marketing

Christmas provides a huge opportunity to attract new customers. People who don't regularly shop with pharmacies will be looking for gifts, flu vaccinations or cold & flu remedies online and in-store. It's also one of the few times people who have a "regular pharmacy" will try shopping in other pharmacies. Most pharmacies in Ireland do not engage in direct marketing about "switching pharmacies" so these seasonal interactions could be your only chance to make a great impression and plant the seed or start the conversation about customers "moving their prescriptions".



Written by Colm Baker,  
The Social Pharmacist

### It's Never Too Late!

I know that many independent pharmacies will miss out on the opportunity to attract new customers due to a lack of planning. Most independent pharmacies have great intentions about creating big marketing campaigns to boost their Christmas sales but few actually do it.

No matter what you've done to date, I'm going to outline some key dates you should focus your attention on and give you some simple tips to boost sales.

### 1st November - Create the Festive Spirit

Although many people start Christmas shopping before October 31st, once Halloween is out of the way, you should start your Christmas marketing campaigns in earnest. Your focus in the early weeks of November should be to sprinkle as much Christmas spirit into your customer's minds as possible when they approach your pharmacy. Decorate your pharmacy, play Christmas music, have Christmas cards hanging and get your Christmas tree up. A fabulous Christmas window display can be a great way to get everybody talking about your pharmacy. By using these tactics, you will create the perception that you're a must-visit store for Christmas shopping.

Fresh marketing ideas, promotional events, and clever merchandising can help attract new visitors to your pharmacy. Ensure that you are front of mind for these seasonal customers by being active on social media and using paid advertising. Providing a fantastic customer experience will encourage them to return for future purchases, prescriptions and clinical services such as flu vaccinations.

If you don't proactively promote your pharmacy during the holiday season, you'll miss out on opportunities to reach new customers, grow your dispensary figures and to enhance loyalty from existing customers.

Continue to fuel festive feelings with consistent Christmas related content on social media. Your messaging at this stage should be seasonal, fun and less focused on direct, hard sales tactics. Show behind the scenes preparations for Christmas i.e. the window displays being created, Christmas orders arriving and shelves being packed with gifts. Build goodwill with your existing customers by giving them Christmas cards, exclusive discounts, and treats.

Make sure to have your team front & centre too so people know they have a friendly face that can help them during the busy Christmas period. Live video is a fantastic way to do this. You could show your team wrapping presents, creating gift hampers and even eating mince pies or drinking hot chocolate. Other simple ideas can be to run competitions for Christmas hampers, create a Christmas colouring competition and start a Christmas campaign for a local charity.

For pharmacies selling online, it's time to spend big on social media adverts to build up your audiences for remarketing on big-spending days like Black Friday and throughout early December. Use festive colours and graphics on your campaigns even if it's just a splash of red and green. It's been shown that ads are 28% more effective when they emphasize the spirit of the holidays along with a deal. Focus on seasonal keywords in your PPC ads that will experience a big jump in popularity at this time of year.

The final quarter of the year is the most expensive time to advertise online due to the intense competition and huge budgets being deployed by major brands. To reduce the impact of this, front-load your budget now so that by the time Black Friday arrives you have large remarketing audiences full of people who already know your pharmacy brand well. For the same reasons, lead generation is particularly important if you are selling online. Email marketing offers a way to easily reach all of your subscribers instantly for free. Encourage people to sign-up online for gift guides, exclusive discounts, competitions and early access to Black Friday offers etc.

Even if you're not selling online you should start spending on Facebook & Instagram adverts to ensure your best content is reaching everyone locally and to entice new people in-store. You should be able to reach about 1,000 people for less than €5, so only a relatively small advertising budget is required to ensure that your target market will know everything about your special offers, promotions and gifts.

### 11th November - Singles Day

Singles Day is a massive Chinese consumer holiday you might not know about that actually smashed sales records of Black Friday & Cyber Monday globally. This date isn't really that important for retail pharmacies in Ireland but any pharmacies selling online can use it to create urgency and convert customers with a time-limited discount before the massive



marketing campaigns of the big retailers start for Black Friday.

#### **25th November – Thanksgiving**

Although most celebrated in America, Thanksgiving continues to make its way around the world. More importantly though, it's the day before Black Friday. With the spirit of giving thanks in the air, create specific incentives to reward past customers. Not only will this build goodwill with previous customers, but your target market will be more likely to purchase from a company over the Christmas period that they know goes the extra mile for their customers. It also allows you to start talking about Black Friday from a different angle than most companies will use. While they focus on sales to new customers, you will be building your relationship and loyalty with existing customers.

Email your customers with a heartfelt thank you for their loyalty and custom. Give them some exclusive bonuses as a way of showing your thanks. For example, if you're selling online, give them exclusive early access to your Black Friday sales, give them an exclusive discount code or free shipping for one day only. You could also launch a Christmas competition only for customers. Make sure to preview this email on social media, go live on Facebook & Instagram to show your thanks and leave some details missing to create some curiosity that will help compel customers to check out your email.

If you're not selling online, there's still so much that you can do in-store. Give extra loyalty points, vouchers or thank you cards to your regular customers who come in during the day. Give free samples, little gifts and discounts to new customers.

#### **26th – 29th November - Black Friday & Cyber Monday**

We all know that Black Friday & Cyber Monday are massively

important dates for your marketing calendars. In 2018, consumers spent £1.23bn in the United Kingdom on Black Friday. Data from AIB also shows a massive increase in purchases online and in-store for health & beauty, jewellery and electronic categories.

It should be blatantly obvious that this is the day you go hard with your sales. However, it's very easy to get your marketing message lost in the noise created by the massive campaigns of the online giants. This is why it's important to front-load your advertising budget to build remarketing audiences for Black Friday. Now it's time to switch your budgets to converting these audiences into customers rather than trying to reach new people. Where your messaging was previously more subtle, it's now time to move into hard direct sales mode.

You should lead with massive offers to capture attention and do everything you can think of to create urgency and scarcity. Your target market will be bombarded with offers, emails and social media posts so you have to make your offers unmissable to stand out. As the famous line goes, make them an offer they can't refuse.

Over this weekend, start your marketing efforts as early as you can, post frequently to social media, email often and have bonuses for customers. Bonuses could include free shipping, threshold related offers, discounts for future purchases before Christmas, and even exclusive competitions for customers. Incentivize early purchases with tactics like "The 1st 100 customers get X% off" or "Get X% off before 12pm". Go live throughout the day on social media showcasing your offers, any stock that's running low and create on the spot offers.

Don't forget to get involved with the Green Friday initiative that aims to encourage people to support independent Irish Businesses. Get involved in local communities,

business groups and media companies that promote Irish businesses on Green Friday. Team up with other local businesses, use the themed hashtags and offer other incentives to get people shopping locally.

#### **2nd December – Small Business Saturday**

Small Business Saturday occurs on the first Saturday of December and was another initiative launched to promote small businesses and shopping locally. Similar to Green Friday, engage with local businesses, media and community groups to ensure you don't miss out on local initiatives, free advertising and marketing opportunities.

#### **8th December – Little Christmas**

December 8th is a holy day that was traditionally when families across Ireland went to larger towns like Dublin, Cork or Galway to do their Christmas shopping. With the growth of online shopping and the urbanisation of many smaller rural towns, this day no longer holds that much importance from a marketing perspective. However, the decline of this tradition also emphasizes the importance of Black Friday & Cyber Monday in your marketing strategy.

#### **14th December – Free Shipping Day**

As it gets closer to Christmas, online sales can start to decline rapidly because people become worried about whether gifts will be delivered on time. Free Shipping Day can be used to create a sense of urgency for people to purchase before it's too late while also offering the added benefit of saving on shipping costs to increase conversions.

#### **18th December – Panic Saturday**

The last Saturday before Christmas typically means there will be big crowds in-store. People will be more frantic because they know

they're running out of time. They know it's probably too risky to order online and that if they don't get something today they could be left doing some dreaded last-minute shopping on Christmas Eve. Make sure to showcase gift ideas on social media and remind people if you have anything to make their lives easier such as free parking, gift wrapping and Christmas hampers early in the week. When panic mode sets in, convenience will be a big selling point. Continue to do this until the last minute so those shoppers (usually men like myself) know that you still have gifts left.

#### **After Christmas**

It can be tempting to take a break from marketing after Christmas but it's important to stay consistent. There is a blurry period before people go back to work where they are spending a huge amount of time on their phones, using vouchers they got for Christmas and are hunting for bargains. You can capitalize on this by starting your January sales early with a large discount clearance sale to shift any seasonal stock that you don't want to be left with.

After that "January Sales" period it's time to shift your marketing messaging again. By this time, everybody is fed up with shopping and nobody has money left after the festivities anyways. Your pharmacy's social media content should shift away from retail-oriented content and showcase your healthcare expertise. Provide tips and advice on things like smoking cessation, weight loss, nutrition and healthy living. Do Q&A's online, publish blogs, host webinars, educate people about your services and show that your pharmacy is so much more than just a place for Christmas shopping. You should be focused on providing fun, engaging and educational content that will help nurture your newest customers into becoming long-term, loyal regulars.

## Death and Taxes – a practical guide to dealing with these certainties

“In this world nothing can be said to be certain, except death and taxes” wrote Benjamin Franklin and this statement has certainly stood the test of time. In this article I hope to offer some practical solutions for dealing with these two certainties along with advice to help reduce the financial impact on you and your dependents.



Written by Kieran Moore Q.F.A, SIA

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For more see [www.mwm.ie](http://www.mwm.ie)

### Death

#### Family Protection Cover

The process for establishing the need or not for family protection cover can too often be premium based and not needs based, some advisors and far too many banks are happy to “sell” this cover based on nothing more than pulling a figure from the sky making an assumption that a client can afford to pay €100 per month and then working from that premium back to the life cover amount. This approach takes no account of the real purpose of life cover in the family protection context. The role of the life cover is to fast track your dependents to financial independence in the event of your untimely death. The factors to consider are the current assets, current liabilities, current and future potential income and the future lifestyle requirements of your dependents. Only by analyzing this data can the appropriate recommendation for the level of cover required be made.

Once the life cover requirement is identified the next step is to look at the term of the policy and if required to add the flexibility of a conversion option (an option to renew cover with no medical evidence at the end of the policy term). As assets grow in value the need for separate life cover will

diminish and having this option allows you to renew cover if needed for the same or more likely a lesser amount in the future. Crucially you control the choice and not your health at that moment.

The final step is establishing the best way to pay for the policy. All too often we see family protection “sold” with tax relief as pension term cover without the limitations attached to this type of cover fully explained. In many cases paying for pension term cover will lead to the dependents having to take an annuity for life instead of the desired and expected lump sum being paid out. Add this to the fact that pension term cover is not as competitively priced as normal term life assurance and you can quickly see that the tax relief is a false economy. In most cases the best way to pay for life cover intended to go to your dependents is to pay for the cover personally.

