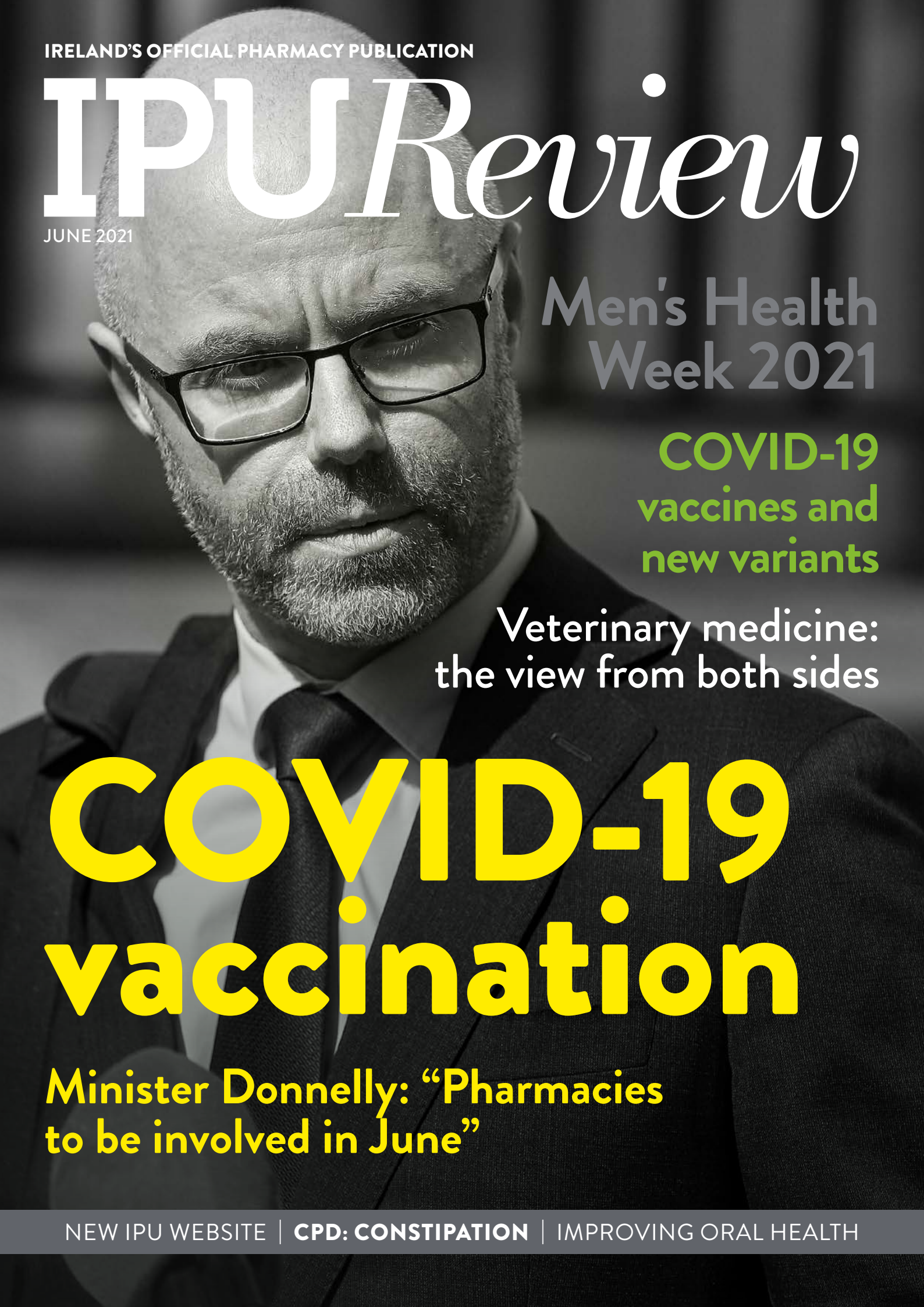
IRELAND'S OFFICIAL PHARMACY PUBLICATION

IPU Review

JUNE 2021



Men's Health Week 2021

COVID-19 vaccines and new variants

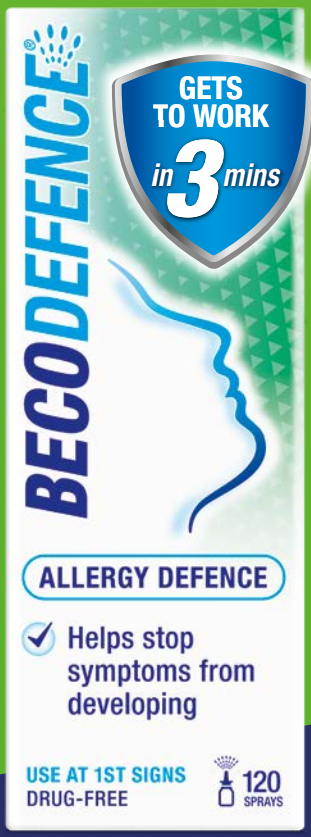
Veterinary medicine: the view from both sides

COVID-19 vaccination

Minister Donnelly: "Pharmacies to be involved in June"

NEW IPU WEBSITE | **CPD: CONSTIPATION** | IMPROVING ORAL HEALTH

RECOMMEND TOTAL HAY FEVER CONTROL



DEFENCE

RELIEF

For more detail and for any training requirements please contact your Perrigo Pharmacy Business Manager

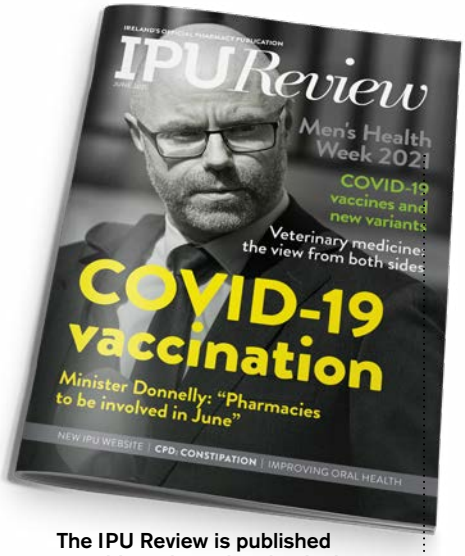
ALAN HARNETT	RUTH GRANT	CHARLIE RICKARD	ANNE MARIE O'NEILL	BRENDAN O'KEEFFE	PAUL FLYNN	OLLIE HIGGINS
Nth Leinster	Midlands	Greater Dublin	South Leinster	Cork and Kerry	Waterford/Tipperary/ Limerick/Clare	West
086-8189846	086-4679113	086-6011643	086-1749626	086-8189843	086-1427717	087-9533161

Beconase Hayfever nasal spray 50 micrograms per spray contains beclometasone dipropionate. For the prevention and relief of symptoms of Hayfever and other seasonal allergic conditions. **Adults aged 18 and over**: 2 sprays into each nostril twice a day. Max 8 applications per day (400 mcg). Seek medical advice if symptoms do not improve after 2 weeks. Do not use continuously for longer than 3 months without consulting a doctor. Do not give to persons under 18 years. Pregnant and breastfeeding mothers should not use without consulting a healthcare professional. **Caution**: Recent nasal injury or surgery. **Side effects**: Rare cases of hypersensitivity reactions. Unpleasant taste/smell, dryness/irritation of the nose and throat, raised intra-ocular pressure, nasal septal perforation. PA 1186/8/1. P. **MAH**: Chefaro Ireland Limited, The Sharp Building, Hogan Place, Dublin 2, Ireland. **SPC**: http://www.medicines.ie/medicine/7169/SPC/Beconase+Hayfever/. Date of preparation March 2021. Always read the leaflet.

Becodefence is a medical device. Contraindications: known hypersensitivity to ingredients or those with a Sesame Oil allergy. Always read the leaflet. IRE BEC 2021 02

IPU Review
JUNE 2021

CONTENTS



The IPU Review is published monthly and circulated to Irish pharmacists. The views expressed by contributors are not those of the IPU nor is responsibility accepted for claims in articles or advertisements.

Subscription:
€100 (Ireland North & South) and €150 (including postage overseas).

Publisher:
Irish Pharmacy Union
(IPU Services Ltd),
Butterfield House,
Butterfield Avenue,
Rathfarnham, Dublin 14,
D14 E126
Tel: (01) 493 6401
Fax: (01) 493 6626
Email: ipureview@ipu.ie
Website: **www.ipu.ie**

Editor: Jack Shanahan MPSI
Editorial Associates:
Daniel Rowan, Ciara Browne
and Jim Curran

Advertising: Daniel Rowan
Email: ipureview@ipu.ie
Tel: (01) 493 6401

Irish Pharmacy Union

IPU News

The latest news and events from Butterfield House

Features

13

17

It's that simple...

... for all women capable of conceiving.

Folic Acid - helps prevent Spina Bifida and other NTDs[1].
Clonfolic is the market-leading brand[2]. Take one tablet daily.

Key Facts

- Studies have shown over 70% of first time NTDs[1], such as Spina Bifida can be prevented by taking 0.4mg of folic acid daily.
- Almost 50% of pregnancies are unplanned.
- It's important to take 0.4 mg of folic acid every day for at least 14 weeks before you become pregnant and continue taking it for at least the first 12 weeks of pregnancy.

You actually need Folic Acid

Clonfolic.ie

Clonfolic is contraindicated in cases of Vitamin B_{12} deficiency. Caution is advised for patients under therapy for folate-dependent tumours when taking folic acid. Women with pre-existing diabetes, obesity, family history of neural tube defects, or previous pregnancy affected by neural tube defect have an increased risk of having a pregnancy affected by a neural tube defect and higher doses should be considered. For women taking anti-seizure medication the requirement for folic acid may be different and they should be under the supervision of a physician while taking folic acid supplements. The tablet also includes lactose monohydrate. A copy of the summary of product characteristics is available on request. Clonfolic 0.4mg tablets. PA 126/95/1. PA Holder: Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co Tipperary, Ireland. www.clonmel-health.ie
Medicinal product not subject to medical prescription. Supply through general sales.

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

CLONMEL HEALTHCARE
STADA GROUP

CONTENTS

Other News

52

40

33

50

IRISH PHARMACY UNION
The voice of community pharmacy

MedicinesComplete

Essential medicines information to support pharmacists make informed treatment choices

95% of people are in favour of pharmacists being able to prescribe some medicines for minor ailments according to a 2020 survey by the Irish Pharmacy Union (IPU).*

With some community pharmacists now trained to administer certain prescription only medicines in emergencies (e.g epinephrine)**, the need to have quick access to trusted, evidence-based information to support their decision-making has never been so important.

MedicinesComplete makes it easy for healthcare professionals to access essential medicines information at the point of care. Providing trusted evidence-based knowledge for confident decision-making and effective patient care.

Accessed at the point of need, MedicinesComplete supports your ability to:

- Find medicines information that is most relevant to the patient's needs
- Make decisions with confidence on the best treatment for patients
- Make safe and effective decisions about dosage queries
- Quickly interpret information to manage adverse drug reactions

With the support of MedicinesComplete, you can be safe in the knowledge that your pharmacy team will have increased ability to make effective decisions at the point of care.

"The IPU is delighted to add yet another benefit to what we offer our members. MedicinesComplete is a great service, and we are very pleased to be working with the Pharmaceutical Press to offer this service at a substantially discounted rate for our members".

— Darragh O'Loughlin, IPU Secretary General

Special offer for members of the IPU

MedicinesComplete are pleased to support members with a 92% reduced rate subscription to essential information through MedicinesComplete. This special offer includes easy-to-use and trusted resources:

- British National Formulary (BNF)
- BNF *for Children*
- Stockley's Drug Interactions
- Stockley's Interactions Checker
- Martindale: The Complete Drug Reference
- Martindale's ADR Checker

Prices start at €452 for one site/premises and €395.50 per site for members who own between 2 and 10 sites/premises.

For more information about this special rate subscription visit:
about.medicinescomplete.com/sector/pharmacy/Ireland

*ipu.ie/home/pharmacy-in-ireland/ ** https://www.thepsi.ie/gns/Pharmacy_Practice/pharmacy_practice_reports/Future_Pharmacy_Practice_Report

The basic truth is more important than ever in this age of alternative facts

It has often been pointed out that one of the great problems of democracy is that people can vote.

The convulsions of partisanship are representative of another global pandemic. While hackneyed phrases like 'post truth' and 'echo chambers' have largely lost the interest of the public, their legacies continue to escalate. I am of the generation that was brought up to believe that there was always a basic truth, a set of undisputable facts. There was always 'your side, my side and the truth'. Not any more. When we had the jaw-dropping 'alternative facts', from the great spinmeister, Kellyanne Conway, there was an underlying feeling that her tongue was firmly planted in her cheek. We re-learned the Abraham Lincoln maxim that "You can fool all of the people some of the time, some of the people all of the time but you can't fool all the people all the time". The evolution of the partisan playbook has been a true revolution. It has shown us that there are circumstances where normal people can become utterly polarised. While this is not news to any of us, the fallout is something that is changing our nature and our futures.

Partisanship is much more than simple opposition. It is an all-in tribalism. It is the very antithesis of democracy, as it denies that your opponent can have a legitimate view. If anyone in your tribe says or does anything, it's OK. Doesn't matter what it is, it is accepted as over enthusiasm, unfortunate or just simply, 'there must be a good reason why they did that'. Some critical faculties are turned off. Just as important, you start to depersonalise the other tribe. This is a leaf from the training manual of the military. It is hard to shoot a person, but relatively easy to take out a subject.

Why am I going over this relatively well-ploughed ground? I am of the belief that there is a risk of a similar partisanship developing in Irish community pharmacy. The last decade has seen some fundamental changes in the direction of pharmacy. At a macro level, we have seen the rapid adoption of co-operatives and branding groups in the community. We have seen an acceleration in the direct ownership of pharmacies by drug wholesalers. At one level, we see pharmacists agreeing that working together is important. The most obvious aspect of this is the Irish Pharmacy Union. The beauty of this Union is that it has one, simple, clear objective. It is to advocate for, and act on, initiatives to improve the lot of pharmacists in Ireland. It is democratic, in that positions on all committees are electable. These committees decide policy that is then implemented by an executive team, led by the Secretary General.

There is no doubt that the IPU hasn't always got everything right. But it is also clear that there are checks and balances to ensure a steady, solid service. We all benefit. Whether it is as an advocate, answering a query authoritatively, some CPD, or more serious support, the IPU is there. Obviously there are caveats. Miracles are in short supply. It isn't always possible to unconditionally support members. For instance, if a member finds themselves in a spot of bother with the authorities because of fraudulent misbehaviour, support is, by necessity, limited. Equally, the Union cannot be expected to spend its resources on what would be perceived as fool's errands. There are enough issues that have attainable objectives without squandering capital by tilting at windmills. For instance, FMD. Suddenly, when the letters started to come from the regulator, people finally realised that this is actually a legal requirement. Immediately it became 'what is the Union doing about it?'. The previous decade of opposition, progressing to amelioration of the effects of FMD are forgotten or ignored. We are stuck with an EU solution to a global problem. It may not be good, but you get used to it. There are more important issues.

One salient aspect is the right of the Union to do what it feels is right for its members, within the parameters of its rules and what is considered legal. This can mean difficult choices, which, by definition, are not going to please everyone. Those that are not pleased can get upset. They can be vocal, which, in today's internet-based social media can make quite a storm. That is their prerogative. Yet, it is important to be able to disagree without resorting to scorched earth policies. Cancel culture is a phenomenon that nobody gains from. I am a proud member of the IPU for over thirty years, as was my father before me. I trust the structure, the processes and the people, many volunteers, that give their time and energy to the profession. It would be a sad day if partisanship, bitterness, targeting and general nastiness created a structure that most people would actively avoid. As I started, I will finish. The IPU is a democratic organisation. It is our Union. It is our actions, our decisions that will determine its future.

If you have any comments, queries or issues to raise, send your "Letters to the Editor" by email to **ipureview@ipu.ie.**

Message from the Minister for Health, Stephen Donnelly TD to the members of the Irish Pharmacy Union

The past year has been a period of unprecedented difficulty for the country, and you have been at the forefront of the response to the COVID-19 crisis and have played a pivotal role in responding to the health needs of the public. You have ensured the continued availability of a professional, accessible service and have successfully managed to alleviate concerns around continuity of medicine supply in the face of great uncertainty.