#### Mortgage Protection Cover

The acceptance terms on most loans especially home loans will require suitable security in the form of life assurance on the borrowers. You will need life cover equal to the value of the outstanding loan balance for the entire loan term. This form of cover is most commonly referred to as mortgage protection cover or the technical term decreasing term cover. In simple terms a €200,000 loan for 20 years will have a policy that starts with €200,000 cover on day one which will reduce each year to zero at

“As assets grow in value the need for separate life cover will diminish and having this option allows you to renew cover if needed for the same or more likely a lesser amount in the future. Crucially you control the choice and not your health at that moment”

Most of you reading this will have life assurance, some related to loans, family protection, business protection or for inheritance tax purposes. Some advice in the financial services sector can be a little subjective in terms of it being right or wrong and often hindsight reveals these truths when dealing with investment advice for example. However other areas of advice around like how to best quantify life assurance needs, how to structure suitable products to maximise value and how to choose the appropriate payment source fall firmly into the right and wrong way to do things category. We will deal with each in turn.



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“The key point here is that if the business pays the premium the cover amount goes into the business account and is subject to normal taxation on extraction”

the end of the loan term. In theory the life cover should always be equal to the outstanding loan on a standard capital and interest repayment schedule. Too often we see situations where banks sell more expensive options to people during the loan application process. Many people feel compelled to accept the banks recommendations for fear of jeopardizing the loan.

The second and one of the most widespread problems we see here is people being sold this cover from insurers that may be linked to the bank, AIB & Irish Life for example even though the premiums may not be remotely competitive. You are free to get your loan protection from anywhere and not just a partner institution of the bank lending to you. At any point you are entitled to replace this cover with a more suitably priced one. It is quite common in the reviews I carry out to see savings in the thousands of euros on just this one type of cover alone. It is not uncommon to see substantial savings by shopping around for better priced replacement cover.

### **Business protection**

These policies are typically paid for by your company to protect itself from your loss and having a lump sum paid into the company on your death can provide a financial buffer. This can help offset the costs associated with disposing of your business assets if this is the best option or possibly employing someone to carry out your duties while your dependents decide on the best course of action. It is more common where you have more than one owner and can be used to buy out the deceased shareholders shares in the business their dependents get fair value, and the business survives in the remaining shareholders hands. The key point here is that if the business pays the premium the cover amount goes into the business account and is subject to normal taxation on extraction.

### **Inheritance tax cover**

The starting point here is to establish the current potential inheritance tax liability, with the current tax-free inheritance tax thresholds from parent to children being just €335,000 per child this is an issue we see regularly with our pharmacy clients and one that is too often left on the long finger. Capital Acquisition Tax is paid at 33% on amounts over the threshold and this problem typically increases over time as the asset base increases faster than the tax-free threshold.

The revenue allows you to take out life assurance, specifically a Section 60 policy which can be used to offset this tax. The policy itself does not form part of your estate like other life assurance policies but is instead used to pay the tax. In some cases, the problem can be reduced over time if business assets are being

transferred to children. Your estate for the purpose of this tax is all of your assets personal and business plus your standard life assurance policies so it is not difficult to see how a large potential liability can accrue.

The good news is that the cost of insuring this risk is relatively cheap, but the policy must be set up correctly and with a Section 60 policy in place you then have time to see how other plans regarding business succession and estate planning can help mitigate the problem.

### **Taxes**

As we approach another tax deadline here are a few things you can do between now and the end of the year to reduce your personal and corporate liabilities.

### **Make an Additional voluntary contribution (AVC)**

Most of you will have set up executive pensions into which your company is making contributions, however these pensions can also accommodate a contribution from you personally, this contribution subject to revenue limits will allow you to personally claim full tax relief on these contributions at your marginal rate of tax. For example, someone aged between 50-54 on a salary of €100,000 could put in a contribution of €30,000 before November 12th and reduce their personal income tax bill for 2020 by €12,000 making the net cost of the contribution just €18,000. This instantly has the effect of giving you a 66.60% return on your money. With current interest rates not even protecting savings from inflation this is a clear win for those with money on deposit right now.

Top up your company pension with an employer single premium

If this is done before your company year end your company can use the contribution (treated as a trading expense) to reduce your corporation tax liability for year. The contribution will reduce or even eliminate profit and therefore help minimize corporate tax. Most of you in company pensions will have unused backdated allowances to reflect back service or salary increases from the time you initially set up your pension. Unlike personal pensions unused allowances are not lost if not used each year and accumulate over time. For many this “hidden” corporate tax break is not used as it should be.

This year prior to closing off your accounts you should establish what unused pension allowances you have and consider using them to reduce or even wipe out your corporation tax. Surplus cash sitting on the company books earning nothing on deposit and eroding in value through inflation can be earmarked for extraction in this way. Again, in simple math’s if your company puts €100,000 into your pension utilizing these unused backdated allowances it will reduce the corporation tax by €12,500 the net cost to the company is therefore €87,500 so the effective immediate return on this €87,500 is just over 14%.

Add to this the fact that the €100,000 can now be invested and make returns in a tax-free environment and you incurred no personal tax for extracting it from your company and you have a powerful wealth generating tool to help secure your personal financial goals. Everyone of you should at a minimum know the exact amount of these unused corporate tax breaks so they can be used when the time is right.

Hopefully there are some suggestions here that can help reduce the costs associated with dealing with these two issues.





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# The Future of Pharmacy - Part 5

## The Future of Wellbeing - Opportunities for Pharmacy Services

### LEARNING OUTCOMES

At the end of article, you will be able to...

- Consider how 4Front's 6Ps of Pharmacy Excellence model can inform strategic decisions regarding choice of product and service offering
- Discuss 'health and wellbeing' in a personal, professional, community and global context
- Examine the evolving role of community pharmacy and the context in which it operates
- Identify local, national and global policies that may impact the product and services you offer now and in the future
- Prioritise your next steps towards reviewing your current product and service offering and creating your compelling vision for how your pharmacy will thrive into the future.

### INTRODUCTION:

IPN's Pharmacy Business Excellence Series is for community pharmacists committed to growing their personal, professional and business value to overcome challenges and thrive as a community pharmacist.

IPN is proud to partner with 4Front Pharmacy to bring you the 'IPN/4Front Pharmacy Business Excellence Series.'

In this series, you will apply 4Front's 6P's of Pharmacy Excellence to navigate the 'Future of Pharmacy.'

#### 4Front's 6P's of Pharmacy Excellence are

1. Personal Leadership
2. Professional Practice
3. People
4. Products and Services
5. Promotion
6. Prosperity (Profit and Time)

Each month, Rachel Dungan 'The Pharmacist Coach,' guides you to apply 4Front's 6Ps of Pharmacy Excellence Framework to create your pharmacy future. While Rachel is the creator of this framework and the author of these articles, YOU are the author of your career, your future. The future of pharmacy is in your hands, in your heart, in your head.

Your mission, should you choose to accept it, is to use this framework as a guide to

- (re)activate your inner scientist, so you run the experiments required to take your next bold move towards an ever more compelling future
- develop mastery as you embrace your challenges and opportunities
- take PRIDE in what you do as you create an ever more prosperous future
- equip, enable, engage and empower yourself, your team and your patients to become more proactive about managing your own health and wellbeing.

In Part 1 (July 2021) of 'The Future of Pharmacy,' Business CPD Series, we identified 4Front's **Personal Leadership pillar** as the foundation of Pharmacy Excellence. In Part 2 (Aug 2021), we discussed how mastery of 4Front's **Promotion pillar** amplifies your ability to promote the value of health, the value of pharmacy, the value of your products and services, and the value of your professional expertise. In Part 3 (Sept 2021) we focused on how 4Front's **Professional pillar** can equip us to navigate potential conflicts of interest between personal, professional and business priorities. In Part 4 (Oct 2021) 4Front's **People pillar**, focused on the evolving role of supervision and the supervising pharmacist in pharmacy practice. In this article, we focus on 4Front's **Product and Services pillar** as it relates to individual, societal and global wellbeing.

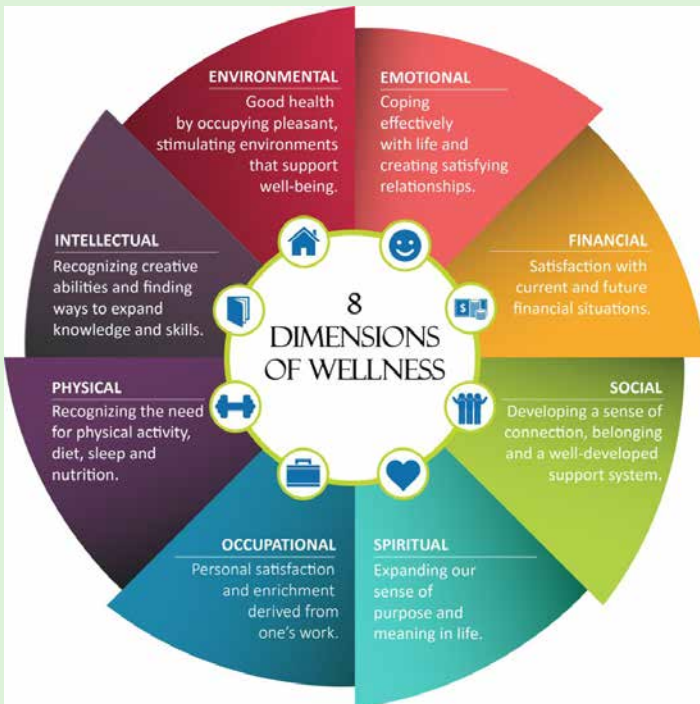
Consider your current product and service range. Does it

1. Positively cultivate (you and) your patients wellbeing, resilience, gratitude and compassion?
2. Engage, empower, equip and enable (you and) your patients to be proactive about managing their own health and wellbeing?
3. Foster Relationships, collaborations and partnerships within and between families, workplaces, communities, professions and organisations?
4. Meaningfully align with the absolute necessity to face the societal and global challenges of our times?
5. Accomplish lasting benefits that enhance (you and) your patients' wellbeing, fulfillment and long-term value?



If not, how could you envision and deliver a more compelling product/service offering? 4Front's **Products and Services pillar** integrates with and builds upon development in the other 5Ps.

- P – **Products and Services** is a key pillar of Pharmacy Excellence, because this represents the unique value you provide your patients, your community and the health service. By applying current, evidence based, legal and ethical decision making criteria to the selection, sourcing and sale of products and services from pharmacies, you optimise your ability to respond to patients needs, the changing nature of healthcare and the evolution of the highest value roles of pharmacists and community pharmacies. *Signals that Saboteur forces may be at play include paralysis analysis (seeking perfection before service launch), inconsistent communication of the value proposition to customers and vague team training or standards. (Products and Services)*
- P – As a pharmacist and pharmacy worker, YOU are the product. It is you that oversees and delivers the additional value that enable products to be used safely and effectively. It is you and your team's expertise, ability to empathise, willingness to listen for what is most important to the patient that equips you to spot the real problems to be solved and create value in the services you offer. The more masterful you become at skillfully guiding you and your team through wellbeing challenges, the more credible and inspiring a role-model you become. *Lack of a regular personal wellbeing practice increases the risk of poor health, stress and burnout, negatively impacting team dynamics, leadership decisions and service delivery. (Personal)*
- P. Exemplary professional performance requires an ever growing ability to trust in the quality and integrity of your professional judgement, act with the patients' best interest at heart, create physically and psychologically safe working environments and be accountable for delivering,



### What do we mean by health and well-being?

The current WHO definition of health, formulated in 1948, describes health as

“a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.”

In more recent years it has been modified to include the ability to lead a ‘socially and economically productive life.’ This definition has inspired models which typically include 6-8 dimensions of wellness to help build a holistic sense of individual wellness and fulfillment.

When we think about products and services, we typically think about physical health — medication, nutrition, weight management, but it is so much more. At an individual level, wellness is a holistic integration of physical, mental, emotional, social, environmental, financial, occupational and spiritual well-being.

At a professional level, wellness necessitates good self-stewardship, for ourselves, for our team, for the patients we serve and for the world we live in. In pharmacy, wellness is a personal and professional responsibility and opportunity to be of service. We have an ethical obligation to attend to our own health and well-being, to choose products and services that empower those we serve to do the same and to simultaneously ensure that we safeguard the health and well-being of this planet we call home.

From a global perspective, on 25th Sept 2015 (World Pharmacists’ Day), world leaders from 193 countries agreed to 17 Global Goals for Sustainable Development. Goal #3 is worldwide ‘Good Health and Wellbeing.’ In service of the targets named in this global goal (to be achieved by 2030), what products and services do/could you provide aligned to this global priority?

- 3.1 & 3.2 Reduce maternal & child mortality (e.g. breastfeeding products and services, promote vaccinations, drugs in pregnancy, lactation and infancy)
- 3.3 Fight communicable diseases (e.g. UTI infection screening, vaccination services, hygiene products, appropriate dispensing of antibiotics, patient education)
- 3.4 Reduce mortality from non-communicable diseases (lifestyle medicine interventions e.g. screening and monitoring of blood pressure, cholesterol, blood glucose, HBA1C, BMI, waist circumference, peak

expiratory flow, skin cancer screens, treatment adherence, dispense prescription medicines to manage long-term health conditions, offer medication use reviews, provide products and services aimed to optimise/protect heart, gut, immune, brain health)

- 3.4 Promote mental health and wellbeing. (e.g. Routinely ask questions about mental health in pharmacy consultations. Get training in suicide prevention such as LivingWorks Start Online Programme. Develop your mental fitness practice and training with Create a list of appropriate referral resources such as [www.stresscontrol.ie](http://www.stresscontrol.ie), [www.practitionerhealth.ie](http://www.practitionerhealth.ie), [www.yourmentalhealth.ie](http://www.yourmentalhealth.ie)
  - 3.5 Prevent and treat substance abuse (e.g. tobacco cessation products and services, methadone programmes, needle exchange programmes, identify potentially harmful use of alcohol, prevent misuse of prescription or OTC medicines prone to abuse such as codeine)
  - 3.6 Reduce road injuries and deaths (e.g. promote safer use of prescription and OTC medicines by drivers, by counselling patients and carers that certain medicines can impair driving ability while others are important to be used to ensure safe driving)
  - 3.7 Promote access to sexual and reproductive care, family planning and education (e.g. sexual health education, sexually transmitted infection test kits, family planning products and services for erectile dysfunction, contraception, fertility medicines).
  - 6.3 Improve water quality by reducing pollution, eliminating dumping and minimising release of hazardous chemicals and materials. (e.g. Provide a Dispose of Unused Medicines Properly (DUMP) service to reduce inappropriate disposal of medicines dumped with other household waste, flushed down the toilet or poured down the sink. Educate patients and carers of the serious harm to the environment from medicines that end up in landfill, permeating the soil, entering the food chain and water supplies).
- As a signatory to the Global Goals, at a national level, Ireland has a vision of a Healthy Ireland “where everyone can enjoy physical and mental health and wellbeing to their full potential, where wellbeing is valued and supported at every level of society and is everyone’s responsibility.”

reviewing and upgrading our product and service offering, in service of the greater good. Part of your professional role is to offer products and services that empower your patients to proactively manage their own health and wellbeing. The degree to which the staff demonstrate competence and the selected products and services meet professional standards and solve your patients’ problems can be audited. An example of internal audit is the PSI Pharmacy Assessment System Self-Audit performed by a staff member. An example of an external audit could be the Pharmacy Assessment System Audit performed by an external consultant). *If you ever catch yourself considering NOT offering a new product or service (e.g. vaccination) for fear of triggering the wrath of another healthcare provider, you have a professional conflict of interest to navigate. Do you choose to make your decision informed by Saboteur-led fears or do you choose to recruit your Sage to learn and practice the skills to host crucial conversations, for the sake of advocating for your patients, honouring the Code of Conduct and building collaborative relationships with other healthcare providers?* **(Professional)**

- P – As a Sage-Driven leader, your patients must be at the heart of your decision making. You ensure the best products and services are selected and delivered to empower your patients to proactively manage

their own health and wellbeing. You do this by equipping your entire team with the necessary product knowledge, consultation skill and wellbeing training to recommend the best products and services to meet the patients’ needs. *Tragically, many pharmacies do not provide the same level of development and training to part-time and full time staff. This results in inconsistent service at best and unsafe practice at worst.* **(People)**

- P – Promoting the value of health and the value of medicinal products and pharmacy services are PSI core competencies. *Any unwillingness or inability, to effectively promote the value of your products and service to your patients, not only sabotages your personal fulfillment, professional reputation and business growth, but also deprives your patients of choice and reduces their ability to self-manage their condition.* **(Promotion)**
- P – By consistently demonstrating that you genuinely have the patient’s best interest at heart, and by proactively curating products and service for their benefit, you inspire trust, goodwill, loyalty and prosperity. *By habitually having an insular, stress-based, Saboteur driven approach, much time is often wasted on defending, avoiding or reacting to circumstances, that consume your time with negative energy and do not give you a positive return on your time or financial investment.* **(Prosperity)**

In addition, the HSE Corporate Plan 2021-2024 states that 'Our vision is: a healthier Ireland, with the right care, at the right time and in the right place'.

NOTE: These national visions both include practitioners' health and wellbeing, as well as that of the people we serve.

Three areas of focus to consider when balancing your Product and Service Offering

1. Harm prevention
2. Wellbeing enhancement and illness prevention
3. Self-management with a long term medical condition

#### Harm Prevention

Of many, the one service I have chosen to focus on is the WHO Medications Without Harm initiative and the HSE's Know. Check. Ask. Campaign. To create safer, more informed partnerships between pharmacists and patients, improve medication adherence and reduce the risk of Adverse Drug Reactions (ADRs), I recommend that you and your patients download and complete the WHO MedSafe App together. It focuses on the Five Moments of Medication Safety namely

1. Starting a medication
2. Taking medication
3. Adding a medication
4. Reviewing a medication
5. Stopping a medication

Since these are the five highest risk times for patient safety, empowering your patients and their carers to request a consultation with the pharmacist at these times, and go through the five question prompts provided is a highly effective harm reduction strategy.

In addition, the HSE have Irish resources, aligned with the WHO Medications Without Harm initiative at [www.safermeds.ie](http://www.safermeds.ie). The Irish campaign is called Know. Check. Ask.

Know (your medicines and make a list)

Check (that you are using the right medicine, the right way)

Ask (if you are unsure)

#### Wellbeing Enhancement and Illness Prevention

According to Healthy Ireland, 92% of Irish people want to improve their health and wellbeing. Pharmacy is perfectly placed to help people achieve that goal. Pharmacy health screening services enable a person to 'know their numbers' to make more informed decisions. It equips them

to work in partnership with you to measure the impact of any lifestyle behaviour changes they have implemented. In addition, proactive annual screening (e.g. on the person's birthday), enables them to track changes and take corrective action, before symptoms become apparent. There are six priority focus areas for Healthy Ireland named in the 2021-2025 Strategic Action Plan. These are:

1. Keeping Active
2. Staying Connected
3. Switching Off and Being Creative
4. Eating Well
5. Minding Your Mood
6. Minding Your Body

Examples of wellbeing pharmacy products and services aligned with these areas have already been mentioned in the Global Goals section, (and there are many more possibilities).

#### Self-Management with a Long Term Medical Condition

If you or your patient lives with one or more long term medical condition, being an active self-manager requires that you and your healthcare team understand what Kate Lorig refers to as 'The Symptom Cycle.'

In pharmacy consultations, one of our roles is to seek to understand the variety of symptoms that are feeding a patient's vicious symptom cycle and to partner with the patient to help them to Problem Solve, Make Informed Self-Management Decisions and create an Action Plan. It is important for patients and pharmacy staff to recognise that different problems can cause similar symptoms, that many symptoms can have the same root cause and that one symptom may trigger other symptoms.

If your patient is trapped in a vicious symptom cycle, you are in prime position to be of service and to help the patient deepen their understanding of what IS within their control, what IS within their influence and what may not be changeable right now.

A powerful tool to partner with your patient to break their symptom cycle and instead create a virtuous cycle is the expert and empathic application of 4Front's STEPS™ Consultation Framework. For patients with more complex health needs, it is likely that you will be able to provide some, but not all solutions to break their symptom cycle. In these situations, it is vital that you and your team sign-post the patient to resources that are most likely to empower them to actively manage their health condition such as Living Well programme - HSE.ie.

Through

- Empathy,
- The quality of the information gathered through medical data, your questions and active listening (Seek to Understand),
- The accurate identification of the cause(s) of the problems to be solved (Problem Solve)
- The quality of your recommendations (Then be Understood)
- You can come up with potential solutions and monitor their impact (Safety Net)

Pharmacy Products and Services in this category focus on the treatment and management of health conditions. All of the screening products and services mentioned earlier can be used to monitor the efficacy of any intervention offered to break the symptom cycle.