I do, however, acknowledge, that there have been impacts on the business model of many community pharmacies over the course of the pandemic. I fully appreciate that you, as with many other sectors, have experienced added financial pressures during the crisis. I gratefully acknowledge that, notwithstanding this, you have played a vital role in protecting the essential medicine supply to the public.

I wish to thank community pharmacists for embracing the use of Healthmail during Covid-19. I understand that work is ongoing on introducing a full E-prescribing system and I welcome the IPU's

"I appreciate that community pharmacists are eager to be involved in the administration of the COVID-19 vaccine programme. I understand that work is ongoing within the HSE in this regard and anticipate that you will be involved in June."

involvement in advancing this important innovation further in 2021.

I am pleased that the Community Pharmacy Contingency Forum, which formed in April 2020, is still ongoing. I believe that this forum has been important in responding to clinical and operational challenges that have faced community pharmacists over the past year. It is my hope that this forum will continue to meet in the long term.

I wish to express my sincere appreciation to all community pharmacists for their participation in the recent flu vaccination campaign. I am aware that there has never been a greater demand for the adult vaccination and that the rates of uptake have been unprecedented.

I appreciate that community pharmacists are eager to be involved in the administration of the COVID-19 vaccine programme. I understand that work is ongoing within the HSE in this regard and anticipate that you will be involved in June.

As we are all aware, Brexit posed an unprecedented risk to many aspects of life in Ireland, not least to the healthcare system and the continuity of supply of medicines and medical devices. Safeguarding that supply and ensuring continuity of care and treatment to Irish patients was and continues to be of the utmost importance to this Government. As key stakeholders in the supply of medical products to Irish patients, your continued support in relaying clear and accurate information to the public has been crucial.

I also wish to emphasise the important role community pharmacists play in the wider Irish Health Service in the delivery of holistic patient care. I am committed to further developing that role in the context of health service reform. I have listened to and met with the IPU, both in Opposition and since I was appointed Minister for Health, and firmly believe that there is much merit in initiatives you are seeking progress such as a Minor Ailment Scheme.

I believe that we cannot reform our health system unless we work collaboratively, and with other healthcare providers, to make a significant difference to patient outcomes. The full potential of your profession should be maximised.

NEWS

Statement of Strategy 2021-2024

The *IPU Statement of Strategy 2021-2024* was recently published. The Statement will build on the progress of the previous Strategy and will inform our work as an organisation over the next three years. The Statement of Strategy has evolved and been updated to respond to the current legislative and economic context and to take account of the ever changing professional and business environment over the next number of years. You can read further information on the new Strategy and download a copy from the IPU website www.ipu.ie under the About tab.

Pharmacy in the Media

The Irish Times carried an article regarding the number of vaccinators in Ireland and the delays in the COVID vaccination roll out in pharmacies. This was also highlighted on Newstalk's *Down to Business with Bobby Kerr*. IPU PCC Committee member Tom Murray was interviewed for an RTE *SixOne* piece where he discussed the roll-out of the vaccination service and the role for pharmacies. This also appeared on the 9 o'clock news. Tom also gave an interview to Radio Foyle. On the same subject, IPU member, Jack Shanahan also gave an interview to Radio Kerry.

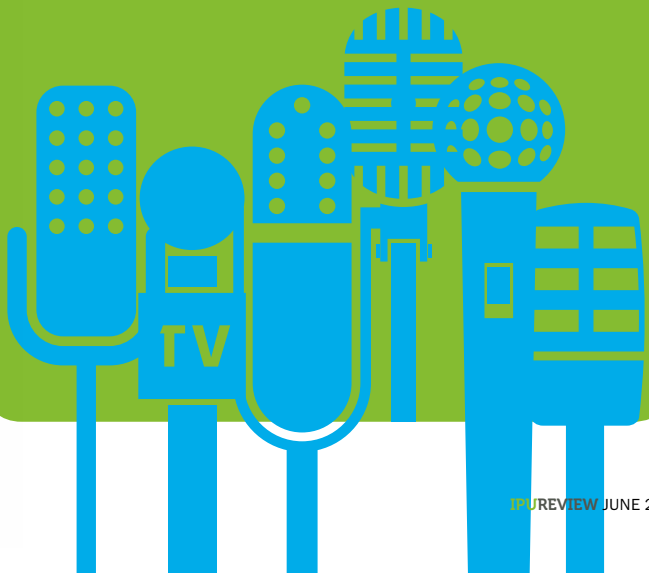
The Secretary General was interviewed on RTÉ Radio 1 *Today with Claire Byrne* advocating for the immediate roll-out of COVID-19 vaccination through local pharmacies instead of only focusing on mass vaccination centres. This interview gained extensive national coverage and was picked up on RTÉ 2FM, RTÉ.ie, *Irish Examiner*, *Irish Daily Mail* and *Irish Mirror*. Fergal Bowers also addressed this in his weekend report. IPU member Ultan Molloy was also interviewed for an *Irish Independent* article on the topic.

Past President, Daragh Connolly and the Secretary General were quoted in an article in the *Sunday Independent* discussing pharmacy services and the pharmacy contract.

IPU Employee Pharmacy Committee Chair, Rebecca Barry was interviewed on Limerick 95FM where she discussed, among other issues, the IPU's call for access to contraception to be made available directly from a pharmacy without prescription and without charge.

RTÉ.ie and RTÉ Radio 1 reported on the HSE cyber-attack and carried comments from the IPU regarding the effect the attack could have on certain patients getting their medications. The Secretary General was interviewed on Newstalk Breakfast and this was picked up on multiple regional radio stations. There was also coverage in the *Irish Examiner* and *Irish Daily Star*, as well as online media on Buzz.ie.

To stay up to date with all of our coverage, check out our Pharmacy in the Media section, which you can access under News & Publications on the IPU website.



Roll-out of COVID vaccinations in Pharmacies – why are we waiting?

Email sent from the IPU to all TDs and Senators on 7th May

I'm writing to you in relation to the continued exclusion of pharmacists from the COVID-19 National Vaccination Programme and to seek your support in enabling people to get vaccinated by their local pharmacist.

Pharmacists have vast experience as vaccinators and are ready and willing to help the Government reach its ambitious vaccination targets. There are 1,200 pharmacy locations available throughout the country with 2,000 fully trained vaccinators ready and available to vaccinate.

The reopening of Ireland's economy and society depends on the pace of the vaccine roll-out. Why leave 2,000 experienced vaccinators on the side-lines? We estimate that pharmacists have the capacity to vaccinate over 50,000 people per week.

However, pharmacists have, so far, not been allowed to vaccinate their patients against COVID-19 by the HSE. This is despite having been allocated a central role in the in the Government's National COVID-19 Vaccination Strategy and Implementation Plan last December alongside GPs and vaccination centres. No clinical or operational rationale has been given for this ongoing exclusion.

Members of the public are used to being vaccinated by their local pharmacist. Last flu season, pharmacists vaccinated over 300,000 people. Many of these people want to get their COVID-19 vaccination from their pharmacist too. We know this because our pharmacists are constantly getting calls and queries in relation to it from people in their communities.

Furthermore, for people in remote rural areas, it makes little sense for them to make long journeys to, and face long waits in, vaccination centres when they can get vaccinated in their local pharmacy.

For example, there is only one vaccination centre in Co. Galway, so, for someone from Ballyconneely, it is a 3.5-hour round trip to the vaccination centre in Ballybrit. Why make people go to such lengths when they can get vaccinated in their own communities by someone they know?

Pharmacy vaccination is easy, convenient and it's local. It is also a key, but as yet unrealised, part of the Government's COVID-19 Vaccination Strategy.

In January of this year, the Irish Pharmacy Union, along with the IMO, reached agreement with the Government on the fees to be paid for administering the vaccine. GPs have been vaccinating since February. So far, all pharmacists have gotten from the Minister and the HSE is vague assurances of a non-specific future role.

It is simply not sustainable to place the full burden of community vaccination onto over-stretched GPs who have been vaccinating since early this year, often at the expense of normal GP services.

We have seen the pivotal role that pharmacists are playing in Northern Ireland and in countries such as the United States, Canada and Germany in getting large numbers of people vaccinated.

We hope you agree that it is very much in the public interest for people here to be able to be vaccinated locally by their pharmacist.

I would greatly appreciate if you could use your platform as a public representative and Member of the Oireachtas to call on the Minister for Health, Stephen Donnelly TD to enable pharmacists to vaccinate without any further delay. We would greatly appreciate if you could lend your support to this matter in the Oireachtas, on local and national media and on social media.

I have attached some concise information in relation to this issue which may be of use to you. I would be very happy to talk to you at any stage in relation to this matter.

New IPU website

We recently launched our new website. The purpose of the new design is to make the website easy for members to navigate and to find information, therefore improving the user's experience.
Turn to *pages 13-16* for an overview of the new designs and layout.

Dates for your Diary

JUNE 2021

14 June	World Blood Donor Day, www.giveblood.ie
14-20 June	Men's Health Week, www.mhfi.org

Updated IPU logo

We have freshened up the IPU logo and colours to modernise our branding. The symbol shape remains the same, but the colours have been enhanced to make them more vibrant for digital use and printed publications. The font has also been updated and changed to title case, which is visually more pleasing while keeping the logo symmetrical.

Unveiling the new ipu.ie

We have officially launched our new website. Ipu.ie is a tool for IPU members to source up-to-date information on a wide range of issues relevant to their profession and their business. The purpose of the new design is to make the website easier for members to navigate and to find important information. In this article, Ciara Browne, the IPU's Communications and Events Executive, takes you through the new designs and layout and explains how the new ipu.ie will improve the user's experience.

Background

Earlier this year, work commenced on this project, with Refill Assistant commissioned as the website developer. Refill Assistant previously developed the website for National Health Products Catalogue (NHPC), launched by the IPU last year. They also worked with a number of IPU member pharmacies to build their individual pharmacy websites and offer a Pharmacy Services Booking Engine to their customers.

To help get the most out of the design process, we also commissioned a creative agency named Language, who we have used for IPU advertising campaigns, as our design consultants and to facilitate a series of workshops. These workshops were completed with IPU staff and IPU committee members providing useful feedback and suggestions. Through the combined input of feedback from our staff and members, and the expertise of the designers and developers, we produced the new IPU website.

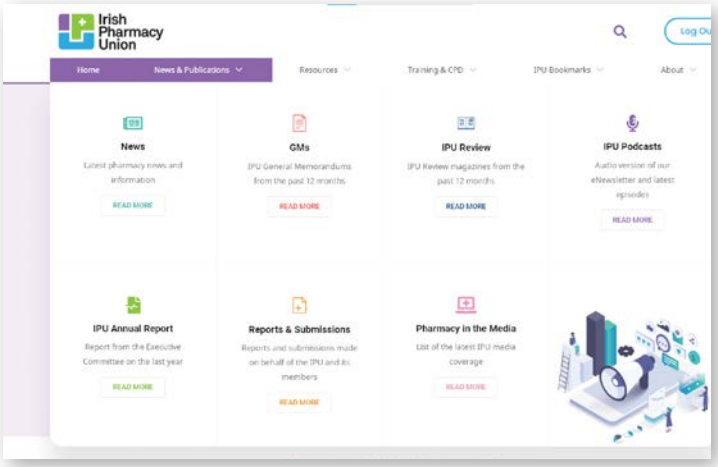
Mega menu

A significant difference between the last website and this one is the menu structure. Previously, the menu was positioned vertically to the left of the screen and you could see pages as you hovered over them with the mouse or clicked for drop-down menus on your phone.

We have now introduced a "Mega Menu" which sits at the top of the page and displays all the website sections at once, giving you a clear picture of the content within each section at a glance.

Taking the member's section as an example, the main headers in the menu are:

- ***News & Publications*** – News, GMs, the *IPU Review*, the Annual Report and Reports & Submissions all have their own homes;
- ***Resources*** – Most content is in this part of the mega menu and laid out as individual sections, such as Professional, HSE Contract etc, with their sub-sections clearly placed underneath. We have made these changes to the menu in order to group content together more efficiently. Employee Pharmacists, Recruitment, Human Resources and Lobbying are now housed in their own sections;
- ***Training & CPD*** – IPU Training courses and access to IPU Academy;
- ***IPU Bookmarks*** – Easy access to IPUnet, IPU Pharmacist Link, the IPU Product File download site and more; and
- ***About*** – Information about IPU staff, IPU committees, the Statement of Strategy and member benefits.



Search function

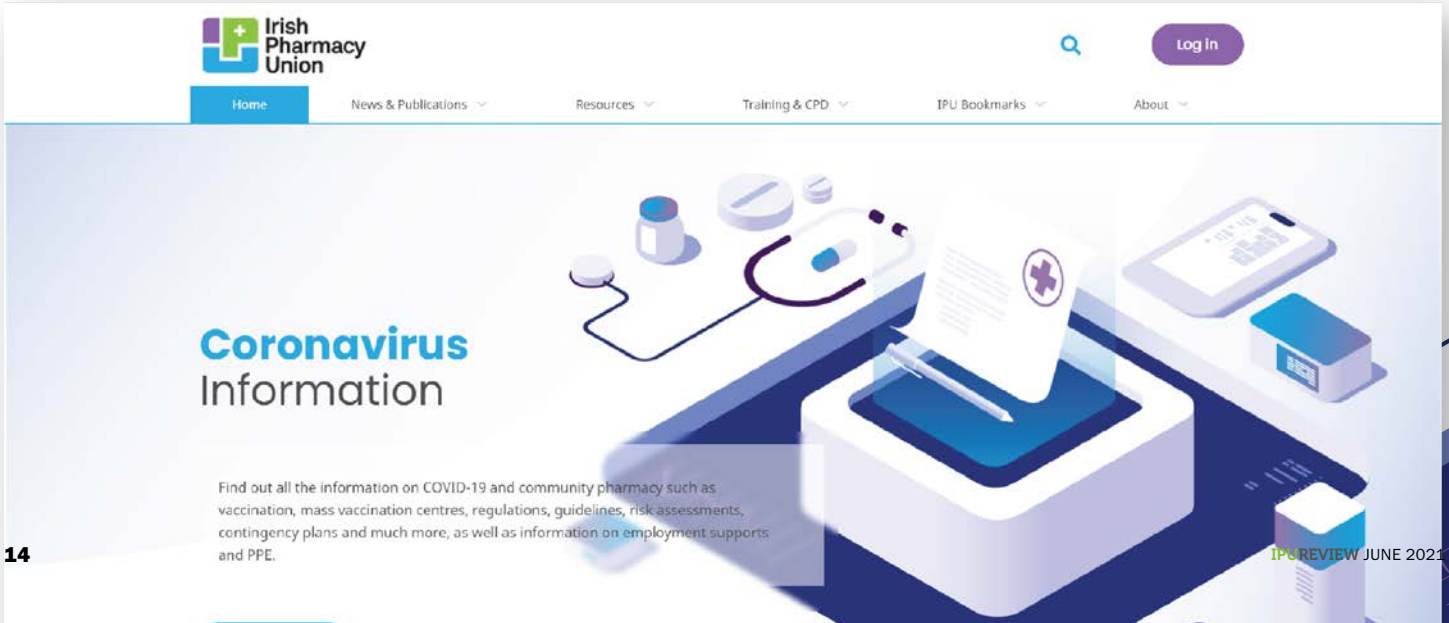
The Search function appears on all pages of the website in the top right-hand corner. It has been designed to work similar to a Google search; if your search consists of just one word, type that word into the bar and click the button, but if you are searching a phrase, such as "medicines authentication" or "high tech hub", then you need to include the double quotation marks for accuracy. The Search function reads all of the text in documents, posts and titles, as well as tags given to items by the IPU website administrators. The results that come back are displayed in a list, similar to Google, and are displayed in chronological order so that you see the newest item first. The results will also be a mix of posts and documents but it will be easy to differentiate the two.

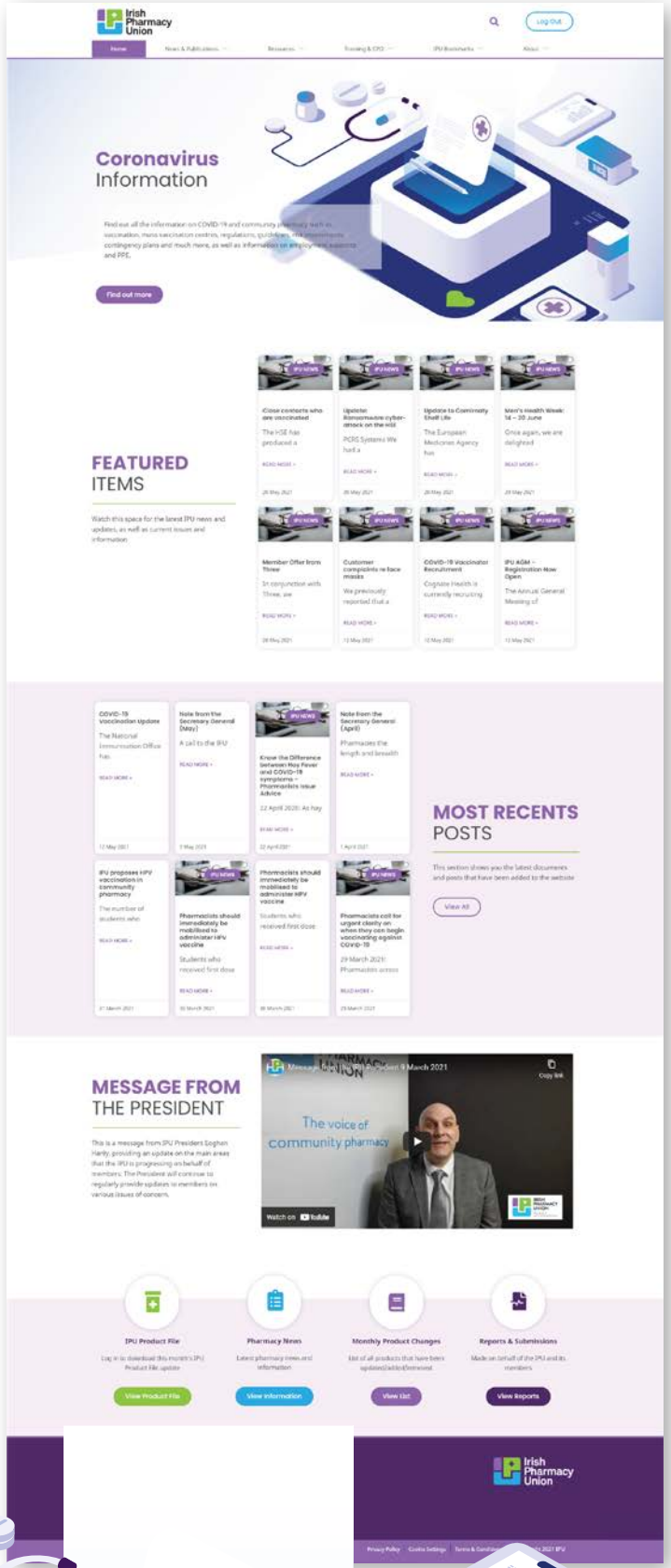
Improving the Search function was a key priority in this development. If users are still finding issues with this function, we want to know so that we can continue improving it. Please send any suggestions or feedback to communications@ipu.ie.

Homepages

The homepage of the website is the user's landing page and should display content that you want to find as quickly as possible. To help distinguish between the public and member's homepages, we made the public site blue and the member's site purple. Below is an overview of the two homepages and their content.

Public:
From our workshops, we identified that the purpose of the public-facing website is to be resourceful and informative. We want to display information on current health issues that impact Irish patients and community pharmacies. For example, the top of this page currently highlights access





to our Coronavirus section but over time we will use this area to highlight other topics of concern, as well as IPU campaigns and initiatives.

We have introduced an eye catching *"Pharmacy Can Help With"* section, which emphasises the varied services provided by community pharmacy.

Our *Latest News* section will pinpoint the latest in pharmacy news such as press releases, campaigns and items of interest to the public. The homepage also has an area for the *IPU Review*, displaying the latest editions and information on advertising.

Also on this page is a *Who We Are* section, and a *Quick Access* area to sections we want to highlight to the public, such as the NHPC website, training courses and how to become a member.

Members:

As with the public homepage, the top of this page highlight issues of current importance. For example, it is currently focused on the Coronavirus.

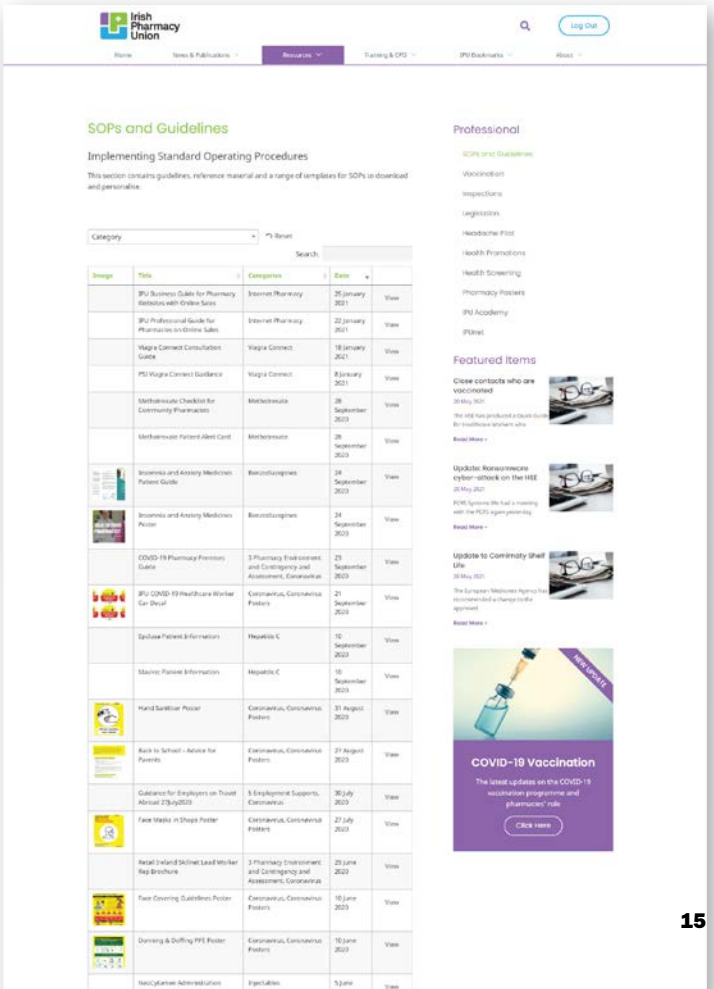
Our *Featured Items* section will display IPU news from the previous week, such as items from the eNewsletter, press releases issued and updates sent by email to members. The *Most Recent Posts* section works automatically and is populated when a document or post is added to the site. It is a snapshot look at the latest content that has been uploaded so if we have produced a new guide, FAQ or SOP, it will appear here for a period of time.

The homepage also allows for videos to be uploaded, which we will use to present IPU campaigns, media appearances and recorded messages.

Also on this page, similar to the public homepage, is a *Quick Access* area to sections of the website that are important to members, as per our workshops.

Pages with tables

We have introduced tables that list all of the relevant content for that section which we feel is a big improvement on the previous site. Items in this list will be a mix of downloadable items and posts, and they will be listed in chronological order so that you always see the newest item at the top.



Some pages contain large amounts of content, in particular, the SOPs and Guidelines page, which you will find under "Resources > Professional" in the mega menu. When you first access the page the list on the screen will display all items associated with this section. Similar to the previous website, use the drop-down menu above the table on the left, labelled *Categories*, to select the particular subject you are looking for the SOPs and guidelines for. Alternatively you can use the search box above the table on the right to start searching for the item you need. For the search box on these tables, the search will start as you type. Click *View* on the item you want and you will be taken to a page to either download the document or to read the information if it is a post.

Posts

Posts are pages that just have page content and an associated document to download if applicable. Many people access websites these days on their phones or tablets, and downloading files is not always a suitable option if you are conscious of your device's memory storage. Our aim is to upload content as posts where possible so that you can read the information on your device and download it as a file if you choose. On each post will be a PDF icon which will covert the post into a customised PDF file that you can then download. Also on posts will be a printer icon should you wish to print the page.

Book a training course

For information on our training courses, click on the Training & CPD tab in the mega menu and click Training Courses; this will bring you to a list of all courses which you can click on to view all the details.

Booking the courses works differently to the last website. On the previous website, you were only able to book one student at a time per course meaning you had to keep inputting the same information (if it was the same student on multiple courses) and make multiple transactions.

On the new website, it works more like a shop:

1. You can add courses to a shopping cart by hovering over the course you want and clicking *Add to Cart*. You will be able to increase the quantity at the *Checkout* point. You can continue adding other courses to the cart, or when you are done, click *View Cart* on the last course you added.

2. From here, you can increase the quantity but make sure to click ***Update Cart*** if you do so.

3. Click *Proceed to Checkout* and enter your billing details and pharmacist details.

4. You can then scroll down to enter the student details. For example, if you are intending on booking one student on one course and then two students on to a different course, you will see three student fields appear in the *Checkout*, since you are booking three slots. Any course you clicked *Add to Cart* on will appear in the drop-down menu labelled *Student Course* so you can easily select the course and enter the details of the student enrolling on that course. You would then repeat the same for the next two student fields.

5. After entering all the relevant information, enter your card details and click *Place Order* to pay for all of the bookings in one go.

Important: If you are logged in to the website, you will automatically be charged the member's fee for the course; however, if you are viewing the course from the public site, then you will be charged the non-member price unless you check the box to say you are a member.

Sidebar

On each page there is a sidebar that displays *Quick Access* links to other pages, Featured Items from the homepage to display some items from the news of the week, and a highlighted item, in this case COVID-19 vaccination. The sidebar is just another feature applied to improve access to key information and areas on the website.

We encourage all members to browse the new website and search for items in order to get used to the new look and feel. Our website is maintained every day and over time new menu items and pages will appear to keep the content updated and organised. Our eNewsletter will still be used to direct members to relevant documents or sections on the website. If you have any questions or feedback in relation to the IPU website, please email us on communications@ipu.ie.

PROFESSIONAL Pamela Logan, Director of Pharmacy Services, IPU

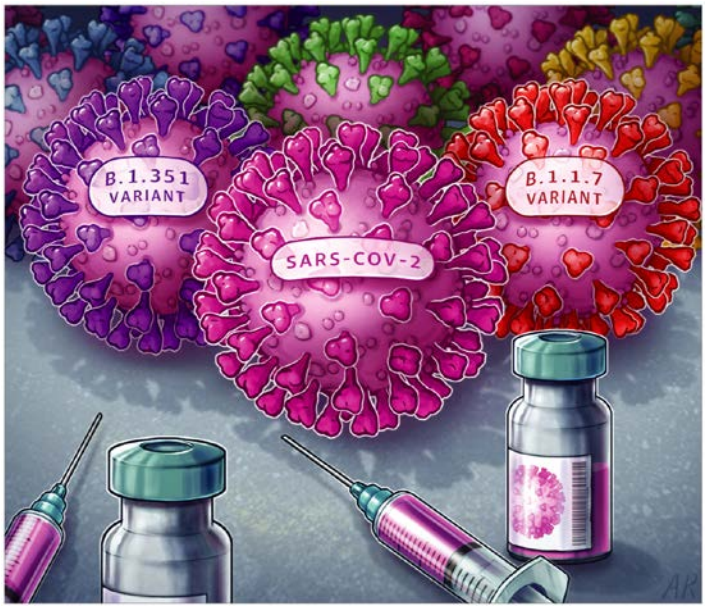
COVID-19 Vaccines: will they work against new variants?

There's been much talk in the media about new variants of coronavirus and whether the COVID-19 vaccines will work against them. The good news is that studies to date show that they will. In this article, Pamela Logan, Director of Pharmacy Services at the IPU, gives an overview of the new Variants of Concern and how the current vaccines perform.

Viruses constantly change through mutation, and variations in the SARS-CoV-2 virus due to evolution and adaptation processes have been observed worldwide. While most emerging mutations will not have a significant impact on the spread of the virus, some mutations or combinations of mutations may provide the virus with a selective advantage, such as increased transmissibility or the ability to evade the host immune response. The increased transmissibility of SARS-CoV-2 variants first identified in the UK/Kent (B.1.1.7), South Africa (B.1.351) and Brazil (P.1) have led to them being designated as Variants of Concern (VOC).

The latest variants to cause concern globally are a range of B.1.617 variants. First reported in India in December 2020, the variants B.1.617.1, B.1.617.2 and B.1.617.3 have been increasingly detected in other countries. Over the past few months, India and some surrounding countries have seen a sharp increase in the number of reported COVID-19 cases and deaths. This has been associated with a rising proportion of sequenced viruses belonging to lineages B.1.617.1 and B.1.617.2. The World Health Organisation (WHO) has designated B.1.617 as the fourth Variant of Concern.

The UK has seen a rapid increase in detection of lineage B.1.617.1 and, to a greater extent, B.1.617.2, associated with travel to India and onward community transmission. In the EU/EEA, there are indications that



the frequency of detection of both lineages B.1.617.1 and B.1.617.2 is increasing. Currently described lineages B.1.617.1, B.1.617.2 and B.1.617.3 have distinct mutation profiles and warrant individual assessment. Given the still very limited available data with respect to their transmissibility, disease severity and immune escape potential relative to other co-circulating SARS-CoV-2 variants in the EU/EEA, the full impact of these lineages on public health is not yet possible to assess.

In Ireland, latest data indicates that B.1.1.7 (UK/Kent) accounts for over 90% of cases sequenced. It has been seen in all age groups and in all areas of the country. The aim of the Irish public health response is to delay importation and spread of VOC. This is achieved by a combination of testing before arrival in Ireland, and quarantine and testing of incoming travellers from states where there is a risk of importation of VOC, due either to high levels of the virus in the community and/or known circulation of VOC.

An analysis of VOC from seven EU/EEA countries, including Ireland, published on eurosurveillance.org on 22 April 2021, showed an increased risk for hospitalisations and ICU admissions associated with B.1.1.7, B.1.351 and P1. The increased risk was also observed in middle-aged individuals, which underlines the necessity to rapidly reach high levels of vaccine coverage.

COVID-19 vaccines are indisputably effective. Although they don't prevent infection, they protect most people against severe illness and death.

Scientists believe existing vaccines will help control the variants when it comes to preventing severe disease. Vaccines produce antibodies against many regions in the spike protein, so it is unlikely that a single change would make the current COVID-19 vaccines less effective. If someone received a COVID-19 vaccine for an older generation of the virus, they would likely have protection against new ones.

Data from a number of studies indicate that fully vaccinated patients are able to stave off severe disease from the B.1.1.7, B.1.351, and P.1 variants.