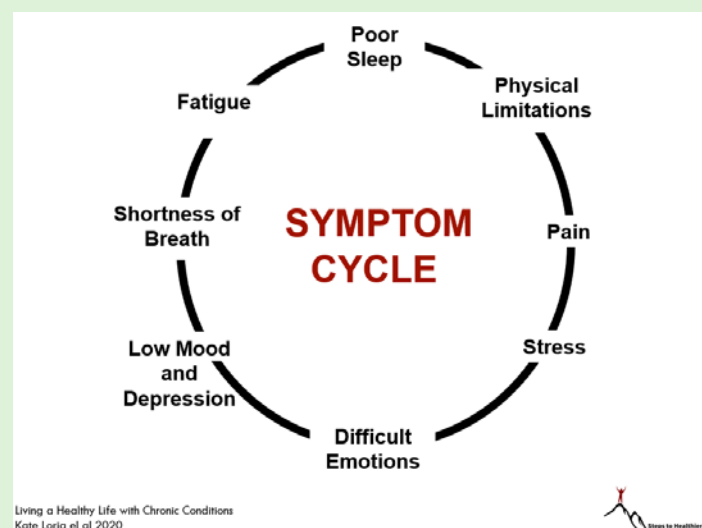
4Front's 6P Framework can provide additional insights to help

strategically select the products and service you choose to provide. Some questions to consider include:

- Personal: To what degree does providing (or not providing) the product/service align with your personal, professional and business mission, vision and values?
- Personal: How committed are you to the success of this product/service?
- Personal: How much bandwidth/energy is required to start, maintain or grow your proposed product/service offering?
- Professional: How does provision of this product or service align with global and national policy?
- Professional: What is the evidence base for the product/service?
- Professional: To what degree is offering the product/service within your professional and personal scope of practice?
- People: What customer wants/needs does it fulfil?
- People: What health/wellbeing benefits does it offer you, your team and your patients? Any potential negative impacts?
- People: What knowledge or skill strengths exist within your team to provide this?
- People: What knowledge or skill gaps would need to be addressed within your team to offer this?
- People: Who are the other stakeholders to consider?
- Promowetion: How will the product or service be marketed? By whom?
- Promotion: How will you articulate the value of the product/service to the payer?
- Prosperity: What are the projected short/medium and longer term costs/benefits of providing/not providing this product/service?
- Prosperity: What is the break even point, target goal and desired outcome (time-line and money)?
- Prosperity: How will success of this product/service be defined and measured? By whom?
- Prosperity: How will it be funded? (Privately? Publicly)

#### Summary

Community Pharmacy is changing. Our product and service mix will continue to evolve. For strategic pharmacies, with motivated, engaged, well-trained staff, there is a wealth of opportunity to be creative and add value with innovative products and services,





aligned with global, national and local needs and our expertise. I hope the rising tide of your product and service innovations lifts your personal, professional, people, promotion and prosperity boats (and vice versa).

#### Next Steps

1. Answer the Self-Reflection questions and record your thinking through journaling, recording a CPD cycle, voice to text software etc.
2. Dedicate regular time in your diary to pause, reflect and debrief your reflections to ensure that you are not just busy, but intentionally moving in the right direction, for the right reasons.
3. Re-read Part 1-4 of this Future of Pharmacy series and reflect on how 4Front's 6Ps of Pharmacy Excellence inter-relate for you.

Share your successes and submit your questions for the IPN/4Front Pharmacy Business Excellence to [rachel@racheldungan.com](mailto:rachel@racheldungan.com)

#### RESOURCE ANNOUNCEMENTS

1. As an IPN reader, we invite you to register for FREE pharmacy team training [www.4FrontPharmacy.ie](http://www.4FrontPharmacy.ie). You can also browse our range of online programmes to support you and your team to develop your consultation skills, gain OTC product knowledge and deal with medical emergencies.
2. 4FrontPharmacy Solutions will be hosting two cohorts of the Positive Intelligence® flagship 8-week Mental Fitness Programme specifically for pharmacists and their teams over the coming months. To find out more about how this Programme and Coaching can help you improve morale, wellbeing and team performance, drive your sales and improve patient safety email [rachel@racheldungan.com](mailto:rachel@racheldungan.com) and use the subject line 'IPN Nov 2021.'

#### AUTHOR: Rachel Dungan MPSI, ACC.

Rachel Dungan MPSI, MIF, ACC. Community Pharmacist. Lifestyle Medicine Advisor. Positive Intelligence Certified Coach. European Mentoring & Coaching Council Senior Practitioner. Award-Winning Wellbeing and Leadership Coach known as 'The Pharmacist Coach.' Rachel worked for 20 years as a supervising and superintendent pharmacist. Now, more than ever, her vision is to empower, equip, enable and engage pharmacists and their teams with the knowledge and skills required to focus on what is most important, rediscover joy and happiness and help them build the habits to put their own oxygen mask on first. She is co-founder of [www.4FrontPharmacy.ie](http://www.4FrontPharmacy.ie).

Its mission is to raise the global standard of pharmacy consultations by empowering pharmacists and their teams to expand their perspective, knowledge and skills to create sustainable health behaviour change.



Contributed by Rachel Dungan MPSI of 4Front Pharmacy. To find out more about how 4Front Pharmacy's Positive Intelligence® Programme and Coaching can help you improve morale, wellbeing and team performance, drive your sales and improve patient safety email [rachel@racheldungan.com](mailto:rachel@racheldungan.com) and use the subject line 'IPN Nov 2021'

## Using the Symptom Cycle to Inform My Decisions

### S

#### Self-Appraisal WHAT I intend to learn and why

I intend to introduce paid pharmacy services into my product mix in 2022. I want to analyse the personal, professional, training and staffing, operational, marketing, health promotion and financial aspects to inform my project plan and to reflect on how the Symptom Cycle can inform my communication strategy.

### P

#### Personal Plan HOW I intend to learn it

I plan to

- Log into the PSI Website and download any guidance for Testing Services
- Speak with colleagues who already operate paid pharmacy services.
- Make an appointment with my accountant re: financial projections
- Record my learnings in this CPD cycle

### A

#### Action What I actually did

- As above PLUS
- I reviewed the IPN business CPD articles on 'the Future of Pharmacy,' because they have an article specifically about Pharmacy Products and Services
- I contacted the article author Rachel Dungan MPSI

### D

#### Document What I have learned specifically

- I learned how to structure my pharmacy consultations for positive impact using the symptom cycle and STEPS Framework.
- I incorporated lifestyle factors into my patient consultation, and didn't just focus on the prescription.
- I let my technician do what she does best in the dispensary, and I focused on the patient consultation, which resulted in a much better consultation.
- I felt good, because the consultation empowered my patient to be more proactive about managing her own health and gave me the confidence to focus on the products, services and advice that they truly value

### E

#### Evaluate ONE example of how I put my learning into practice

Here is one pharmacy consultation that demonstrated impact. Ms D, a 58 year old woman was referred by me, to her GP last week, as her blood pressure reading had been elevated. She presented to me today with a prescription for a new antihypertensive. My technician began the dispensing process, and I took the opportunity to have a consultation with Ms D. She has never been on medication before and feels old.

Initially, when asked, she said that she had no symptoms. But on further enquiry, she shares that she has not been sleeping well lately. Her back has been killing her, but she prefers to 'soldier on.' Ibuprofen OTC seems to take the edge off. She hasn't had her usual level of energy. In fact, quite the opposite. She's been 'worried sick' about her youngest daughter, who has just moved to Dublin. Her usual high tolerance is now razor thin – everyone just seems to be bugging her. I realise that while she perceives herself to have 'no symptoms,' she has, in fact, described most of the symptoms on the symptom cycle. When I show the Symptom Cycle to her, she exhales a sigh of relief. She had thought she was just getting old and was getting more and more exhausted trying to 'just push through.'

I ask her what she knows about ways to manage her blood pressure and these symptoms. She knows salt and smoking are no-nos. After acknowledging this, I asked her if she would be interested in looking at other factors that are proven to reduce elevated blood pressure. She agrees. In addition to her agreeing to take the new medication as prescribed, I mention healthy eating, regular exercise, maintaining a healthy weight, maintaining alcohol intake below 11 units per week, managing stress, getting a good night's sleep, avoiding certain OTC or prescription pain killers such as ibuprofen.

She decides she is going to focus on losing weight, and decides her first action plan is to go to her physiotherapist, so that she can receive treatment for her back and learn to move safely. She will start her BP meds and stop the OTC ibuprofen immediately. She asked to buy a baseline BP, weight, BMI, waist circumference, cholesterol, and pre-books a monitoring visit next Thursday at 2pm.

#### CCF Domains (and Competencies)

The Pharmacist selected Competencies under all six domains for this CPD Cycle  
1. Professional Practice 2. Personal Skills 3. Supply of Medicines. 4. Safe and Rational Use of Medicines.  
5. Public Health. 6. Organisation and Management Skills

# How Winter Affects our Health

Medical Director of Healthspan Dr Sarah Brewer on why our health can suffer in winter, and how the right nutrients can help.



Written by Medical Director of Healthspan Dr Sarah Brewer

Winter can have several unexpected effects on your health. For example, reduced exposure to sunlight not only reduces the synthesis of vitamin D, but it can also have profound effects on your mood and energy levels, and worsen pre-existing conditions such as high blood pressure, asthma, migraine, depression and arthritis.

## Winter heart health

A study published in the North American Journal of Medical Sciences looked at annual patterns for twelve cardiovascular diseases and found a clear seasonal trend. The highest incidences occurred during the colder months of the year, with a 14% increased risk of deep vein thrombosis and pulmonary embolism, as well as increased risks for ruptured aortic aneurysm and stroke.

Blood pressure also tends to be higher during the colder months, and risks for developing symptoms of heart failure, atrial fibrillation (rapid irregular pulse) and other abnormal heart rhythms, angina, and heart attack are also greater.

Possible reasons include reduced physical activity during winter, reduced blood flow in the lower limbs, increased blood stickiness, a 23% increase in fibrinogen levels (a blood clotting factor) and decreased activity of enzymes that break down unwanted blood clots. Low levels of vitamin D and increased secretion of certain hormones (aldosterone, noradrenaline, adrenaline) during cold weather may play a role, with exposure to pollution and infections.<sup>i</sup>

## Winter asthma

Asthma symptoms tend to worsen during winter, as exposure to cold air can inflame airways to trigger cough, wheeze and shortness of breath. Mould spores can also trigger allergic asthma in damp conditions, while low vitamin D levels have been linked with seasonal asthma flare-ups.

A Cochrane review of nine trials, involving 435 children and 658 adults across the UK, US, Canada, India, Japan and Poland, looked at the effects of adding oral vitamin D supplements to usual asthma treatment. During follow-up periods of between four months to one year, those taking vitamin D tablets had a 61% lower risk of experiencing at least one severe asthma attack requiring hospital admission or emergency department attendance compared with placebo.

Vitamin D supplements also reduced the need for rescue therapy with oral steroids, such as prednisolone, by 37%. It's thought that vitamin D boosts immunity to protect against bacterial and viral respiratory infections, which can worsen asthma symptoms. Vitamin D also suppresses inflammation and enhances the response to inhaled corticosteroids.<sup>ii</sup>

## Winter depression

Low mood during winter may indicate Seasonal Affective Disorder (SAD), a syndrome that may be a natural hibernation response to reduced exposure to sunlight. Symptoms include tearfulness, low mood, lethargy, sleepiness, carbohydrate cravings and a general slowing up.