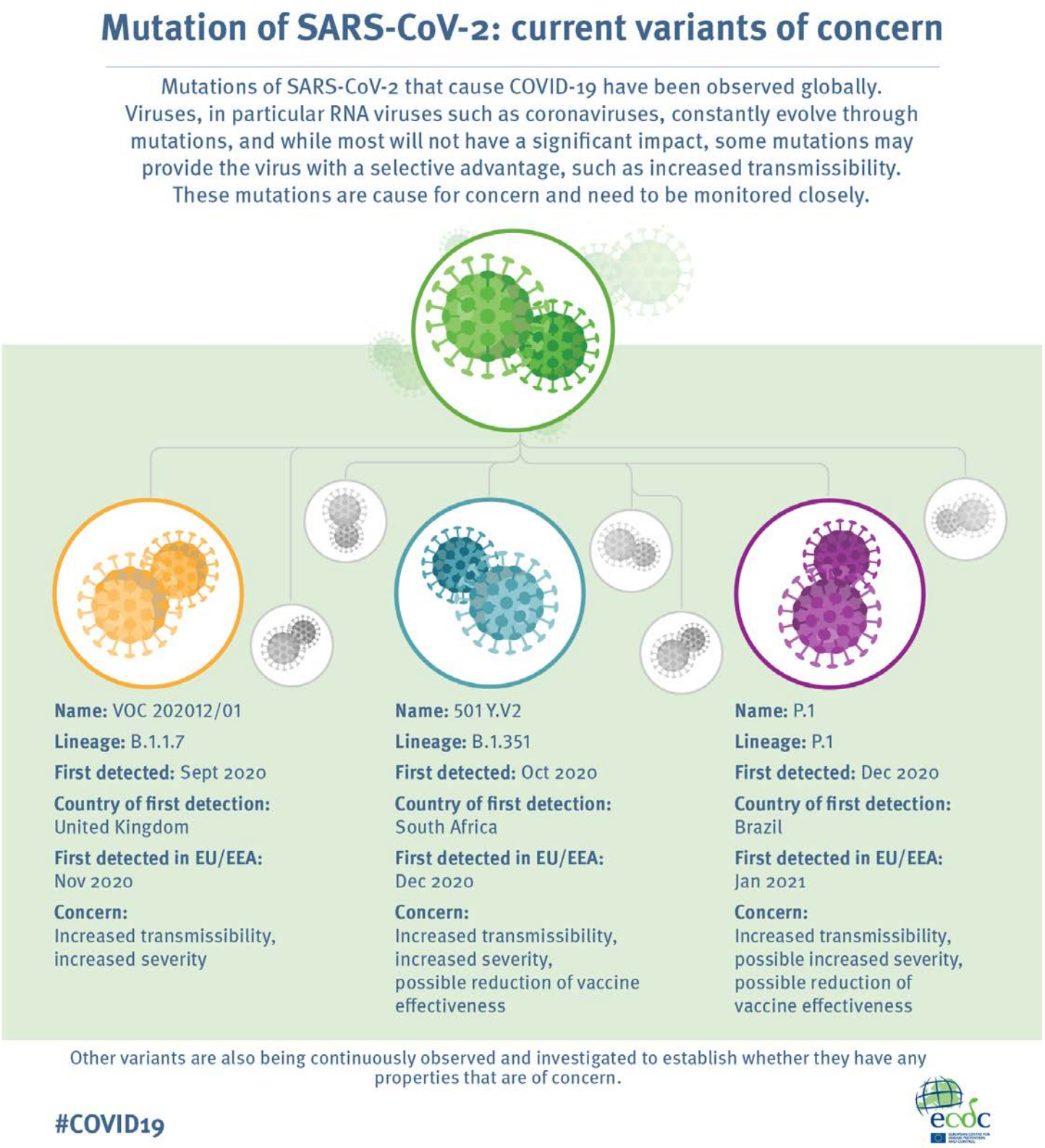
- A study published in the New England Journal of Medicine showed that the Pfizer/BioNTech vaccine was effective against infection and disease in the population of Qatar, despite the B.1.1.7 and B.1.351 variants being predominant within the country.
- A study published in the Lancet showed that, in Israel, the Pfizer/BioNTech vaccine was effective against B.1.1.7. Vaccine effectiveness against B.1.351, however, could not be estimated in the study because of the small number of B.1.351 infections identified in Israel during the study period.
- Moderna released a statement indicating that early results from an ongoing study of a booster shot are encouraging with regard to the B.1.351 and P.1 variants.

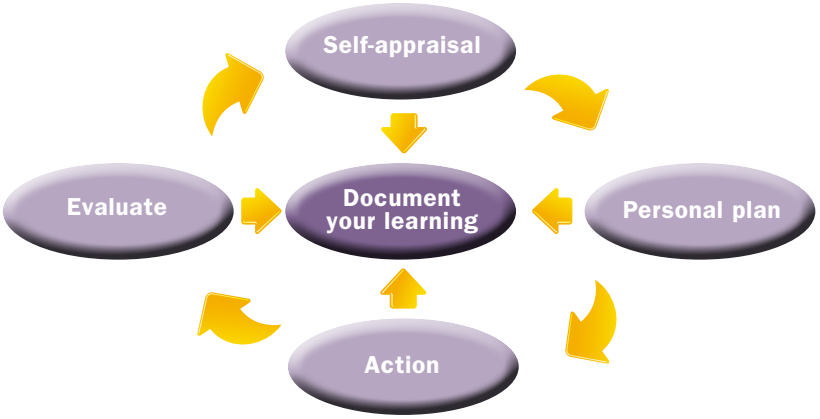
"Vaccines produce antibodies against many regions in the spike protein, so it is unlikely that a single change would make the current COVID-19 vaccines less effective."

■ A study published in *The Lancet* showed that efficacy of the AstraZeneca vaccine against the B.1.1.7 variant was similar to the efficacy of the vaccine against other lineages. Furthermore, vaccination with AstraZeneca vaccine resulted in a reduction in the duration of shedding and viral load.

Luckily, the modern technologies for vaccine production, especially for mRNA and viral vector vaccines, can facilitate rapid development and manufacture of second generation COVID-19 vaccines against new variants or mixtures of variants. This is already underway, with new vaccines expected to be manufactured and tested within a few months. Booster vaccines are being prepared for new variants that have emerged and some companies are looking for a vaccine that will work against any variant.

The European Commission has announced that it's in talks to buy another 1.8 billion vaccine doses from Pfizer/BioNTech for distribution between 2021-23. The additional doses are expected to help in the event that we need booster shots or retooled vaccines to fight coronavirus variants.





Constipation

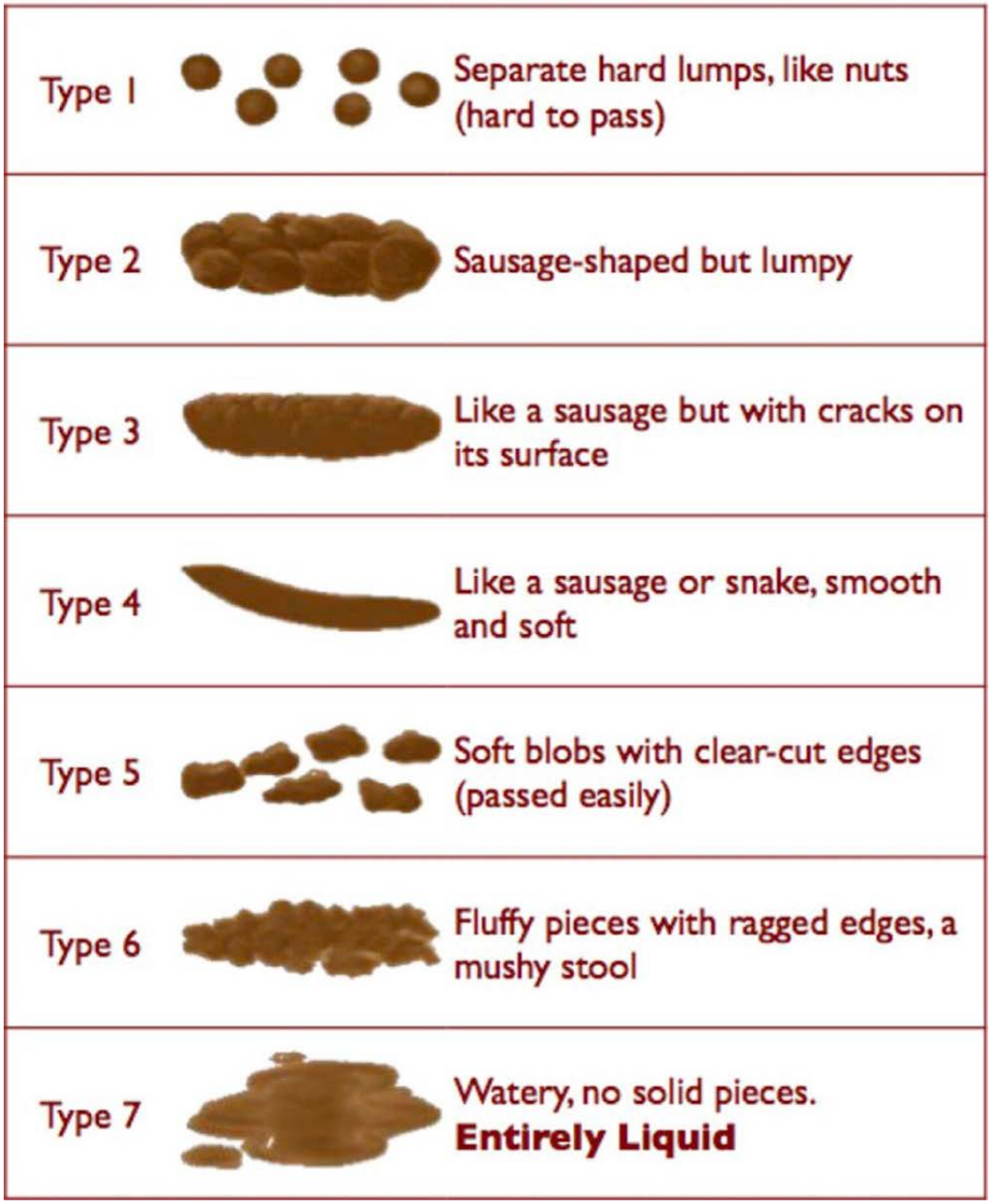
Constipation affects many of us and can greatly impact on quality of life. Community pharmacist, Grainne Doyle looks at the symptoms, causes and treatment for constipation and outlines how simple lifestyle changes can help to prevent and alleviate it.

Constipation describes the infrequency and difficulty when emptying the bowels. It can affect people of all ages, although it is twice as likely to affect women, particularly those who are pregnant due to hormonal fluctuations. Approximately 40% of pregnant women experience constipation during their pregnancy. Older people, particularly those aged over 70 years, are five times more likely than younger adults to have constipation, usually because of several factors, including a more sedentary lifestyle, level of fluid intake, diet and delaying the urge to defecate because of mobility issues. Chronic constipation with faecal incontinence in children is commonly seen by GPs. It affects 4% of preschool children and 2% of school children.

Symptoms

Typical symptoms of constipation include abdominal pain, cramping, bloating, nausea, loss of appetite and straining during bowel movements. In children, as well as infrequent or irregular bowel movements, a child with constipation may also have the following signs and symptoms, such as lack of energy, being irritable, foul-smelling wind, soiling clothes and generally feeling unwell. Stools associated with constipation tend to be dry,

Figure 1: **The Bristol Stool Chart**



hard and lumpy and indicated as type 1 or 2 on the Bristol stool chart *(see Figure 1)*. The pain and discomfort from chronic constipation and the associated complications can greatly impact a person's quality of life.

Causes

Chronic constipation can be classified as functional (or idiopathic) or secondary constipation. Functional constipation occurs without an anatomical or physiological cause. A person with functional constipation may be healthy, yet has difficulty defecating leading to a belief that it may be neurological, psychological or psychosomatic. It is diagnosed by the exclusion of a pharmacological or medical cause. Secondary constipation is generally caused by a drug or medical condition.

Medical conditions

Conditions known to cause constipation include disorders that alter the functionality of the GI tract, such as Crohn's disease and ulcerative colitis. Conditions such as Parkinson's disease and multiple sclerosis can also have direct effects on the nerves that control bowel function resulting in uncoordinated contraction of abdominal muscles and inhibiting the passage of stools. Secondary constipation can occur in patients with diabetes and hypothyroidism due to weight gain and reduced mobility associated with such conditions.

Medications

1. ***Antihypertensives (diuretics, clonidine, calcium channel blockers)***
   If clinically appropriate, switch to less constipating medicines such as ACE inhibitors, beta-blockers or angiotensin-II receptor antagonists. Diuretics can cause constipation due to less available fluid. Laxatives, such as docusate, can act as a surfactant and softener or osmotic laxatives can be used to increase the amount of water in the large bowel.

2. ***Tricyclic antidepressants (eg amitriptyline)***
   Serotonin and noradrenaline re-uptake inhibitors are alternatives less associated with constipation.

3. ***Antimuscarinics (procyclidine, oxybutynin)***
   These agents decrease GI motility and therefore a stimulant laxative may be necessary.

4. ***Antiparkinsonian medicines (levodopa, dopamine agonists, amantadine)***

5. ***Iron supplements***
   Intravenous iron could be used or a laxative may be co-prescribed.

6. ***Aluminium-containing agents (sucralfate and antacids)***
   Proton pump inhibitors could be used instead.

7. ***Analgesics (Opioids and NSAIDs)***
   Opioids cause constipation by decreasing peristalsis and enhancing the resorption of fluids and electrolytes. A stimulant laxative, eg senna, is recommended at the lowest effective dose. Osmotic laxatives are also effective for this type of constipation and are often better tolerated than stimulant laxatives which can cause abdominal cramping.

Other causes of constipation

Pregnancy: Constipation is mostly experienced during the early stages of pregnancy as a result of hormonal changes. During pregnancy, more progesterone which acts as a muscle relaxant is produced. As food moves through the gut, the gut wall muscles contract and relax in a rippling wave-like motion. The increased progesterone interferes with the contraction of the bowel muscles making it harder for waste products to move along.

In young children: About one in three parents report constipation at some time in their child's life. Poor diet, fear about using the toilet and poor toilet training can all be responsible.

Diagnosis

Doctors define constipation in a number of ways:

- Opening the bowels less than three times a week;
- Needing to strain to open bowels on more than a quarter of occasions; or
- Passing a hard or pellet-like stool on more than a quarter of occasions.

When assessing a patient for constipation, possible causes, such as medication and comorbidities along with diet, level of exercise and recent changes in routines, are taken into consideration. A physical or internal rectal examination may sometimes be performed to confirm that faecal masses are palpable abdominally or perianally. Patients with any red flag symptoms (unexplained weight loss, rectal bleeding, family history of colon cancer or inflammatory bowel disease or signs of obstruction) should be referred to a specialist for further investigation.

The Rome III diagnostic criteria *(Figure 2)* can be used to classify functional gastrointestinal disorders and may be useful when functional constipation is suspected and contributing medicines or medical conditions have been excluded.

Figure 2: **Rome III diagnostic criteria of functional constipation**

1. Two or more of the following:
   - **Fewer than 3 defecations per week**
   - Hard stools, straining
   - Sensation of anorectal obstruction
   - Sensation of incomplete evacuations
   - Manual manoeuvres to defecate

   During at least 25% of defecations
2. Loose stools are rarely present without laxatives
3. Insufficient criteria for IBS*

Criteria fulfilled for the last three months with onset at least six months prior diagnosis.
*IBS: Irritable Bowel Syndrome

Lifestyle advice can help to prevent and alleviate constipation. In many cases, constipation may be as a result of poor diet and lack of exercise. Patients should be encouraged to increase fibre in their diet and fluid intake before trying laxatives.

- Fibre increases the bulk and plasticity of stools which encourages movement through the colon. It is advised to consume at least 18 to 30g of fibre (fruit, veg, pasta, rice) each day. Also adding some bulking agents such as wheat bran to your diet will contribute to softer stools and allow to pass through the bowel easier.
- Increase fluid intake: It is recommended for adults to drink at least two litres of water each day. Children aged 1 to 3 years should drink 900mls per day, aged 4 to 8 years should drink 1,200mls per day, and aged 9 to 13 years should drink 1,800mls per day for boys and 1,600mls per day for girls.
- Exercise – Daily walk/run: There is little evidence that exercise can increase gut motility, however, one study found that women who report physical activity of once a week or more were significantly less likely to report constipation. Individuals who lead sedentary lives are more likely to get constipated.
- Toilet routines: As a rule, it is best to try going to the toilet first thing in the morning or about 30 minutes after a meal. This is because the movement (propulsion) of stools in the lower bowel is greatest in the mornings and after meals. 'Bowel training' with kids can be useful. Ask your child to sit on the toilet four times a day after meals for five minutes, even if nothing happens. Maintaining a good toilet position using a footstool will also aid the passage of stools *(Figure 3)*.

Figure 3: **Toilet position**

Pharmacological treatment may be required if lifestyle changes do not fully alleviate symptoms of constipation. The NICE guidelines advises that prescribing of laxatives for adults are limited to the short-term treatment of constipation when dietary and lifestyle measures proved unsuccessful or if there is an immediate clinical need.

Laxatives

- Bulk-forming laxatives (eg ispaghula husk, methylcellulose, sterculia): They increase faecal mass through water binding which stimulates peristalsis. This class of laxative usually takes two to three days to be effective. Plenty of fluids must be consumed with this type of laxative and are not advised to take before bedtime.
- Osmotic laxatives (eg macrogols, lactulose): If stools remain hard after taking a bulk-forming laxative, osmotic laxatives may be advised instead. They work by drawing fluid into the large bowel from elsewhere in the body or retaining the fluid consumed with the medicine. It is advised to drink plenty of fluids when taking this laxative to prevent dehydration. As like bulk-forming laxatives, they take two to three days to become effective.
- Stimulant laxatives (eg senna, bisacodyl): They are used generally on a short-term basis. They improve intestinal motility via muscle contractions and reduce water loss from the faeces keeping the stool soft. They usually start to work within 6 to 12 hours. A potential unpleasant side-effect of stimulant laxatives is abdominal cramping due to the increased muscle contractions in the gut wall.
- Faecal softeners (eg docusate): They act by lowering the surface tension of the stool allowing water to penetrate the dry faeces and increase faecal mass size stimulating peristalsis.

Faecal compaction occurs when hard dry stools collect in the rectum causing an obstruction. Faecal compaction may initially be treated with a high dose of osmotic laxative macrogol followed by a stimulant laxative days later. If this combination is not successful, a suppository (eg bisacodyl or glycerol) or mini enema (e.g. docusate or sodium citrate) may be administered.

Complications of chronic constipation

1. Haemorrhoids: Excessive straining to pass stools can lead to developing haemorrhoids.
2. Severe faecal impaction can lead to several other complications such as swelling of the rectum, loss of sensation in and around the anus, faecal incontinence and anal bleeding.
3. Rectal prolapse is a protrusion of the lower intestine through the anus due to repeated straining during bowel movement.
4. Anal fissures: The forced passage of hard stools causes small tears through the lining of the anal canal.
5. Psychological effects: Faecal incontinence in children can affect children psychologically making them feel embarrassed and upset. It is important that parents and their support network are compassionate and understanding when dealing with this condition in children.

References available upon request.

Your 5-minute assessment

Answer the following questions:

1. True or false: approximately 25% of pregnant women experience constipation during their pregnancy.
2. True or false: chronic constipation can be classified as functional or secondary constipation.
3. Which ONE of the following medicines is not known to cause constipation?
   a) Calcium channel blockers b) ACE Inhibitors
   c) Amitriptyline d) Oxybutynin
4. Which ONE of the following medical conditions does not affect the functionality of the gut?
   a) Parkinson's Disease b) Multiple Sclerosis
   c) Asthma d) Hypothyroidism
5. True or false: Docusate acts by lowering the surface tension of the stool allowing water to penetrate the dry faeces and increase faecal mass size stimulating peristalsis.

Answers
1. False. **2.** True. **3.** (b). **4.** (c). **5.** True.

"The NICE guidelines advises that prescribing of laxatives for adults are limited to the short-term treatment of constipation when dietary and lifestyle measures proved unsuccessful or if there is an immediate clinical need."

CPD overview

Self-appraisal

- [ ] What do you know about constipation?
- [ ] What causes constipation?
- [ ] What are the symptoms of constipation?
- [ ] Do I see many cases presenting in pharmacy?
- [ ] What is the best advice to give patients with these symptoms?

Personal plan

Including a list of desired learning outcomes in a personal learning plan is a helpful self-analytical tool.

- [ ] Create a list of desired learning outcomes.
- [ ] How will I accomplish these learning outcomes?
- [ ] Identify resources available to achieve learning outcomes.
- [ ] Develop a realistic timeframe for the plan.

Action

Activities chosen should be outcomes based to meet learning objectives.

- [ ] Implement plan.
- [ ] Read this article on constipation.
- [ ] Consider the treatment options you are currently recommending and examine if you might be able to offer more effective advice.
- [ ] Review the OTC products you are currently recommending.
- [ ] Consider identifying and reviewing patients with constipation.

Evaluate

Consider outcomes of learning and impact of learning.

- [ ] Have I met my desired learning outcomes?
- [ ] Do I now feel confident to engage with and counsel patients (and carers) about constipation?
- [ ] Provide an example(s) of changes that I have implemented in my pharmacy practice.
- [ ] Have further learning needs been identified?

Document your learning

- [ ] Create a record in my ePortfolio.
- [ ] As part of this record, complete an evaluation, noting whether learning outcomes were achieved and identifying any future learning needs.

Men's Health. Are you making the connections? Check in. Check up. Check it out.

Ahead of Men's Health Week, which takes place from 14 – 21 June, Colin Fowler of Men's Health Forum in Ireland highlights some of the most important men's health issues and the role that pharmacies can play in addressing them.

Why focus on men?

Not too long ago, we were unaware of the full extent of men's poor health status and the specific health issues that they are contending with. However, this is no longer the case. In recent years, a broad range of research has highlighted the challenges which face males in Ireland and further afield. Indeed, the key hard facts were crystallised in the *Men's Health in Numbers* publications which were launched in December 2020.

But what does this situation look like on-the-ground?

- Local men continue to die, on average, younger than women do;
- Poor lifestyles (including smoking, drinking, diet and lack of exercise) are responsible for a high proportion of chronic diseases;
- Males have higher death rates than women for almost all of the leading causes of death, and at all ages;
- Men's mental health needs are often not recognised or met; and
- Late presentation to health services leads to a large number of problems becoming untreatable

Yet, although the health of men in Ireland is poor, it is not a lost cause and it can be improved in many significant ways. More importantly, local pharmacies can play a crucial gatekeeper role in supporting changes for the better.

Men's Health Week 2021

Men's Health Week (MHW) 2021 begins on the Monday before Father's Day and ends on Father's Day itself. This year, it will take place from Monday 14 June - Sunday 20 June. It is celebrated in many European countries, as well as in the USA, Australia, New Zealand, Canada and a number of other places worldwide, and offers an ideal opportunity for everyone to do their bit to improve the health of men and boys.

The core aims of MHW each year are to:

- Heighten awareness of preventable health problems for males of all ages;
- Support men and boys to engage in healthier lifestyle choices/ activities; and
- Encourage the early detection and treatment of health difficulties in males.

Exceptional times

In any *normal* year, men's health requires attention. However, 2021 has, once again, been an exceptional year in many ways, and the island of Ireland continues to wrestle with the global COVID-19 pandemic. Worldwide, this virus is having a major and disproportionate impact upon men's health and wellbeing, as well as other aspects of their lives (see: www.mhfi.org/coronavirus.html). Even with the hope of vaccination, these are still extremely challenging times.

MHW 2021 will take place against a backdrop of the COVID-19 pandemic. Individuals across the country are trying to re-build their lives, relationships, jobs, finances, physical health, emotional resilience, networks and routines. Some people are still living with trauma and bereavement. Others are having to re-focus their priorities. Everyone's mental health has been impacted to some degree.

This is why the theme chosen for MHW 2021 in Ireland is *Making the Connections* and the call to action is:

- ***Check In*** with yourself to see how you are coping/ feeling, and to identify any health worries that you might have;
- ***Check Up*** on your family, friends, neighbours and colleagues to see how they're doing and to offer support; and
- If you notice anything worrying or which needs medical attention, ***Check It Out*** and seek information, help, support or treatment as soon as possible.

So, where do pharmacies fit in?

One of the major consequences of the COVID-19 pandemic has been the increasing disconnection between health services and local people. However, even before the current situation, it was well known that some men are not, necessarily, good at going to their GP to have their health issues dealt with. At the same time, there is also important evidence which shows that pharmacies can play a critical gatekeeper role in being the first point of contact for promoting and improving the health of men and boys. For example, findings from research (www.mhfi.org/menandpharmacies.pdf) highlight that:

- Although many men are reluctant to visit their GP to seek advice or treatment, pharmacies can act as a first point of contact between these men and the medical world, especially as pharmacies also sell non-medical products which men need;
- Pharmacies have characteristics that men look for in a service, such as accessibility, flexibility and informality;

- Pharmacies are local, and offer a non-threatening environment to men;
- Pharmacies offer ease of access, with no appointments necessary;
- Staff offer a friendly, relaxed, approachable service, and don't rush men in and out;
- Pharmacists are recognised as experts on medication

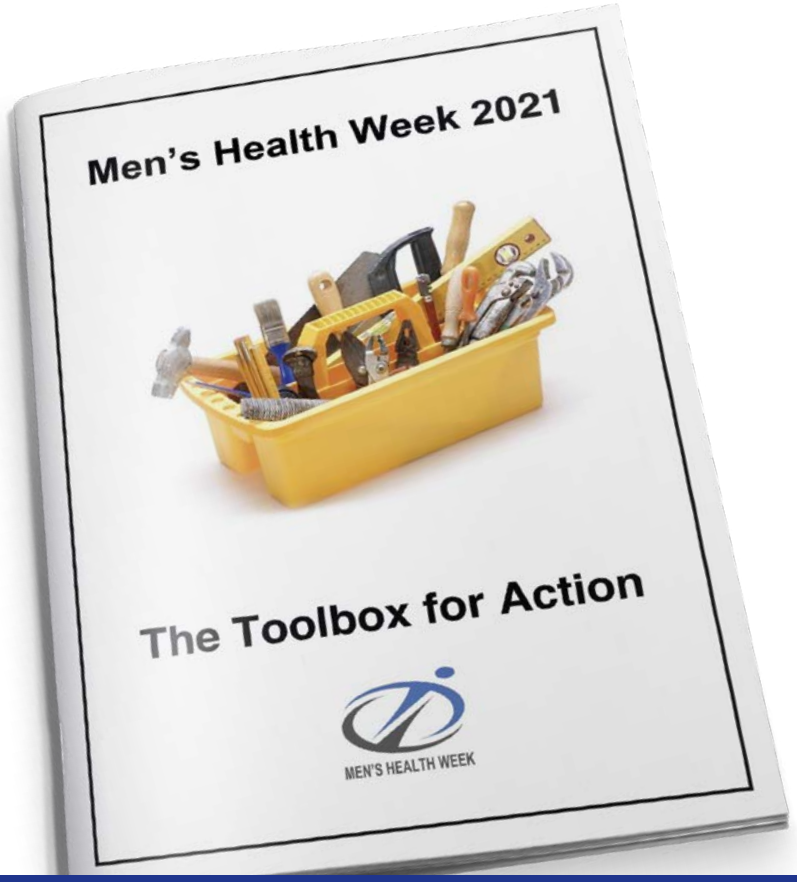
Pharmacies can, therefore, offer an on-street showcase for information which may increase awareness of the health issues facing men and boys. However, pharmacy staff are also well positioned to talk to men about their health needs, explore possible options and, if necessary, suggest that they may need to seek further expert assistance. As such, they play a crucial sign-poster role which has often been under-valued. But this is not one-way traffic; building relationships with men and getting them to use local pharmacies more regularly is also a sound business strategy!

Get involved

Every pharmacy in Ireland can do something to mark MHW 2021. It can be as simple or as complex as you would like it to be. If you're stuck for ideas, download the *Toolbox for Action* and explore the resources for the week from www.mhfi.org > MHW > MHW 2021.

Doing even one of the simple suggestions will contribute hugely to improving the health of local men and boys.

To find out more, email Colin Fowler from Men's Health Forum in Ireland at colin@mhfi.org.



"At the same time, there is also important evidence which shows that pharmacies can play a critical gatekeeper role in being the first point of contact for promoting and improving the health of men and boys."

Pharmacists: Advance your Business Capabilities

Are you a pharmacist, or would you like to own or manage a pharmacy? The new **Executive Diploma in Strategic Pharmacy Business Management** from DBS can help you to learn the skills required to succeed in this field, while dealing with the challenges and pressures that the sector is currently under.

Aims and objectives

The primary objective of this programme is to build and enhance the retail business capability of pharmacists and business owners as part of both the IPU's and independent pharmacy strategic objectives for 2021 and into the future.

Key objectives of the programme

Learn to critically evaluate and review relevant theories, concepts, frameworks, models and key issues in the field of pharmacy retail strategy.

Provide an overview of consumer's decision-making processes, the influences upon consumers' behaviour and their implications for marketing.

Equip learners with an understanding of how market environments affect organisations marketing strategies.

Assist learners to understand the fundamentals of organisational behaviour.

Develop skills to interpret retail data and express its value visually through the use of case studies and datasets.

Demonstrate an understanding of the obligations and limitations imposed by the law on the operation of a retail business.

Awarding Body: Dublin Business School
Schedule: 2 Consecutive days (Thursday / Friday) per month (10am-5pm)
Intake: October - April
Duration: 6 months
Study Mode: Daytime Delivery

Provide a framework from which students can analyse the issues involved in applied management practice through a retail business simulation.

Explore how procurement and supply chain management can add value, enhance organisational performance and be a source of sustainable competitive advantage to a retail organisation.

Provide learners' with an understanding of the core objectives of financial management.

DBS Dublin Business School

IRISH PHARMACY UNION

With the Executive Diploma in Strategic Pharmacy Business Management you will cover the following topics:

- Retail Pharmacy Business Strategy
- Organisational Behaviour in Retail Environment
- Pharmacy Retail Consumer Behaviour
- Legal Issues and Regulation in Retail
- Pharmacy Retail Marketing
- Category Management and Retail Purchasing
- Retail Management Simulation
- Business Intelligence and Data Visualisation
- Finance for non Financial Managers
- Leadership and Communication
- Capstone Project Preparation

Assessment

To be awarded the Executive Diploma in Strategic Pharmacy Business Management, a Pharmacist will be required to complete continuous assessment for all subjects and a final project.

Is this course for you?

If you have a pharmacy qualification and a drive to succeed, with great interpersonal skills then this is the course for you!

This programme will benefit those involved in the pharmacy business, or pharmaceutical industry.

It will help anyone who is keen to invest in multiple pharmacy businesses, acquire existing pharmacies, open a new pharmacy, or advance into senior management with your pharmacy business.

Fees

€2,500 for IPU members
€3,000 for non-IPU members

For more information, or to apply, contact us below:

P: (01) 4177500
E: admissions@dbs.ie
W: www.dbs.ie/pharmacy

DBS Dublin Business School

IRISH PHARMACY UNION

Veterinary medicines: new regulations – what will this mean for pharmacists?

The IPU has spent the last year fighting to keep anti-parasitics for food-producing animals available without prescription. We have written to the Minister for Agriculture, Food and the Marine, appeared before and engaged with the Joint Committee on Agriculture and the Marine, and had a series of meetings with the Department of Agriculture Food and the Marine. In this article, Pamela Logan, Director of Pharmacy Services, IPU, outlines our case.

Many community pharmacists are actively involved in the supply of veterinary medicines to farmers throughout the country. The IPU has serious concerns about the proposed changes to the route of supply of antiparasitic veterinary medicinal products intended for food-producing species under the EU Veterinary Medicines Regulation 2019/6, which comes into force on 28 January 2022.

In February 2019, the Health Products Regulatory Authority's (HPRA) Advisory Committee for Veterinary Medicines (ACVM) established a Task Force to review the route of supply of antiparasitic veterinary medicinal products that are intended for food-producing animals against the criteria set out in Directive 2006/130/EC. The Task Force Report was endorsed by the HPRA on 5 December 2019.

The Report concludes that the available scientific evidence shows that antiparasitic veterinary medicines that are intended for use in food-producing species do not comply with the criteria for derogation from veterinary prescription specified in Regulation (EU) 2019/6. It also states that a consequence of this

determination is that any such products that are supplied without veterinary prescription will need to be upregulated to supply under veterinary prescription, ie reclassified as prescription only medicine (POM).

While it is accepted there is evidence of cases of anthelmintic resistance and this has been reported in published literature, a national field trial has never been carried out or published which confirms a widespread problem due to the presence of anthelmintic resistance in herds and flocks throughout Ireland. The regional veterinary laboratories, which assist in the diagnosis and control of disease in food-producing animals, regularly publish case reports to warn of present and emerging threats in animals submitted for autopsy. They have not reported or warned of a significant problem with anthelmintic resistance in their reports, although these laboratories would be expected to detect such a problem on a regional basis, if it existed.

It is not clear that there is sufficient evidence at this time to warrant regulating antiparasitic medicines using prescription control, and there is no evidence to suggest that such a change will have any positive impact or help to reduce the development of anthelmintic resistance. In fact, two novel anthelmintics, derquantel and monepantel, which are best used as quarantine and interval treatments to slow the development of anthelmintic resistance in sheep, were classified as POM when licensed by the HPRA. This has had the unintended consequences of adversely restricting their use and they have not been appropriately used in flock treatment plans at any appreciable level due to the restricted status of the products. The use of these and other anthelmintics would be better approached as part of a comprehensive parasite management plan developed for specific farm use, with products accessible to the farmer from appropriately trained professionals.

In our opinion, the HPRA and the Department of Agriculture Food and the Marine have adopted a rigid interpretation of the derogation available in Regulation (EU) 2019/6, ie Article 105(4), which states that a Member State may allow a veterinary prescription to be issued by a professional, other than a veterinarian, who is qualified to do so in accordance with applicable national law at the time of entry into force of this Regulation. Such prescriptions shall be valid only in that Member State and shall exclude prescriptions of antimicrobial medicinal products and any other veterinary medicinal products where a diagnosis by a veterinarian is necessary.