The exact cause is unknown, but SAD is linked with changes in the secretion of various hormones and brain chemicals, which are triggered by reduced exposure to sunlight as the days draw in. These changes involve an increased sensitivity to the sedative hormone melatonin; seasonal variations in the secretion of serotonin, thyroid stimulating hormone (TSH) and adrenaline; and reduced vitamin D levels.

A study involving almost 5,400 Finnish men and women found that those with the highest blood vitamin D levels were 35% less likely to have symptoms of depression than those with the lowest levels, after taking other possible factors into account.<sup>iii</sup>

## Winter migraine

Migraine is more common in winter for some people, with three out of four migraine sufferers recognising that cold weather and sudden changes in atmospheric pressure can bring on their symptoms. People with seasonal variations in migraine also report more severe pain, plus more eye symptoms (redness, tears, closing eyelid) and facial sweating, especially on the forehead, suggesting that certain cranial nerves are involved.

Lower vitamin D levels have also been implicated.<sup>iv</sup> Vitamin D has a neuroprotective effect through an antioxidant mechanism, neuronal calcium modulation and detoxification mechanisms. A study involving 53 children (aged 8-16 years) with migraine found that adding vitamin D to anti-migraine treatment (amitriptyline) reduced the number of attacks, compared to controls who did not receive vitamin D.<sup>v</sup>

## Winter joint pain

Many people recognise that exposure to cold weather makes their joints ache more than usual, especially if they have osteoarthritis, rheumatoid arthritis or gout. Researchers have found more hospitalisations for gouty arthritis during November, and a study, involving 810 people with osteoarthritis of the knee, found that a combination of high humidity and cold weather was associated with worsening joint pain.

It's thought that changes in air pressure, constriction of circulation and lower levels of vitamin D (which is involved in immune responses and cartilage regeneration) are involved.<sup>vi</sup>

## Winter colds

The susceptibility to sore throats, colds and 'flu increases during winter, partly because viruses survive better in cold weather, and partly because immunity is reduced by breathing dry, centrally-heated air. Other factors include huddling indoors, which aids the spread of germs, as well as falling levels of vitamin D.

Other vitamins and minerals also play a key role in maintaining immune function – especially vitamins B12 and C, plus minerals such as zinc. Vitamins C and D are especially important to support immunity against winter colds and respiratory diseases.

## Vitamin D and colds

Studies involving over 19,000 adults show that vitamin D deficiency increases the likelihood of developing common cold symptoms by over a third (36%) compared with people with optimal levels.<sup>vii</sup> Conversely, taking a vitamin D3 supplement was found to reduce the risk of developing a respiratory tract infection (including the common cold, influenza and pneumonia) by a third compared with placebo.<sup>viii</sup> The benefits are even greater in people with a pre-existing vitamin D deficiency.

## Vitamin C and colds

Vitamin C has a natural antiviral action, through stimulating the production of immune factors such as interferon and suppressing the activation of viral genes.<sup>ix</sup> The antioxidant action of vitamin C mops up inflammatory chemicals produced during a viral infection, to improve symptoms and hasten healing if a cold should develop.<sup>x</sup>

The combined results from 30 trials involving over 11,300 people showed a consistent treatment benefit from vitamin C supplements, with a reduction in the duration of a cold of 8% in adults and, in children taking 1g to 2g of vitamin C per day, a reduction of 18%. The severity of cold symptoms was also reduced.<sup>xi</sup>

## Winter wellness supplements

Healthspan's ImmunoVit Super C & Vegan D Plus is a perfect way to boost defences during winter, as it provides:

- 500mg vitamin C to support the immune system, nervous system, bones and cartilage and psychological function, as well as reduce tiredness and fatigue
- 15mcg vegan vitamin D3 derived from algae to support immunity and bones
- 10mcg vitamin B12 to support the immune system, nervous system, psychological function and the reduction of tiredness and fatigue
- 5 mg zinc to support the immune system, bones and psychological function.

Each pack provides 120 one-a-day tablets to support winter health.

References available on request



49%\* said they would be likely to buy from the ImmunoVit range



Comprehensive immune health support



Innovative and trending ingredients



Developed alongside nutrition experts



Suitable for vegetarians and vegans



Contact information:

Wholefoods are an approved wholesaler for Healthspan

Wholefoods Wholesale,  
Unit 3, Kylesmore Ind Est,  
Killen Road, D10

To order please call: 01 6262315  
sales@wholefoods.ie

\*Source: Each concept was researched to an exclusive sample of 200 regular supplement users, working age natrep (age 18-65).

# A Guide for Pharmacists

## Starting once-weekly Ozempic®<sup>▼</sup> (semaglutide)

**What is Ozempic®?** - Ozempic is a once-weekly GLP-1\* receptor agonist indicated for the treatment of type 2 diabetes.<sup>1</sup>

### What is the dosing regimen for Ozempic®?

- The Ozempic® starting dose is 0.25 mg once-weekly<sup>1</sup>
- After 4 weeks, the dose should be increased to 0.5 mg once-weekly<sup>1</sup>
- After at least 4 weeks with a dose of 0.5 mg once-weekly the dose can be increased to 1.0 mg once-weekly to further improve glycaemic control<sup>1</sup>

**Please note: Ozempic® 0.25mg is not a maintenance dose.**

#### Method of administration

Ozempic® is to be administered once-weekly at any time of the day, with or without meals.<sup>1</sup>

#### What are the most common side effects that people may experience starting on Ozempic®

- Hypoglycaemia when used with insulin or sulfonylurea<sup>1</sup>
- Nausea<sup>1</sup>
- Diarrhoea<sup>1</sup>

### About the Ozempic® FlexTouch® Pen

Ozempic® is available in Ozempic® FlexTouch® pre-filled pens at three strengths; 0.25 mg, 0.5 mg and 1.0 mg

Patients are initiated on Ozempic® treatment using the 0.25 mg Ozempic® FlexTouch® pen<sup>1#</sup>

Following 4 weeks of treatment on the 0.25 mg Ozempic® dose, patients are titrated to 0.5 mg using the Ozempic® FlexTouch® 0.5 mg pen<sup>1</sup>

Following 4 weeks of treatment on 0.5 mg dose, the 1.0 mg Ozempic® FlexTouch® pen can be considered<sup>1</sup>



#### START

**0.25 mg**  
for  
4 weeks

#### STEP

**0.5 mg**  
for at least  
4 weeks

#### STAY

**0.5 mg or 1.0 mg**  
based on individual  
patient needs



#### About the NovoFine® Plus needle

For patient convenience, each Ozempic® pack includes four NovoFine® Plus 32 gauge 4mm needles.

More information on Ozempic® for Pharmacists and Patients: [www.ozempicare.ie](http://www.ozempicare.ie)

Patients can sign up for a once-weekly SMS reminder at:  
[www.ozempicare.ie](http://www.ozempicare.ie) password: 001010



\*GLP-1 = Glucagon-like peptide-1

#Patients can expect to see residual liquid remain in the the device following administration of 0.25mg dose for 4 weeks

Reference 1. Ozempic® Summary of Product Characteristics, [www.medicines.ie](http://www.medicines.ie)

▼ This medicinal product is subject to additional monitoring.  
This will allow for quick identification of new safety information.

Ozempic and Flextouch are registered trademarks owned by Novo Nordisk A/S. This article has been prepared and funded by Novo Nordisk. Number IE21OZM00094, Date of Preparation, October 2021



# A combined force against LUTS and BPH

49% of men with LUTS report bladder and prostate symptoms<sup>1</sup>  
**VESOMNI treats the symptoms of both the bladder and prostate<sup>2</sup>**



**Abbreviated Prescribing Information** – Vesomni 6 mg/0.4 mg modified release tablets. Please read the Summary of Product Characteristics (SPC) before prescribing. **Presentation:** Each tablet contains a layer of 6 mg solifenacin succinate, corresponding to 4.5 mg solifenacin free base and a layer of 0.4 mg tamsulosin hydrochloride, corresponding to 0.37 mg of tamsulosin free base. **Indication:** Treatment of moderate to severe storage symptoms (urgency, increased micturition frequency) and voiding symptoms associated with benign prostatic hyperplasia (BPH) in men who are not adequately responding to treatment with monotherapy. **Posology and method of administration:** Adult males, including older people: One Vesomni tablet (6 mg/0.4 mg) once daily taken orally with or without food. The maximum daily dose is one Vesomni tablet; the tablet must be swallowed whole, intact without biting or chewing. Do not crush the tablet. **Special populations (see also contraindications below): Renal impairment:** Severe renal impairment (creatinine clearance  $\leq 30$  mL/min): Treat with caution, maximum daily dose in these patients is one Vesomni tablet. **Hepatic impairment:** Moderate hepatic impairment (Child-Pugh score of 7-9): Treat with caution, maximum daily dose in these patients is one Vesomni tablet. In patients with severe hepatic impairment (Child-Pugh score  $> 9$ ), the use of Vesomni is contraindicated. **Concomitant treatment with moderate and strong inhibitors of CYP2C9/3A4:** e.g. verapamil, ketoconazole, rifonavir, neflavin, itraconazole: Treat with caution, maximum daily dose should be limited to one Vesomni tablet. **Pediatric population:** There is no relevant indication for use of Vesomni in children and adolescents. **Contraindications:** Patients with hypersensitivity to the active substance(s) or to any of the excipients (see SPC). Patients undergoing haemodialysis. Patients with severe hepatic impairment. Patients with severe renal impairment who are also treated with a strong cytochrome P450 (CYP3A4) inhibitor e.g. ketoconazole. Patients with moderate hepatic impairment who are also treated with a strong CYP3A4 inhibitor e.g. ketoconazole. Patients with severe gastrointestinal conditions (including toxic megacolon), myofascitis, glaucoma or narrow-angle glaucoma and patients at risk for these conditions. **Warnings:** Patients with a history of orthostatic hypotension. **Special Warnings and Precautions for Use:** Vesomni should be used with caution in patients with: severe renal impairment; risk of urinary retention; gastrointestinal obstructive disorders; risk of decreased gastrointestinal motility; hiatus hernia/gastroesophageal reflux and/or who are concurrently taking medicinal products (such as bisphosphonates) that can cause or exacerbate oesophagitis; autonomic neuropathy. The patient should be examined in order to exclude the presence of other conditions, which can cause similar symptoms to benign prostatic hyperplasia. Other causes of frequent urination (heart failure or renal disease) should be assessed before treatment with Vesomni is initiated. If a urinary tract infection is present, appropriate antibiologic therapy should be started. QT prolongation and Torsade de Pointes have been observed in patients with risk factors, such as pre-existing long QT syndrome and hypokalaemia, who are treated with solifenacin succinate. Angioedema with airway obstruction has been reported in some patients on solifenacin succinate and tamsulosin. If angioedema occurs, Vesomni should be discontinued and not restarted. Appropriate therapy and/or measures should be taken. Anaphylactoid reaction has been reported in some patients treated with solifenacin succinate. In patients who develop anaphylactoid reactions, Vesomni should be discontinued and appropriate therapy and/or measures should be taken. As with other alpha<sub>1</sub>-adrenoceptor antagonists, a reduction in blood pressure can occur in individual cases during treatment with tamsulosin, as a result of which, rarely syncope can occur. Patients starting treatment with Vesomni should be cautioned to sit or lie down at the first signs of orthostatic hypotension (dizziness, weakness) until the symptoms have disappeared. The 'Intraoperative Floppy Iris Syndrome' (IFIS, a variant of small pupil syndrome) has been observed during cataract and glaucoma surgery in some patients on or previously treated with tamsulosin hydrochloride. IFIS may increase the risk of eye complications during and after the operation. Therefore, the initiation of therapy with Vesomni in patients for whom cataract or glaucoma surgery is scheduled is not recommended. Discontinuing treatment with Vesomni 1-2 weeks prior to cataract or glaucoma surgery is anecdotally considered helpful, but the benefit of treatment discontinuation has not been established. During pre-operative assessment, surgeons and ophthalmic teams should consider whether patients scheduled for cataract or glaucoma surgery are being or have been treated with Vesomni in order to ensure that appropriate measures will be in place to manage IFIS during surgery. Vesomni should be used with caution in combination with moderate and strong inhibitors of CYP3A4 and it should not be used in combination with strong inhibitors of CYP3A4, e.g. ketoconazole, in patients who are of the CYP2D6 poor metaboliser phenotype or who are using strong inhibitors of CYP2D6, e.g. paroxetine.