The current position of the Department is that no other professional was in a position to prescribe prescription only

"Pharmacists are ideally placed to continue to advise farmers on the targeted strategic use of these valuable medicines and ensure their rational use as part of herd and flock treatment plans as appropriate."

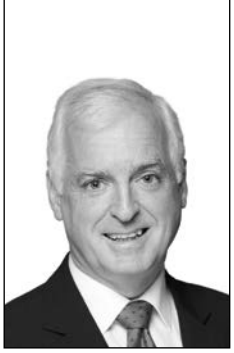
products prior to the coming into force of Regulation (EU) 2019/6; however, this is clearly not the case as pharmacists have supplied what would otherwise be prescription only medicines (POM) under the POM(E) route of supply for many years. Indeed, both pharmacists and vets have equivalent prescribing rights for POM(E) products.

The IPU believes that a balance should be achieved between the availability of safe and effective medicines for routine use in otherwise healthy animals on the one hand and the need to ensure professional input and advice to safeguard animal and public health and welfare on the other. Pharmacists are ideally placed to continue to advise farmers on the targeted strategic use of these valuable medicines and ensure their rational use as part of herd and flock treatment plans as appropriate. Furthermore, we support the need for responsible use of antiparasitic veterinary medicinal products to safeguard the efficacy of the products concerned for the future and to implement any future strategies to minimise the development of anthelmintic resistance.

Most antiparasitic veterinary medicinal products are currently supplied in Ireland as non-prescription medicines, mainly under the Licensed Merchant (LM) category; this has been the case for three or more decades. In our opinion, we feel that upregulating antiparasitics to POM(E) would be sufficient to address the concerns of the Task Force Report. The use of the POM(E) route of supply would allow ready access to antiparasitic veterinary medicinal products through community pharmacies throughout the country, most especially in rural Ireland, where many isolated areas do not have local access to veterinary services. Antiparasitics would also continue to be available through veterinary practitioners. Farmers would benefit from access to quality information and advice on the safe and effective use of these products. Farmers would also benefit from price competition between suppliers in the market.

There is a well-documented shortage of veterinary services in many rural areas, including the Minister's own constituency in Donegal. In Mayo, there is only one veterinarian in all of Erris, an area the size of Louth, and there is no veterinarian in Achill, the nearest being in Westport, 60km away. Contrast this to the extensive availability of pharmacy services throughout the country. Lack of access to veterinary services to obtain a prescription for antiparasitics will impose undue hardship and expense on animal owners and, ultimately, animal welfare will suffer.

The POM(E) route of supply is a vital part of the supply chain of veterinary medicines to farmers from a pharmacist's perspective. This route is used for animal remedies which, by therapeutic classification, would be expected to be POM but, because they do not require veterinary diagnosis, can be otherwise supplied. POM(E) confers a level of importance to a veterinary medicine in that only a vet or a pharmacist can personally supply it to the end user. Like all other POM(E) medicines, these medicines always require professional advice at the point of supply, including details on administration, reconstitution, storage after a container is opened and, ultimately, disposal of used containers and residual material. POM(E) ensures appropriate access to medicines, particularly from pharmacists who, as a matter of course, are available six or seven days a week. Upregulating antiparasitic veterinary medicines to POM(E) utilises the potential of pharmacists for the benefit of farmers and the health of their animals.



Changes ahead in regulation of veterinary medicine

The EU Veterinary Medicines Regulation 2019/6 comes into force next January. The Director of Veterinary Sciences at the Health Products Regulatory Authority (HPRA), JG.Beechinor, outlines the changes to the route of supply of antiparasitic veterinary medicinal products intended for food-producing species.

The EU Veterinary Medicines Regulation 2019/6, which applies from 28 January 2022, signals a number of important changes to the regulation and monitoring of veterinary medicines throughout the EU. The fundamental regulatory processes for gaining a marketing authorisation for a new medicine remain largely unchanged, and the authorisation standards remain as they are currently. However, the new legislation has been largely decoupled from the human medicines one, allowing it to better fit the specificities and budgets of the animal health sector and to streamline some regulatory processes.

There are a number of changes which are expected to be of relevance for pharmacists.

The summary of product characteristics (SPC) and labelling of veterinary medicinal products are set to change. While the SPC changes are relatively minor, of particular note is that much of the current information on the immediate labelling of veterinary medicines will be displaced to the package leaflet. Moreover, the marketing authorisation number will no longer appear on the immediate label and the method of sale/supply will no longer appear on either the immediate product label or outer product label (this information will be available from the package leaflet and SPC).

One of the goals of the legislation is to improve availability; by reducing the amount of text on the labelling, the expectation is that this will facilitate the development of multi-lingual labels making it easier for industry to develop multi-country product batches. Some of the existing text will be replaced by pictograms and abbreviations (e.g. LOT for batch number). The changes will be apparent on new medicines authorised after 28 January 2022, but will be applied to all current veterinary medicines by 2027.

"One of the goals of the legislation is to improve availability; by reducing the amount of text on the labelling, the expectation is that this will facilitate the development of multi-lingual labels making it easier for industry to develop multi-country product batches."

Another goal of the legislation is to mitigate the risk of development of antimicrobial resistance both for animal and human health. While additional data protection is provided for new antibiotics, significant new restrictions are foreseen in respect of existing antibiotics. Some of the new restrictions have yet to be delineated by means of secondary EU legislation (delegated and implementing acts). This legislation, which is to be available over the coming months and will apply from January, will mean that certain critically important antibiotics will be reserved exclusively for human use while other classes of antibiotics will be controlled according to their significance to human and animal health. While the administration of antimicrobials to a group of animals, with the aim of treating the clinically sick animals and controlling the spread of the disease to animals in close contact and at high risk and which may already be subclinically infected (metaphylaxis) will continue to be permitted, indications for the preventative use of antibiotics (use in the absence of an infection in an individual or a group) will disappear.

Enhanced warnings, with the primary intention of promoting prudent use are also expected. According to the regulation, a veterinary prescription for an antimicrobial veterinary medicine will be valid for five days from the date of issue. Further legislation requiring national monitoring of the use of veterinary antimicrobials in a phased basis between 2023 and 2030 is also planned. In addition, legislation is in development to enhance instructions on the use of oral medication that is incorporated in drinking water or for on-farm mixing in feed (eg top-dressing).

A Union Product Database (UPD) containing information on all veterinary medicines that are authorised in the EU is being created. This database will include information in respect of medicines authorised centrally, as well as those authorised nationally. This level of transparency is expected to assist veterinarians and users to identify medicines that are appropriate for the needs of animal patients.

The database, which will be fully searchable, will contain the SPC and product information in respect of over 30,000 veterinary medicines in the EU. While the database is being developed and rolled out by the European Medicines Agency (EMA) currently, it will be up to each Member State to populate it with legacy product information. Subsequently, the data is expected to be updated/enriched by marketing authorisation holders. This database will underpin other EMA databases that are being developed to improve the functioning of regulatory processes and veterinary pharmacovigilance monitoring. It is expected that basic functionality of the UPD will be available from January 2022, but utility will improve during the course of 2022 with future updates. Notwithstanding the availability of such, data consumer expectation may need to be managed. The fact that a medicine is authorised in another EU Member State does not necessarily mean that it is available here. Moreover, the import of veterinary medicines that are not authorised and labelled for the Irish market are subject to licensing by the Department of Agriculture, Food and the Marine (DAFM). Furthermore, information on adverse reaction reports which will be readily accessible from the EU pharmacovigilance database may be misunderstood by the lay public. This is especially the case as the current legal requirement for product causality assessment of suspected adverse reactions has not been carried forward into the new regulation.

While significant change in the regulatory controls for veterinary medicines will apply from January 2022, the regulation provides for further changes over the coming years. The precise changes will be customised by means of secondary EU

legislation. This mechanism allows the EU Commission to future proof the current legislation according to new developments in technologies or animal husbandry. Complementary national legislation on veterinary medicines is also in development by DAFM currently; this is needed as some provisions of the current Animal Remedies legislation will need to be amended so that they will not conflict with the regulation, as well as to cater for provisions in the regulation that are at the discretion of individual Member States.

The regulation provides that non-prescription veterinary medicines may be supplied over the internet, but the system is to be regulated using an EU common logo where the user can verify the authenticity/security of the retailer. The regulation provides that Member States may impose conditions on such supply which are justified on grounds of public health and protection. It is expected that DAFM will elaborate national rules on this matter in due course. The regulation also allows Member States to allow internet sales of prescription medicines within its own country, provided there is a secure national system to control it. Readers should consult DAFM for more information on this point.

While not directly linked to the application of the regulation, in 2019 the HPRA reviewed compliance of antiparasitic veterinary medicines for food-producing animals against the criteria specified in the regulation. A report on this topic is available on the HPRA website (www.hpra.ie). Since the publication of that report the HPRA embarked on a change process with marketing authorisation holders which will see all such medicines that are currently authorised for supply without prescription changed to prescription-only supply by 28 January 2022. The period of validity of a veterinary prescription as well as the conditions under which the prescription may be written are subject to ongoing deliberations between DAFM and the Veterinary Council.

Conclusion

Regulation 2019/6 has been elaborated after a relatively long period of discussion, which began in 2014. It was published in 2019 and applies from 28 January 2022. While comprehensive, many of the changes apply to regulatory processes of companies and competent authorities and might not be visible to those prescribing, dispensing or using veterinary medicinal products. Nonetheless, several changes are expected to result in the simplification / re-engineering of the regulatory processes, with the goal to reduce administrative burden and thereby improve availability. These changes are augmented by new transparency tools, as well as new monitoring tools. Although the new legislation will apply from 28 January 2022, it may take a number of years for the animal health industry to respond fully to the new incentives. Nonetheless, this represents an important opportunity for the animal health industry, which should enhance availability of veterinary medicines in due course. Further information on progress in the implementation of the regulation is available from the HPRA website.

Vaccine scrutiny continues unabated

A sense of optimism is beginning to surface in Leinster House that the worst of the COVID-19 pandemic is finally behind us. Despite this optimism the vaccination campaign, quite appropriately, continues to face intense scrutiny.

Politicians of all persuasion, from both inside government and the opposition benches are continually pressing for details. Among the questions on the supply of vaccines into the country and the pace at which they can be administered, many continue to ask when community pharmacies will become involved.

Minister for Health, Stephen Donnelly faced this question multiple times when updating the Dáil on the vaccine campaign.

"I want to see pharmacists playing a more prominent role in this," the Minister told **Róisín Shortall TD *(Dublin North West, Social Democrats)***.

Deputy Shortall had asked about the role of the pharmacy network particularly as "there is a very significant dip in the administration of vaccines every weekend… The number drops down to about 12,000, which is just not really acceptable at this stage when it should be rolled out as quickly as possible. Pharmacists obviously have a key role as well."

She also pressed him for a timescale, to which Donnelly responded that "it will be in the coming weeks." He claimed to have discussed this at length with the HSE and acknowledged that pharmacists "are ready to go and we have had an agreement in place with them for a very long time."

When the issue of running vaccination centres 24 hours a day was suggested to Minister Donnelly he cited the additional capacity offered by pharmacies as one reason that this might not be required. But he did commit that "If it is needed to run the vaccine centres 24-hours a day, we will absolutely do that."

The Minister also advised that "The IT systems and portals for the pharmacists are being piloted with a number of community pharmacists right now."

During the same debate and in relation to the same matter, the Minister was put under pressure for details on the timeline by **Cormac Devlin TD *(Dún Laoghaire, Fianna Fáil)***. Devlin pressed for clarity on "when will the vaccinations in pharmacies start?" He also highlighted how "many pharmacists have completed the documentation that was required and sent it back to the HSE."

Minister Donnelly advised that he has "taken this up with the HSE on numerous occasions, including this week. I believe there is a role for pharmacists to play in the vaccination roll-out. That is why we put a deal in place with the Irish Pharmacy Union, IPU, at the start of this process."

Devlin's questions were echoed by **Labour leader Alan Kelly TD *(Tipperary, Labour)*** who asked "When are we going to include the pharmacists?… Honestly, pharmacists have a huge reach into the communities. What is the plan? What is the timeline for including pharmacists?"

Representatives of the HSE faced similar questions when updating the Oireachtas Health Committee on vaccinations. **John Lahart TD *(Dublin South West, Fianna Fail)*** pressed HSE Chief Clinical Officer Dr. Colm Henry for details about when pharmacists will join the programme.

Damien McCallion, who is national lead on the COVID 19 vaccination programme responded by outlining work done to date. "We have been working with pharmacists for some time, and with the Irish Pharmacy Union."

McCallion explained how there have been a number of steps to go through "First, we had to reach an agreement. Second, we needed to put in place an operational framework as to how they would operate as vaccinators. Third, we needed to put in a technology solution that would allow them to function."

Ultimately, McCallion explained that there are two factors that will determine the timing. "One relates to when we have supply of the vaccine, the other is the vaccine mix.

Stephen Donnelly
Fianna Fáil

Róisín Shortall
Social Democrats

Cormac Devlin
Fianna Fáil

Alan Kelly
Labour

John Lahart
Fianna Fáil

Pharmacy vaccination will lend itself better to some vaccinations than others, so the decision around the use of the Janssen vaccine and so on will affect that."

Responding to a question on the practicalities of the pharmacies vaccinations from **Senator Seán Kyne *(Fine Gael)*** McCallion admitted, "We are still working through the model of how people will be assigned to pharmacists."

In the Seanad too the Government faced multiple questions. **Senator Maria Byrne *(Fine Gael)*** addressing **An Tánaiste, Leo Varadkar** highlighted how "Some 1,200 pharmacists have registered to become vaccinators... It would certainly help increase the number of vaccinators available."

The Tánaiste, responding to this, acknowledged that some pharmacists "are a little annoyed that they have not been asked to help yet. They will be, almost certainly in June and through to July and thereafter."

Senator Sharon Keogan *(Independent)* cited the IPU's estimate that pharmacies have capacity to administer more than 50,000 a week. "If the Government wants to hit its vaccination target by the end of June, I urge it to delay no longer."

While **Senator Jerry Buttimer *(Fine Gael)*** said it is "extraordinary that one of the most valuable assets we have is the community pharmacists but they are not being utilised at all in the ongoing vaccination programme."

"In the first iteration of the national Covid-19 vaccination strategy implementation plan, community pharmacists were identified in the report as having a central role. Since then, we have seen 27 changes to the vaccination programme but there is no sign of the involvement of community pharmacists despite them being trained vaccinators. I have to ask why."

There were also questions from **Pádraig O'Sullivan TD *(Cork North Central, Fianna Fáil)***, and **Minister Robert Troy TD *(Longford-Westmeath, Fianna Fáil)***.

The cost of involving of pharmacies was also raised by **Ruairi Ó Murchú TD *(Louth, Sinn Fein)*** who was advised that the fees payable to pharmacists were set following consultation with the Irish Pharmacy Union, but no estimate was provided.

Finally, there were also questions put to the Minister on the vaccination of all pharmacy staff by **Brendan Griffin TD *(Kerry, Fine Gael)***, **Réada Cronin TD *(Kildare North, Sinn Fein)*** and **Michael Collins TD *(Cork South West, Independent)***.

Seán Kyne
Fine Gael

Jerry Buttimer
Fine Gael

Brendan Griffin
Fine Gael

Maria Byrne
Fine Gael

Pádraig O'Sullivan
Fianna Fáil

Réada Cronin
Sinn Féin

Leo Varadkar
Fine Gael

Robert Troy
Fianna Fáil

Michael Collins
Independent

Sharon Keogan
Independent

Ruairi Ó Murchú
Sinn Féin

TDs Focus on e-prescribing

As talk begins to move to post pandemic healthcare there has been renewed focused on e-health and in particular e-prescribing. **Neasa Hourigan (Dublin Central, Green Party)** asked **Minister Donnelly** to detail progress on the implementation of an e-prescribing system.

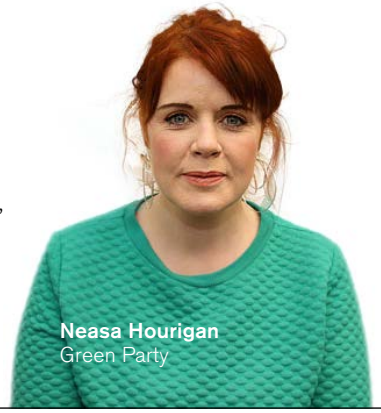
The Minister advised that "implementation of ePrescribing is a significant programme of work and will take time to embed in acute and primary care settings." But also explained that "to support access to prescriptions during the Covid-19 pandemic, a new service to facilitate the secure electronic transfer of prescriptions (ETP) between GPs and community pharmacy was deployed in response to Covid-19."

According to the Minister this service has proven to be successful with approximately 50,000 scripts now being transferred electronically between GPs and community pharmacies every day.

"To build on this work, the HSE has established an ePharmacy Programme which will be responsible for the implementation of a national ePrescribing solution for the health service."

Labour leader Alan Kelly TD also raised the topic in the context of EU recovery funding. Kelly wanted to know how the funding, approximately €853 million in 2021, would be spent.

Kelly said he would welcome if some of this funding was put towards ehealth, specifying the national need for "An ehealth project would allow for the secure electronic sharing of patient information lab results and prescriptions between medical providers."



Neasa Hourigan
Green Party

Healthy Ireland Strategic Action Plan Launched

The Government has published a new five-year Action Plan for the Healthy Ireland Strategy.

A core component of the implementation of Sláintecare, this Healthy Ireland Strategy will have a particular emphasis on reducing inequalities. It will involve a comprehensive cross-government approach, with a total of 14 Government departments responsible for implementing actions for the next five years.

An Taoiseach Micheál Martin said "Healthy Ireland gives us a vision of how we as a society can work together to bring about a Healthier Ireland where everyone can enjoy physical and mental health and wellbeing to their full potential."

The Plan contains 56 actions across six themes which will be implemented over the next five years. This includes a commitment to further develop partnerships with pharmacies in the years ahead.

Bruton seeks unwinding of FEMPI

Former Minister **Richard Bruton TD** ***(Dublin Bay North, Fine Gael)*** has become the latest TD to ask questions in relation to the restoration of FEMPI cuts to the pharmacy sector.

Responding to this parliamentary question, Minister Donnelly stated that it was his intention to honour the commitment made by the previous Government to the IPU for a strategic review of the role of community pharmacists and to develop revised contractual terms.

"The GMS pharmacy contract is substantially outdated," acknowledged Donnelly. "It has not kept pace with developments that have taken place over the course of recent years including the increasing emphasis on maximising the proportion of people's healthcare needs met in primary care, interdisciplinary collaboration and the skillset that pharmacists have by virtue of their education and training."

Detailing the proposed review, the Minister said, "The comprehensive review of the pharmacy contract will address the role to be played by community pharmacy in the context of Sláintecare. It will consider all aspects of pharmacy service provision including delivery of a multi-disciplinary model of service delivery for patients."

Richard Bruton
Fine Gael

Medicinal cannabis products

David Cullinane TD ***(Waterford, Sinn Fein)*** received detailed updates from **Minister Donnelly** on the regulatory treatment of medicinal cannabis products.

Cullinane, who is the Sinn Fein health spokesperson, asked first "if an application has been received to add the PCBD110 product to the medical cannabis access programme". He also sought clarity on the criteria which prospective products for the medical cannabis access programme must meet in order to be recommended for use in the programme and specifically "if trace-THC products may be considered for inclusion."

Minister Donnelly confirmed that the HPRA had received no application from any prospective supplier looking to add PCBD110 to the Medical Cannabis Access Programme (MCAP). In relation to products containing THC at trace levels he said these "are still subject to control under the Misuse of Drugs Act and are eligible for inclusion in the MCAP provided they meet the definition of "specified controlled drugs" in the regulations."

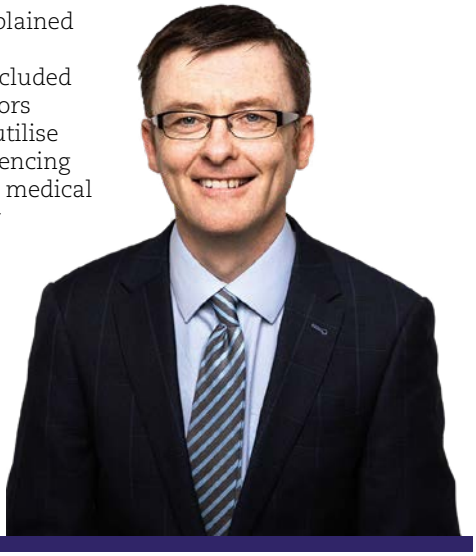
Cullinane then sought an explanation on why none of the four products currently recommended for use in MCAP meet the criteria of less than 2% THC for use in the treatment of resistant epilepsy. To which the Minister responded that, "It is open to any supplier or producer to apply to the HPRA to have their products assessed for inclusion in the programme."

Elsewhere **Pádraig O'Sullivan TD** ***(Cork North Central, Fianna Fail)*** asked for information on the reimbursement of medicinal cannabis oil products PCBD.

The Minister explained that MCAP is restricted to prescribing of cannabis-based products by medical consultants, for patients with multiple sclerosis, nausea and vomiting associated with chemotherapy and severe, refractory (treatment-resistant) epilepsy.

To date, four products have been added to Schedule 1 of the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2019.

However, he explained that "for medical indications not included in the MCAP, doctors may continue to utilise the Ministerial licencing route to prescribe medical cannabis for their patients."



David Cullinane
Sinn Féin

HPRA address Veterinary Medicines

Representatives from the HPRA attended a meeting of the Joint Oireachtas Committee on Agriculture, Food and the Marine. Chief among the topics raised was the proposed changes to the route of supply of antiparasitic veterinary medicinal products intended for food-producing species under the EU Veterinary Medicines Regulation 2019/6, which comes into force on 28 January 2022.

Joe Flaherty
Fianna Fáil

Tim Lombard
Fine Gael

Addressing the committee members Dr. David Murphy, said "It is clear that anti-parasitic resistance is an issue." Explaining that "anti-parasitic compounds are a precious commodity. The last new broad spectrum anti-parasitic wormer product for cattle and sheep was authorised ten years ago."

According to Dr. Murphy the situation "requires that these substances are subject to prescription control."

Joe Flaherty TD *(Longford-Westmeath, Fianna Fáil)* described the insight provided into the anti-parasitic resistance as "a real eye-opener." While **Senator Tim Lombard *(Fine Gael)*** raised the concern that there are "major quantities of food or product moving from the North to South which have different regimes regarding anti-parasitic drugs."

In response to the latter concern Dr JG Beechinor advised the committee that this was "a live issue with the Department through the Northern Ireland protocol." But outlined his understanding that only a suitably qualified person can prescribe anti-parasitics in respect of herds in Northern Ireland.

LETTER TO THE EDITOR

When the *IPU Review* arrives the first page I look at is the editor's comments. There is no doubt that the editor spends a lot of time and thought into setting this up. The May 2021 issue brings back lots of memories to me. In the early 1980s there was the big drive to use computers in pharmacies. Many pharmacists cut their teeth with the BBC and basic programs. I still remember being hauled over the coals for maintaining that this approach was not powerful enough and would have to be replaced with the IBM system.

One problem that arose was the diversity of programs used by wholesalers who wanted to tie in retail pharmacies to their databases.

But with the immense help of Michael Doherty and Teresa Doherty (RIP) we succeeded in getting some form of unification. At that time, there was a tendency of wholesalers to use the PIP code which was the British standard. It was through the help and forethought of Teresa and Michael that we went down the road of the European barcode. And with Michael's help we were allotted a section of the EU barcodes which was then called IPU code.

Following many rather belligerent meetings with wholesalers, software producers and the IPU committee we reached agreement to use this code in ordering, standardising the reception of orders and the information coming back to the pharmacist.

This time around, with the introduction of the 3D codes I believe it is possible to standardise the information that is sent out by the manufacturers into readable information for the suppliers, doctors and pharmacists. This would allow the introduction of an official International Health products catalogue.

While the IPU National Health Products Catalogue is already in existence, why not use it in the format that Jack has suggested? I am sure that there are many knowledgeable people out there to assist with its development.

Wishing the best of luck to Jack and, of course, the hard working and efficient team in the IPU.

Paddy Geoghegan

The role of the Pharmacist in improving oral health

Tooth decay is our most common childhood disease, despite being entirely preventable. Etain Kett of Dental Health Foundation Ireland offers some basic advice on protecting our teeth and gums and outlines the role that pharmacists can play in supporting improved oral hygiene.

Dental caries, more commonly known as tooth decay, is entirely preventable. Yet it is the most widespread non-communicable disease and the most common childhood disease – due to risks like poor oral hygiene and exposure to sugar.

In Ireland, almost half of five year olds without community water fluoridation (CWF) and one in three with CWF have at least one decayed, missing or filled primary/baby tooth or have experienced dental caries.

Almost 100% of adults in the world have dental caries and globally, about 30% of people aged 65–74 years have no natural teeth. It is fair to say that many of the public are not aware of the links between oral and general health or that ignoring your oral health may affect wellbeing.

Maintaining good oral health is not just about the absence of disease such as tooth decay or gum disease. The Dental Health Foundation provides practical and useful information to people about their oral health and all person health. We ensure that its advice is underpinned by science. We take the holistic approach and emphasise that the goal is to have good oral health for your lifetime.

DHF Dental Health Foundation Ireland

The Irish Pharmacy Union commissioned a study in 2019 which showed that 70% of the public are more likely to visit the local pharmacist ahead of the GP, making the pharmacist ideally placed in helping to promote oral health messaging and ensuring that the public has access to professional and trustworthy information.

Getting back to good oral health (which is not just about appearance, it impacts on your overall health), the basics are good oral hygiene and a healthy diet. The key messages around this are a daily routine of brushing your teeth twice a day and eating a balanced diet with lots of fruit and vegetables and sticking with tooth friendly drinks like water and milk.

Eating and snacking has become more common during lockdown. A good diet reduces the risk of tooth decay, and other health related issues. Sugar is the most important dietary cause of tooth decay in children and adults. Drinking one can of a sugary drink a day increases the risk of developing type 2 diabetes by 22%. A lesser-known fact is that the acid in diet drinks can damage the teeth by causing tooth erosion.

The Healthy Food for Life Toolkit for the new Food Pyramid contains useful advice and tips on following a healthy diet, which can only be of benefit from an oral health perspective: https://assets.gov.ie/7650/f3249ad0c7284211b3fa41c69b33c8e2.pdf

How to look after your teeth

Oral health is not just about appearance, it impacts on your overall health and quality of life. With the links between gum disease and oral health such as diabetes and cardiovascular disease it has never been more important to look after your teeth. Pharmacists can provide a wealth of information on effective oral hygiene.

Regular toothbrushing removes plaque, which is good for gum health. It is recommended to use a toothpaste with 1450 ppm F (parts per million fluoride), the fluoride can help to prevent and even reverse decay in its early stages.

Effective Toothbrushing Routine

1. A gentle scrub technique involving very short horizontal movements is recommended.
2. Spit out toothpaste and do not rinse after brushing.
3. Brush twice a day – at bedtime and at one other time during the day.
4. Daily flossing reduces the amount of periodontal disease-causing bacteria present in plaque between the teeth – this is particularly important for diabetics. It also helps to reduce bad breath.
5. Most people don't think about tongue brushing, but it has also been proved to be an effective measure in reducing bad breath.

Children

1. Parents and carers of children aged 0-2 are encouraged to brush their child's teeth twice a day as soon as the first tooth appears, using a soft toothbrush and water.
2. It is not recommended to use toothpaste for children aged 0-2 years, unless advised by the dentist.
3. From age 2-7 years use a small pea size amount of fluoride toothpaste.
4. Children under the age of seven should be supervised by an adult when brushing to avoid swallowing toothpaste. Do not rinse after brushing so that the effects of fluoride toothpaste are not diluted.

Research shows if a child has dental decay at a young age, they are more likely to have dental decay and gum disease as an adult.

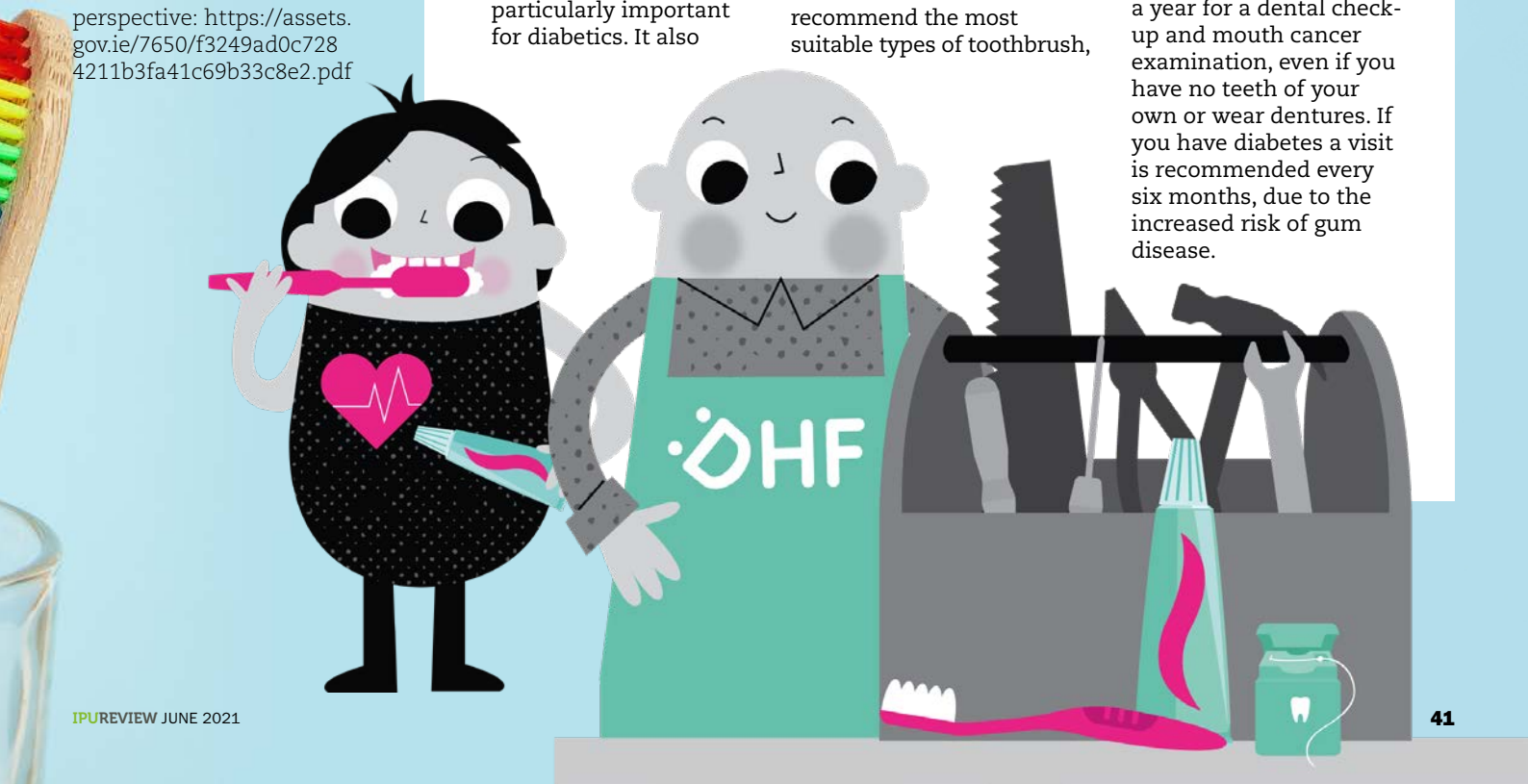
Pharmacists can recommend the most suitable types of toothbrush, either manual or powered. It is important to choose a toothbrush that effectively and gently cleans your teeth and gums, soft/medium is best. Modified toothbrushes are available for carers or people who may have difficulty holding brushes. Powered toothbrushes are also beneficial for people who do not have the dexterity to brush effectively with a manual toothbrush.

Mouthwash

While mouthwash may help fight tooth decay and gum disease, it shouldn't be used as a replacement for toothbrushing or shouldn't be used straight after brushing the teeth as it only rinses away the higher fluoride concentration from the fluoride toothpaste. Using a fluoride mouthwash between brushings is very useful if you wear braces. The Dental Health Foundation recommends the use of alcohol-free mouthwash and your dentist will recommend the most suitable mouthwash. It is not recommended for under seven years of age.