**Interactions:** **Pharmacological interactions:** Concomitant medication with other anticholinergic medicinal products may result in more pronounced therapeutic and undesirable effects. Allow approximately one week after stopping treatment with Vesomni before commencing any anticholinergic therapy. The therapeutic effect of solifenacin may be reduced by concomitant administration of cholinergic receptor agonists. **Pharmacokinetic interactions:** **Pharmacokinetic interactions involving the potential for other medicinal products to affect Vesomni exposure:** **Interactions with CYP3A4 and CYP2D6 inhibitors:** See Contraindications, Posology and administration and Special warnings and precautions above. Concomitant administration may lead to increased exposure to both solifenacin (ketoconazole 400 mg/day resulted in a 1.5-fold increase in C<sub>max</sub> and a 2.8-fold increase in AUC) and tamsulosin (ketoconazole 400 mg/day resulted in a 2.2-fold increase in C<sub>max</sub> and a 2.8-fold increase in AUC). Vesomni should be used with caution in combination with strong CYP3A4 inhibitors. Vesomni should not be given together with strong CYP3A4 inhibitors in patients who are also CYP2D6 poor metaboliser phenotype or who are using strong CYP2D6 inhibitors. See SPC for details of the effects of other CYP3A4 and CYP2D6 inhibitors. **Inducers:** Inducers of CYP3A4 (e.g. rifampicin) may decrease the plasma concentrations of solifenacin and tamsulosin. **Information available for the individual active substances:** Solifenacin can reduce the effect of medicinal products that stimulate the motility of the gastrointestinal tract, such as metoclopramide and cisapride. Solifenacin did not affect the pharmacokinetics of digoxin, or the pharmacokinetics or effect on prothrombin time of R<sub>1</sub> or Swartwin. Co-administration of tamsulosin and other alpha<sub>1</sub>-adrenoceptor antagonists could lead to hypotensive effects. Difenoxin and warfarin may increase the elimination rate of tamsulosin. No interactions have been seen when tamsulosin was given concurrently with atenolol, enalapril or theophylline. **Fertility, pregnancy and lactation:** The effect of Vesomni on fertility has not been established. Ejaculation disorders have been observed in short and long term clinical studies with tamsulosin. Events of ejaculation disorder, retrograde ejaculation and ejaculation failure have been reported in the post authorization phase. Vesomni is not indicated for use in women. **Driving and use of machines:** No studies have been performed, however patients should be informed about the possible occurrence of dizziness, blurred vision, fatigue and uncommonly somnolence, which may negatively affect the ability to drive or use machines. **Undesirable Effects:** Summary of the safety profile: Vesomni may cause anticholinergic undesirable effects of, in general, mild to moderate severity. The most frequently reported adverse reactions during the clinical studies performed for the development of Vesomni were dry mouth (9.5%), followed by constipation (3.2%) and dyspepsia (including abdominal pain; 2.4%). Other common undesirable effects are dizziness (including vertigo; 1.4%), vision blurred (1.2%), fatigue (1.2%) and ejaculation disorder (including retrograde ejaculation; 1.5%). Acute urinary retention (0.5%, uncommon) is the most serious adverse drug reaction that has been observed during treatment with Vesomni in clinical studies. **List of adverse reactions:** The 'Vesomni frequency' below reflects adverse drug reactions that have been observed during the double-blind clinical studies performed for the development of Vesomni (based on reports of treatment-related adverse events, which have been reported by at least two patients and occurred with a frequency higher than for placebo in the double-blind studies). The 'solifenacin frequency' and 'tamsulosin frequency' below reflect adverse drug reactions (ADRs) previously reported with one of the individual components (as presented in the Summary of Product Characteristics (SPCs) of solifenacin 5 and 10 mg and tamsulosin 0.4 mg respectively that may also occur when receiving Vesomni (some of these have not been observed during the clinical development program of Vesomni)). The frequency of adverse reactions is defined as follows: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated from the available data). The adverse events are grouped by MedDRA system organ class preferred term (PT). **Vesomni frequency:** Nervous system disorders: Common: dizziness. Eye disorders: Common: vision blurred. Gastrointestinal disorders: Common: dry mouth, dyspepsia, constipation. Skin and subcutaneous tissue disorders: Uncommon: pruritus. Renal and urinary disorders: Uncommon: urinary retention. Reproductive system and breast disorders: Common: ejaculation disorders including retrograde ejaculation and ejaculation failure. General disorders and administration site conditions: Common: fatigue. Solifenacin 5mg & 10mg frequency: Infections and infestations: Uncommon: urinary tract infection, cystitis. Immune system disorders: Not known: anaphylactoid reaction. Metabolism and nutrition disorders: Not known: decreased appetite, hyperkalaemia. Psychiatric disorders: Very rare: hallucination, confusional state. Not known:

delirium. Nervous system disorders: Uncommon: somnolence, dysgeusia. Rare: ataxia, headache. Eye disorders: Common: vision blurred. Uncommon: dry eyes. Not known: glaucoma. Cardiac disorders: Not known: palpitations, Torsade de Pointes, electrocardiogram QT prolongation, atrial fibrillation, tachycardia. Respiratory, thoracic and mediastinal disorders: Uncommon: nasal dryness. Not known: dysphonia. Gastrointestinal disorders: Very common: dry mouth. Common: dyspepsia, constipation, nausea, abdominal pain. Uncommon: gastro-oesophageal reflux disease, dry throat. Rare: vomiting, colonic obstruction, faecal impaction. Not known: ileus, abdominal discomfort. Hepatobiliary disorders: Not known: liver disorder, liver function test abnormal. Skin and subcutaneous tissue disorders: Uncommon: dry skin. Rare: pruritus, rash. Very rare: urticaria, angioedema. Erythema multiforme. Not known: exfoliative dermatitis. Musculoskeletal and connective tissue disorders: Not known: muscular weakness. Renal and urinary disorders: Uncommon: difficulty in micturition. Rare: urinary retention. Not known: renal impairment. General disorders and administration site conditions: Uncommon: fatigue, peripheral oedema. **Tamsulosin 0.4mg frequency:** Nervous system disorders: Common: dizziness. Uncommon: headache. Rare: syncope. Eye disorders: Not known: vision blurred. Intraoperative Floppy Iris Syndrome (IFIS), visual impairment. Cardiac disorders: Uncommon: palpitations. Not known: atrial fibrillation, arrhythmia, tachycardia. Vascular disorders: Uncommon: orthostatic hypotension. Respiratory, thoracic and mediastinal disorders: Uncommon: rhinitis. Not known: dyspnoea. Epistaxis. Gastrointestinal disorders: Uncommon: constipation, nausea, diarrhoea, vomiting. Skin and subcutaneous tissue disorders: Uncommon: pruritus, rash, urticaria. Rare: angioedema. Very Rare: Stevens-Johnson syndrome. Not known: erythema multiforme, exfoliative dermatitis. Reproductive system and breast disorders: Common: ejaculation disorders including retrograde ejaculation and ejaculation failure. Very rare: priapism. General disorders and administration site conditions: Uncommon: asthenia. The ADRs from solifenacin and tamsulosin included are the ADRs listed in the summary of product characteristics of both products. \*: from post-marketing reporting. Because these spontaneously reported events are from the worldwide post-marketing experience, the frequency of events and the role of solifenacin or tamsulosin and their causation cannot be reliably determined. \*\*: from post-marketing reporting, observed during cataract and glaucoma surgery. \*\*\*: see Special warnings and precautions for use. **Long-term safety of Vesomni:** The profile of undesirable effects seen with treatment up to 1 year was similar to that observed in the 12-week studies. The product is well-tolerated and no specific adverse reactions have been associated with long-term use. **Description of selected adverse reactions:** For urinary retention see Special warnings and precautions for use. **Older people:** The therapeutic indication of Vesomni, moderate to severe storage symptoms (urgency, increased micturition frequency) and voiding symptoms associated with BPH, is a disease affecting elderly men. The clinical development of Vesomni has been performed in patients 45 to 91 years of age, with an average age of 65 years. Adverse reactions in the elderly population were similar to the younger population. **Reporting of suspected adverse reactions:** see below. **Overdose:** Overdosage with the combination of solifenacin and tamsulosin can potentially result in severe anticholinergic effects plus acute hypotension. Refer to SPC for details of treatment of overdose. **Legal Category:** Prescription Only Medicine (S3). **Nature and contents of container:** Aluminium blister packs containing 30 tablets. **Product Authorisation Number:** PA1241/016/001. **Marketing Authorisation holder:** Astellas Pharma Co. Ltd. **Further information is available from:** Astellas Pharma Co. Ltd, 5 Waterside, Citywest Business Campus, Naas Road, Dublin 24. Phone: +353 1 467 1555. Summary of Product Characteristics with full prescribing information available upon request. **Job number:** VESOMI\_2019\_0001. **IE Date of preparation of API:** 24 May 2019.

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via:  
 HPRRA Pharmacovigilance, Astellas Pharma Co. Ltd  
 Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 467 1555  
 Tel: +353 1 674971, Fax: +353 1 6762517  
 Website: www.hpra.ie  
 E-mail: m.edsafety@hpra.ie

### WEST ESTABLISHES NEW GLOBAL FINANCE CENTER IN DUBLIN CREATING 60 JOBS

West Pharmaceutical Services, Inc. (NYSE: WST), a global leader in innovative solutions for injectable drug administration, has created 60 new jobs in Dublin as part of establishing a new global finance shared service model here.

The new shared service model centralises West's key finance activities in Dublin and Exton, Pennsylvania, to drive efficiency and support increasing company growth. The new center in Dublin includes various accounting and finance activities and will create greater scale and value for West's global business and operations. West now employs over a thousand team members across Ireland, including its manufacturing facilities in Waterford and Dublin.

Bernard J. Birkett, West Senior Vice President & Chief Financial Officer, said the new finance service center in Dublin will ultimately support the company's overall mission to improve patient lives: "This new finance support model enables our overall business strategy of responding and transforming to meet the changing needs of the market to deliver high quality components and service to our customers that will ultimately improve more patient lives—and that's what matters most."

Tánaiste and Minister for Enterprise, Trade and Employment Leo Varadkar said: "I'm really pleased to see West adding 60 new highly skilled jobs to its operations here in Ireland. Our pharma industry continues to grow from strength to strength and companies like West are an important part of that story. The company employs over a thousand people here and this new Global Finance Centre is a further testament to our attractive business environment, robust regulatory framework and skilled labour force. I wish the team at West all the best with this new chapter."

This is West's latest expansion of its Irish operations and follows the company's scaling up of its Waterford plant's working schedules late last year in response to a big surge in customer demand as a result of the COVID-19 pandemic. The Waterford plant is now supplying millions of rubber vial stoppers to a dozen global customers to package vaccine doses as part of the COVID-19 vaccine programme. The plant doubled

its workforce to meet this new demand over the past year.

Led by Site Director Tom Clarke, West's Dublin facility has 20 years of operations and sustained growth including high volume, complex device manufacturing. With almost 100 years of experience and a reputation for leadership in quality, West is internationally recognised for its excellence in the manufacturing of pharmaceutical packaging and medical devices. It is a leading manufacturer of delivery systems for injectable drugs and healthcare products.

### DASSIET NEW PRODUCT LINE UCAST

the materials company Dassiet is launching UCAST – a product line targeted towards hospitals and health centres, making fracture treatment faster and safer both for the patient and nursing staff. Thermoplastic UCAST cast takes only about 5 minutes to apply, while a traditional cast can take up to 30 minutes to prepare. UCAST splints are made of completely non-allergenic and non-toxic materials, and the medical staff does not need to protect themselves for casting. The splint is light-weight, breathable and unobtrusive to the patient.

The UCAST splint is made of the wood composite material called Woodcast, which has already been used in hospitals in Finland and around the world for more than 10 years. Woodcast is also used in the field of veterinary medicine, including institutions such as the Veterinary Teaching Hospital in Helsinki. The material is in widespread use in the medical field due to its safety and ease of use. UCAST, developed

by casting professionals, will be a big step forward in trauma treatment. It is a breathable and non-toxic cast that removes the need to measure, cut and clean up during fracture treatment. UCAST also helps hospitals to fight against climate change, as the splint is completely biodegradable, and the fabric can be recycled.

Michael Lindroos, COO at Dassiet, is responsible for the product development and has created UCAST in cooperation with physicians, researchers and other casters.

"I have carried out the duties of a casting specialist since 1999. Patients' wellbeing and proper treatment have always been my top priorities, which is why I have spent the past years developing UCAST to make the daily lives of my colleagues and the patient easier. UCAST consists of only two materials: thermoplastic Woodcast splint and padded fabric. Our innovative fabric completely replaces the stockinets, paddings, bandages and tapes needed during casting. Units using UCAST spend less time on the procedure, which in turn can reduce the waiting time for patients. UCAST is an effective, fast and safe cast, which is something that I always wanted when I was working in a hospital", Lindroos comments.

In addition to launching UCAST, Dassiet continues product and material development. Recently, the company acquired a leading US company OrthoPets, that produces animal orthoses. Improving veterinary treatment is one of the main focuses of the company. Furthermore, Dassiet offers various industries

an opportunity to replace plastic parts with durable and ecological wood composite and biopolymer options.

The first products available in the UCAST product line include a wrist splint and a short thumb splint. Additional products for the treatment of upper and lower limbs will become available soon.

Additional information on UCAST products can be read at [www.ucasmedical.com](http://www.ucasmedical.com)

### DR THORSTEN GIESECKE APPOINTED GENERAL MANAGER, COMMERCIAL BUSINESS, JANSSEN SCIENCES IRELAND UC

Janssen, the pharmaceutical companies of Johnson & Johnson, has appointed Dr Thorsten Giesecke as General Manager, Commercial Business, Janssen Sciences Ireland UC, which is responsible for commercialising six areas of medicines where the need is high including: oncology, immunology, neuroscience, infectious diseases and vaccines, pulmonary hypertension and cardiovascular and metabolism.

Thorsten joins Janssen from the Company's headquarters in New Jersey where he worked as Director of Global Commercial Strategy for early assets in oncology and prior to that as lead of the EMEA regional haematology strategy for multiple myeloma.

Thorsten, who has relocated to Ireland from the US, is a performance and purpose-driven leader with an impressive track record of building and leading high performing teams, together with solid experience in Global/Regional Strategic leadership roles.



Used to treat  
and prevent  
the recurrence  
of urinary tract  
infections.

Safe to take during Pregnancy

5 day treatment course

Complement to antibiotics

Available in sachets & capsules





Dr Thorsten Giesecke  
as General Manager,  
Commercial Business,  
Janssen Sciences  
Ireland UC

In these roles, Thorsten has spearheaded several strategic projects including ensuring a transformational pipeline in prostate cancer through earlier and better commercial input, improving the global patient advocacy interaction, assessing the dynamic impact of new market entrants on cancer epidemiology, and developing biomarker strategies. He has also driven the digital agenda in EMEA, introducing and implementing a digital customer experience at scientific conferences across the region.

Thorsten first joined Janssen Germany in 2006 as Medical Development Manager and assumed roles of increasing responsibility before being appointed as Business Unit Director for therapy areas including neuroscience and metabolics.

Originally from Germany, Thorsten began his career as an anaesthesiologist and scientist at University Hospitals in Germany and the US. He is a board-certified anaesthesiologist and pain therapist and holds an MD and a PhD from the University of Cologne.

Commenting on his appointment, Thorsten said, "I am delighted to be joining the Irish team and to be taking on the role of General Manager with responsibility for the Janssen commercial business at such an important time, and I believe we have a huge opportunity ahead of us. As we emerge from this pandemic, a new era of partnership between the government, the health service and industry will be vital to achieving the best for Irish patients. I am fully committed to building on

the remarkable work that has already been done here to improve care and ensure timely access to innovative treatments as we continue to make a real difference to the lives of people, health systems and society as a whole."

With a passion for putting patients first, Thorsten brings his vast international experience to support the teams at Janssen working to address some of Ireland's most pressing health challenges including the COVID-19 pandemic and tackling cancer with precision medicines and cutting-edge technologies in cell and gene therapy.

Janssen is part of the Johnson & Johnson family of companies in Ireland which employs over 5,000 people at 10 sites in Ireland across manufacturing, R&D and business operations, representing all three sectors of the company – Pharmaceutical, Medical Devices and Consumer Health. Many of Janssen's innovative medicines are manufactured for global export from Irish sites.

#### **SANOFI ANNOUNCES POSITIVE PHASE 1/2 STUDY INTERIM RESULTS FOR ITS FIRST MRNA-BASED VACCINE CANDIDATE**

Positive interim results from a Phase 1/2 study<sup>1</sup> of Sanofi's mRNA-based COVID-19 vaccine candidate confirm the potential of recently-acquired Translate Bio's messenger RNA (mRNA) and lipid nanoparticle (LNP) platform and support Sanofi's mRNA strategy.

The initial data from Phase 1/2 showed neutralizing antibody seroconversion (defined as 4-fold increase vs baseline) in 91% to 100% of study participants, two

weeks after a second injection, across all 3 dosages tested. No safety concern has been observed and the tolerability profile is comparable to that of other unmodified mRNA COVID-19 vaccines. Further data from this first study of Sanofi's mRNA platform will be presented at a later date.

"We are happy to see those positive initial results. We have made an impressive move just 9 months after the worldwide proof of concept of mRNA vaccines and only 17 since we started this first mRNA vaccine project", says Jean-Francois Toussaint, Global Head of Research and Development, Sanofi Pasteur. "These results will clearly help inform the path forward for our mRNA development programs. Today, we have a promising mRNA platform, which we're taking to the next level in development, including moving to modified mRNA, and against other diseases, including flu."

Targeting 2022 initiation of its clinical studies for an influenza vaccine with modified mRNA, Sanofi launched a Phase 1 clinical trial in June 2021 evaluating an mRNA-based investigational vaccine against seasonal influenza. The trial will evaluate the safety and immunogenicity of a monovalent flu vaccine candidate coding for the hemagglutinin protein of the A/H3N2 strain of the influenza virus across two formulations (MRT5400 and MRT5401) with different lipid nanoparticles.

At the same time, Sanofi continues its efforts in the fight against the COVID-19 pandemic with its adjuvanted recombinant protein candidate vaccine, developed in partnership with GSK. In parallel to its ongoing Phase 3 efficacy and safety study, Sanofi has expanded its development program to include a study of the vaccine as a potentially broadly protective booster to address evolving public health needs. Recently published preclinical data<sup>3</sup> indicated the candidate has the potential to strongly boost immune responses following primary vaccination across multiple vaccine technology platforms and against a broad spectrum of variants of concern. The booster studies<sup>4</sup> began this summer in the U.S., Australia, France, and the UK. First results are expected by the end of Q4 2021.

Sanofi also keeps its commitment to making a strong contribution to current global public health priorities, with the supply of half a billion doses of authorized vaccines. Sanofi is the only company leveraging its worldwide

manufacturing capacity and expertise for the supply of three different authorized COVID-19 vaccines from BioNTech / Pfizer, Moderna, and Johnson & Johnson. Manufacturing teams on three industrial sites of the company in France, Germany and the U.S. are mobilized, with 30 million doses released so far.

#### **FDA ACCELERATED APPROVAL FOR TIVDAK™ (TISOTUMAB VEDOTIN-TFTV)**

Genmab A/S (Nasdaq: GMAB) and Seagen Inc. (Nasdaq: SGEN) have announced that the U.S. Food and Drug Administration (FDA) has granted accelerated approval to TIVDAK™ (tisotumab vedotin-tftv), the first and only approved antibody-drug conjugate (ADC) for the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. TIVDAK is approved under the FDA's Accelerated Approval Program based on tumor response and the durability of the response. Continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials.<sup>1</sup>

In the innovaTV 204 clinical trial, TIVDAK was evaluated in 101 patients with recurrent or metastatic cervical cancer who had received no more than two prior systemic regimens in the recurrent or metastatic setting, including at least one prior platinum-based chemotherapy regimen. Results from the trial showed a 24 percent confirmed objective response rate (ORR) (95% CI; 15.9-33.3), as assessed by an independent review committee (IRC) using Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 criteria. The median duration of response (DOR) was 8.3 months (95% CI; 4.2 to not reached).

The prescribing information for TIVDAK includes a BOXED WARNING for ocular toxicity, and Warnings for peripheral neuropathy, hemorrhage, pneumonitis, and embryo-fetal toxicity. The most common (≥25%) adverse reactions, including laboratory abnormalities, were hemoglobin decreased (52%), fatigue (50%), lymphocytes decreased (42%), nausea (41%), peripheral neuropathy (39%), alopecia (39%), epistaxis (39%), conjunctival adverse reactions (37%), hemorrhage (32%), leukocytes decreased (30%), creatinine increased (29%), dry eye (29%), prothrombin international normalized ratio increased (26%), activated partial thromboplastin time prolonged





# FOR RECURRING HEARTBURN MORE THAN ONCE A WEEK



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RECOMMEND IRELAND'S NO.1 PHARMACY ONLY 24 HOUR HEARTBURN PROTECTION TREATMENT\*

\*IQVIA category summary by brand April 2021

**Product information: Nexium Control 20 mg gastroresistant tablets and hard capsules:** Each gastroresistant hard capsule/tablet contains 20 mg esomeprazole (as magnesium trihydrate).  
**Indications:** The short-term treatment of reflux symptoms (e.g. heartburn and acid regurgitation) in adults. **Dosage:** The recommended dose is 20 mg esomeprazole (one tablet or capsule) per day. It might be necessary to take the tablets or capsules for 23 consecutive days to achieve improvement of symptoms. The duration of treatment is up to 2 weeks. Once complete relief of symptoms has occurred, treatment should be discontinued. If no symptom relief is obtained within 2 weeks of continuous treatment, the patient should be instructed to consult a doctor. **Contraindications:** Hypersensitivity to the active substance, substituted benzimidazoles or to any of the excipients. Esomeprazole must not be used concomitantly with nelfinavir. **Precautions:** Jaundice or severe liver disease. Unintentional weight loss, recurrent vomiting, dysphagia, haematemesis or melaena and when gastric ulcer is suspected or present, malignancy should be excluded as treatment with esomeprazole may alleviate symptoms and delay diagnosis. Gastric ulcer or gastrointestinal surgery. Treatment of indigestion or heartburn for 4 or more weeks. Over 55 years old with new or recently changed symptoms. Not suitable for long term use. Treatment with proton pump inhibitors (PPIs) may lead to a slightly increased risk of gastrointestinal infections such as *Salmonella* and *Campylobacter* and in hospitalised patients, also possibly *Clostridium difficile*. Consult doctor prior to have an endoscopy or urea breath test. Co-administration with atazanavir is not recommended. Interactions with medicinal products metabolised through CYP2C19 should be considered. The use of esomeprazole with clopidogrel should be discouraged. Patients should not take another PPI or H<sub>2</sub> antagonist concomitantly. PPI are associated with very infrequent cases of SCLÉ. If lesions occur, especially in sun-exposed areas of the skin, and if accompanied by arthralgia, the patient should seek medical help promptly. **Pregnancy and lactation:** Avoid use of Nexium Control during pregnancy and breastfeeding. **Side effects:** Common: headache, abdominal pain, constipation, diarrhoea, flatulence, nausea/ vomiting, fundic gland polyps (benign). Uncommon: peripheral oedema, insomnia, dizziness, paraesthesia, somnolence, vertigo, dry mouth, increased liver enzymes, dermatitis, pruritus, rash urticaria. Rare: leukopenia, thrombocytopenia, hypersensitivity reactions e.g. fever, angioedema and anaphylactic reaction/shock, hyponatraemia, agitation, confusion, depression, taste disturbance, blurred vision, bronchospasm, stomatitis, gastrointestinal candidiasis, hepatitis with or without jaundice, alopecia, photosensitivity, arthralgia, myalgia, malaise, increased sweating. Very rare: agranulocytosis, pancytopenia, aggression, hallucinations, hepatic failure, hepatic encephalopathy in patients with pre-existing liver disease, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN), muscular weakness, interstitial nephritis, gynaecomastia. Not known: hypomagnesaemia; severe hypomagnesaemia which can correlate with hypocalcaemia; hypomagnesaemia may also result in hypokalaemia, microscopic colitis, subacute cutaneous lupus erythematosus (SCLÉ). **Legal category:** Supply through pharmacy only. **Product licence number:** EU/1/13/860/001; EU/1/13/860/002; EU/1/13/860/003; EU/1/13/860/004 and EU/1/13/860/005. **MAH:** GlaxoSmithKline Consumer Healthcare (Ireland) Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland. Full product information is available in the SPC. Additional information is available upon request. **Text prepared:** July 2021.

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(26%), diarrhea (25%), and rash (25%). Please see Important Safety Information below.<sup>1</sup>

The Biologics License Application (BLA) for TIVDAK was submitted in February 2021 and accepted with Priority Review in April 2021. The submission was based on the results of the innovaTV 204 trial.

The FDA's Accelerated Approval Program allows for approval of a medicine based on a surrogate endpoint that is reasonably likely to predict clinical benefit, if the medicine fills an unmet medical need for a serious condition. A global, randomized phase 3 clinical trial (innovaTV 301) is underway and is also intended to support global registrations.

#### MS IRELAND AND NOVARTIS LAUNCH MS PODCAST

MS Explored – The Podcast, a new series created by MS Ireland in partnership with Novartis Ireland was launched recently, providing support and advice to the 9,000 people in Ireland currently living with Multiple Sclerosis (MS). The podcast series has been developed in response to the increased demand for information and support witnessed by MS

Ireland throughout the pandemic and the distinct need for easily accessible resources.

Hosted by Aoife Kirwan, Information, Advocacy and Research Officer, at MS Ireland, MS Explored – The Podcast explores a range of topics from diagnosis through to managing family and work pressures. Listeners will hear from top healthcare experts as well as individuals who have been diagnosed with the condition as they share their first-hand experiences.

MS Explored – The Podcast featured leading healthcare professionals including:

- Dr Eddie Murphy - Clinical Psychologist & Mental Health Expert at RTE's Operation Transformation
- Dr Lisa Costello, Consultant Neurologist at Beaumont Hospital
- Dr Maria Gaughan, MS Fellow
- Sinead Jordan, Clinical Nurse Specialist
- Sinead Brady, Career Psychologist

Audrey Derveloy, General Manager and Country President, Novartis Ireland speaking about the podcast launch said, "We are delighted to be launching MS Explored – The Podcast today in partnership with MS Ireland. We believe that the series will serve to provide support and advice to those living with MS whenever they need it. Access to resources such as this is critical for people navigating their way through living with a condition like MS, and we hope that the series addresses key areas of concern for the MS community."

Three episodes were released weekly beginning Tuesday, 21st September 2021 and each covered an important topic relating to the life of someone living with MS and potential challenges.

#### • Episode 1: MS the journey

A diagnosis of MS can be overwhelming, and the treatment journey is different for every person with MS. In the first episode of MS Explored – The Podcast, host Aoife Kirwan is joined by Consultant Neurologist, Dr. Lisa Costello and Laura Lee who was diagnosed with MS ten years ago, to break down a diagnosis of MS, discuss what the future might look like and how to best manage the condition.

#### • Episode 2: Family life & MS

Having MS doesn't just affect the person living with it, it can hugely impact the lives of families and loved ones too. In this episode of MS Explored – The Podcast, Aoife Kirwan is joined by Sharon Henvey who is living with MS, MS Fellow Dr. Maria Gaughan, MS Nurse Specialist, Sinead Jordan and Clinical Psychologist Dr. Eddie Murphy to explore the challenges faced by people living with MS and how they can communicate their diagnosis to loved ones.

#### • Episode 3: Work and education

Living with MS can have a big impact on work-life and/or the education journey. In this episode of MS Explored – The Podcast, Aoife Kirwan is joined by Lauren McAuley and Keith Byrne who are both living with MS, and by Career Psychologist Sinead Brady to discuss the supports and resources that are available to people living with MS, as well as tips on how and when to talk to your employer about your diagnosis.

Dr Lisa Costello, Consultant Neurologist at Beaumont Hospital

Aoife Kirwan, Information, Advocacy and Research Officer, at MS Ireland, MS Explored

and MS Explored – The Podcast contributor commented, "It is great to have such a useful resource for people living with MS that we can guide them to for support on many important areas. It is not always possible for us to support across every element of life with MS as part of the treatment pathway and so we welcome resources such as this as they can provide great comfort to people at all stages of their MS journey whether they have just been diagnosed or are at a different juncture."

Listen, rate, and subscribe and find more information about MS at **MS-Society.ie**

To join the conversation, use the hashtag **#MSExplored**.

#### TREMFYA®▼ (GUSELKUMAB), APPROVED FOR REIMBURSEMENT IN IRELAND

The Janssen Pharmaceutical Companies of Johnson & Johnson have announced that TREMFYA®▼ (guselkumab), a first-in-class treatment for adult patients with active psoriatic arthritis (PsA) who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy has been granted reimbursement in Ireland.

Guselkumab is the first approved fully human monoclonal antibody that selectively binds to the p19 subunit of interleukin (IL)-23 and inhibits its interaction with the IL-23 receptor. It is already approved for the treatment of patients with moderate to severe plaque psoriasis. IL-23 is an important driver of the progression of inflammatory diseases including psoriasis and PsA, among others.

PsA is a multifaceted, chronic, immune-mediated inflammatory disease that is progressive and is characterised by debilitating joint damage and inflammation, in addition to enthesitis, dactylitis, axial disease, and the skin lesions associated with psoriasis.

The approval for this new indication was based on results from the DISCOVER-1 and DISCOVER-2 Phase 3 clinical studies, which assessed safety and efficacy of guselkumab 100 mg q4w and q8w in adult patients with active PsA. DISCOVER-1 evaluated 381 participants with active PsA who had an inadequate response to standard therapies, including participants (~30 percent) previously treated with anti-tumour necrosis factor (TNF) alpha biologics. DISCOVER-2 included 739 patients who were biologic-naïve only and had an inadequate response to standard therapies.



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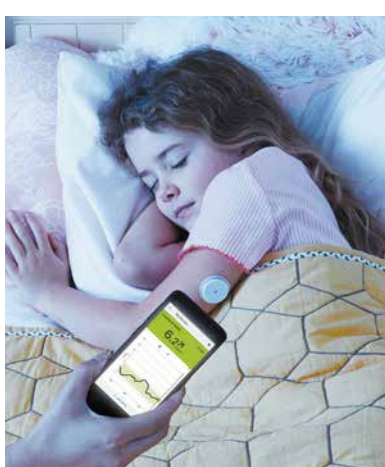
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