Dental Visits

It is recommended to visit the dentist at least once a year for a dental check-up and mouth cancer examination, even if you have no teeth of your own or wear dentures. If you have diabetes a visit is recommended every six months, due to the increased risk of gum disease.



Gum disease

Gum disease is caused by a build-up of plaque on the teeth and around the gums, causing red swollen gums which bleed when brushing. If left untreated, gum disease (or gingivitis) will progress to periodontal disease which causes bad breath, receding gums, wobbly teeth and, ultimately, loss of teeth. Smoking also increases the risk of periodontal disease, smokers are more likely to get periodontal disease and prematurely lose their teeth than non-smokers.

Poorly controlled diabetes increases the risk of periodontal disease development, which in turn can make it more difficult to control diabetes. People with diabetes should be encouraged to have a good oral hygiene routine and regular visits to their dentist.

It's also worth noting that hormonal changes during pregnancy can make women's gums more vulnerable to pregnancy gingivitis. Advice to pregnant women about their oral health during pregnancy is important to both the mother and baby. Making healthy choices can positively affect a baby's development including in relation to his or her teeth.

Dry mouth and medication

Certain medications may cause dry mouth. To help relieve it sip water, chew sugar-free gum or use oral lubricants to help with dry mouth. Sucking on sweets or sipping on soft drinks and juices is bad for the teeth.

Cold sores

Cold sores are painful red blisters that occur on or around the mouth and are caused by herpes simplex virus (HSV) types 1 and 2. HSV type 1 is the most common cause of cold sores. HSV type 2 usually causes genital herpes, but it can also cause cold sores.

How to prevent cold sores

Prevention is difficult and cold sores are contagious, strict hygiene measures should be adopted when a person is infected. Here are some things that can be done to reduce the number of outbreaks and prevent spreading the virus.

Avoiding triggers such as stress, colds or the flu; too much sunlight can cause cold sores to flare so always use sunscreen on the face and lip balm with a factor on the lips. Avoid sharing toothbrushes, towels, razors, cutlery, cups or other objects that a person with a cold sore may have used, good hand hygiene is important. A well-established product on the market (containing 5% w/w acyclovir), if applied during the early burning phase of cold sores, has been shown to be effective in reducing the duration of the episode.

If a person gets cold sores often advise them to talk to their dentist or doctor as they may be able to take prescription pills to prevent cold sore outbreaks.

Cold sores can be very serious for young babies as their immune systems aren't developed enough to fight off the infection. Advise people not to kiss their newborn and to wash their hands before touching their baby.

Mouth ulcers

Many people suffer from recurrent ulcers in the mouth. These can be extremely painful and may make speaking and eating difficult. Mouth ulcers can be triggered by a wide range of factors including:

Accidental biting of the inside of your cheek; vigorous toothbrushing; constant rubbing against misaligned/sharp teeth, an irregular filling, dentures or braces; emotional stress; deficiencies in Vitamin B12, iron and folic acid; burns from eating hot food or irritation from strong antiseptics, such as a mouthwash; mouth cancer.

Usually, one to five small ulcers appear (less than 1mm in diameter) on the inside of lips or cheeks or the floor of the mouth or tongue. The ulcers tend to be concentrated towards the front of the mouth. They can last from a few days to a little over two weeks, but usually about 10 days. Aphthous ulcers are recurring ulcers with no known cause and affect around 20-30% of the population. As a pharmacist you can suggest some of the following for ulcers:

Avoid spicy and sour foods until the ulcers heal; drink plenty of fluids; regularly rinse the mouth out with warm, slightly salted water; keep the mouth clean; take pain-relieving medication, such as paracetamol; apply antiseptic gel to the ulcers.

However, you should recommend that the person visits their dentist or GP if the mouth ulcers don't clear up within a few days, or if they get them frequently. It's important to seek the advice of a dentist who may refer more severe cases to a specialist in oral medicine for a thorough investigation.

Mouth, head and neck cancer

Mouth Head and Neck Cancer is the sixth most common cancer in men worldwide. Smoking and drinking alcohol are the most important risk factors, but the risk is even greater if you smoke and drink. Alcohol plays a role in up to half of all cancers of the mouth, head and neck in men in Ireland with over 700 cases diagnosed every year in Ireland.

Early diagnosis means the chance of survival is greatly improved, so if a person notices any changes in their mouth and has them for more than three weeks, the pharmacist should recommend that they visit their dentist or doctor straight away. Things to look out for include a lump in your mouth or neck, a sore or ulcer, a persistent sore throat and hoarseness, problems with your tongue (including mobility or numbness).

For more information see **www.mouthcancer.ie**

Advice on quitting smoking is available at **www.quit.ie**

Visit **www.askaboutalcohol.ie** for advice on alcohol.

For additional information and free downloadable resources on these topics and more, visit www.dentalhealth.ie

Lancet publishes results from Trinity College clinical trial for Atopic Dermatitis

The findings of a clinical trial by Trinity College Dublin researchers of treatment for atopic dermatitis have been published in *The Lancet* journal. Results of the clinical trial at the School of Medicine, Trinity College and St James's Hospital, Dublin have shown the drug *upadacitinib* to be the most effective treatment to date for this chronic, relapsing inflammatory condition. The research is significant as there is an unmet need which exists for therapies that provide remission of symptoms in moderate-to-severe atopic dermatitis.

The Lancet reports efficacy and safety results of *upadacitinib* compared with placebo for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents. This pivotal Global Phase 3 study involved 1,600 patients and took place over the last two years at The Wellcome Trust/Health Research Board Clinical Research Facility at St James's Hospital.

Atopic dermatitis is a chronic, relapsing inflammatory condition characterised by a cycle of intense itching and scratching leading to cracked, scaly, oozing skin. It affects up to an estimated 10 percent of adults and 25 percent of children. Between 20 and 46 percent of adults with atopic dermatitis have moderate to severe disease. The range of symptoms pose significant physical, psychological and economic burden on individuals impacted by the disease.

Results show *upadacitinib* to so far be the most effective treatment for atopic dermatitis in clinical trials. The magnitude and breadth of the treatment effect versus placebo across multifaceted aspects of atopic dermatitis provides evidence that a targeted therapy blocking multiple inflammatory pathways could help to address the substantial unmet needs in the treatment of moderate-to-severe atopic dermatitis.

These pivotal findings could potentially transform the treatment goals and standards of care for patients with moderate-to-severe atopic dermatitis.

Professor Alan Irvine, School of Medicine, Trinity College and Principal Investigator said: "Atopic dermatitis is a common inflammatory skin disease which, when severe, has a very significant impact on quality of life. These results are hugely encouraging and will hopefully offer an additional treatment option for patients very soon. The success of this clinical trial also shows the value of investment in our Trinity research facility at St James's Hospital, meaning Irish patients have access to advanced therapies and Irish medical and nursing trainees gain valuable research skills."

The St James's/Trinity Clinical Research Centre is funded by the Wellcome Trust and the Health Research Board (HRB).
Link to full transcript in The Lancet is available at: https://bit.ly/2QB31es

Positive CHMP Opinion Recommending Darzalex Subcutaneous Formulation for Patients with Light-chain (AL) Amyloidosis

Genmab A/S has announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion and recommended granting marketing authorisation for the daratumumab subcutaneous (SC) formulation (daratumumab and hyaluronidase-fihj), known as DARZALEX® SC in the European Union, in combination with bortezomib, cyclophosphamide, and dexamethasone (VCd) for the treatment of adult patients with newly diagnosed systemic light-chain (AL) amyloidosis.

The CHMP also issued a positive opinion recommending DARZALEX SC in combination with pomalidomide and dexamethasone (Pd) for the treatment of adult patients with multiple myeloma who have received one prior therapy containing a proteasome inhibitor (PI) and lenalidomide and were lenalidomide refractory, or who have received at least two prior therapies that included lenalidomide and a PI and have demonstrated disease progression on or after the last therapy. Janssen Pharmaceutica NV submitted Type II variation applications to the EMA for these indications in November 2020. In August 2012, Genmab granted Janssen Biotech, Inc. (Janssen) an exclusive worldwide license to develop, manufacture and commercialize daratumumab.

"We are extremely pleased about the positive CHMP opinions for DARZALEX SC and hopeful that the positive opinion in AL amyloidosis will lead to the first approved treatment option for European patients with this devastating disease," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

About the ANDROMEDA (AMY3001) study
The Phase 3 study (NCT03201965) included 416 patients newly diagnosed with AL amyloidosis. Patients were randomised to receive treatment with either daratumumab and hyaluronidase-fihj in combination with bortezomib (a proteasome inhibitor), cyclophosphamide (a chemotherapy), and dexamethasone (a corticosteroid) or treatment with VCd alone. The primary endpoint of the study was the percentage of patients who achieve hematologic complete response.

About the APOLLO (MMY3013) study
The Phase 3 (NCT03180736), randomised, open-label, multicentre study included 304 patients with multiple myeloma who have previously been treated with lenalidomide and a PI. Patients were randomised 1:1 to either receive daratumumab in combination with Pd or Pd alone. In the original design of the study, patients in the daratumumab plus Pd arm were treated with the intravenous (IV) formulation of daratumumab. As of Amendment 1 to the study protocol, all new subjects in the experimental arm were dosed with the SC formulation of daratumumab and patients who had already begun treatment with IV daratumumab had the option to switch to the SC formulation. The primary endpoint of the study was progression free survival (PFS). The study was conducted in Europe under an agreement between Janssen, the European Myeloma Network (EMN) and Stichting Hemato-Oncologie voor Volwassenen Nederland (HOVON).

Survey reveals 66% of people don't wear sunscreen in summer

Results of a new survey carried out on behalf of LloydsPharmacy show that barely a third (34%) of adults wear sunscreen during the summer months but only when it's a sunny day. Only 16% wear sunscreen every day.

Over 12,000 cases of Non-melanoma skin cancer (NMSC)[1] are diagnosed in Ireland each year with sun exposure acting as the main risk factor.

Even though ''sun holidays" have been off limits, over a quarter (27%) of adults admitted to having experienced sunburn in the last year, with men (33%) more likely than women (22%) to fall into that category.

Denis O'Driscoll Superintendent Pharmacist with LloydsPharmacy says people should follow these basic principles in relation to sunscreen:

(1) **Use more than you think! It is advised that you should use approximately a shot glass of product to cover your body, so don't use it too sparingly.**

(2) **Apply sunscreen 30 minutes before leaving the house to make sure the product has had enough time to soak in.**

(3) **I'm only popping out; do I really need it? In short, yes. It's still exposure, and depending on the time of day, you can get sunburnt quite quickly. Also, 20 minutes can easily turn into 40.**

(4) **Reapply every two hours – yes, that is right, every two hours at least. If you go swimming you should reapply every time you get out of the water. Reapply more frequently if you are sweating a lot as well.**

(5) **Remember to protect your eyes too, make sure that the sunnies you are wearing have UV protection and aren't just stylish!**

LloydsPharmacy research conducted by Empathy Research (Base: All Adults 18+ n=1,018)

1. Irish Cancer Society: https://www.cancer.ie/cancer-information-and-support/cancer-types/skin-cancer/non-melanoma-skin-cancer

MSc in Clinical Pharmacy in UCC

Applications are invited for the two-year (part-time) distance learning MSc in Clinical Pharmacy, which is offered by the School of Pharmacy, University College Cork and which will commence in September 2021.

The course is structured to provide specialist training to enable pharmacists working in hospital and community pharmacies to extend their professional role within the clinical healthcare system.

The course administrators say that the course will help its students to develop a greater understanding of the major pharmacotherapeutic issues of various disease states and a better understanding of the particular needs of patients with these diseases. It will also provide graduates with the skills needed to become leaders in clinical pharmacy services, such as critical appraisal of drug therapies, rational drug use (including pharmacoeconomic evaluation), medication safety management, research project management, presentation skills and report writing.

The distance learning format allows students to remain in employment throughout the course. Students will be able to communicate with each other and the teaching staff by means of regular teleconferences/webinars and interactive internet systems.

Applicants must hold a primary pharmacy degree and, ideally, should have a minimum of one-year practical experience. Applicants must be registered as a pharmacist with the professional accreditation authority in the country in which they are practising.

Closing date for applications is 30 June 2021. Applicants can apply online at www.ucc.ie/apply, and further information about this course is available at www.ucc.ie/en/ckx03/, or by contacting Dr Teresa Barbosa, Programme Director, at t.barbosa@ucc.ie or on 021 490 1792.

Newly elected President of PGEU highlights role played by community pharmacists in pandemic

The Pharmaceutical Group of the European Union has elected Mr. Roberto Tobia, from the Italian Pharmacy Owners Federation (Federfarma) as PGEU President for 2022 and Mr. Raimund Podroschko from the Austrian Chamber of Pharmacists as PGEU Vice-President for 2022.

In his acceptance speech at the PGEU General Assembly meeting, Mr. Tobia praised the work of community pharmacists during the pandemic: "The pandemic has revealed all the strengths and the weaknesses of our health care systems and has clearly shown that community pharmacists, in the front line against Covid-19 since day one, are a strong and indispensable pillar, working with tireless commitment 24/7 at the services of patients. Next year will be crucial for the reshaping of the role of the EU in public health. Many EU legislative initiatives will have a significant impact on pharmacy daily practices, from the revision of the EU pharmaceutical legislation to the creation of an EU health data space.

"Within PGEU will work together to bring the voice of community pharmacists to policy makers and stakeholders and we will also make sure that the important changes of the legislation many countries have implemented to expand the scope of pharmacy practice in response to the emergency will be further consolidated".

A practicing pharmacy owner in Palermo, Sicily, Roberto Tobia is Federfarma National Secretary, Federfarma Palermo's President and Utifar (Technical Union of Italian Pharmacists) Vicepresident. Federfarma represents more than 90 % of Italian private pharmacy owners.

Mr. Podroschko works in a community pharmacy in Vienna. Currently he is president of the Austrian Association of Employed Pharmacists as well as Vice-President of the Austrian Chamber of Pharmacists.

Change to Madopar dosing with respect to food

In May, the HPRA issued a safety notice entitled *Update in dosing information in the Madopar product information with respect to food.*

HPRA safety notice

The HPRA safety notice states: "It was noted that the dosing information (specifically the timing of dosing with respect to food) in the product information for Madopar products was not optimal: it did not make clear that dosing without food is possible and may be preferable for some patients. This update makes the Madopar dosing information with respect to food more consistent with other levodopa-containing medicines and with most clinical guidance."

SPC Section 4.2 Method of Administration – updated the dosing information with respect to food to include the below:

- Where possible, Madopar should be taken in-between meals, so that the competitive effect of dietary protein on levodopa can be avoided and to facilitate a more rapid onset of action;
- A delay between a meal and Madopar dosing may be advisable to avoid lower absorption of levodopa by food; and
- Undesirable gastro-intestinal effects, which may occur mainly in the early stages of the treatment, can largely be controlled by taking Madopar with a low protein snack or liquid or by increasing the dose slowly.

There are three licensed preparations of Madopar available in Ireland – Madopar 200mg/50mg hard capsules, Madopar 100mg/25mg dispersible tablets, and Madopar 50mg/12.5mg dispersible tablets.

Madopar contains two active ingredients – levodopa and bensarazide. The licensed indication is for the treatment of Parkinsonism.

Posology

Madopar 200mg/50mg capsules are only for maintenance therapy once the optimal dosage has been determined using Madopar 100mg/25mg dispersible tablets.

The recommended initial dose is one dispersible tablet of Madopar 50mg/12.5mg three or four times daily. If the disease is at an advanced stage, the starting dose should be one dispersible tablet of Madopar 100mg/25mg three times daily.

The daily dosage should then be increased by one dispersible tablet of Madopar 100mg/25mg, or the equivalent, once or twice weekly until a full therapeutic effect is obtained, or side-effects supervene. In some elderly patients, it may suffice to initiate treatment with one dispersible tablet of Madopar 50mg/12.5mg once or twice daily, increasing by one dispersible tablet every third or fourth day.

The effective dose usually lies within the range of four to eight dispersible tablets of Madopar 100mg/25mg (two to four capsules of Madopar 200mg/50mg) daily in divided doses; most patients require no more than six dispersible tablets of Madopar 100mg/25mg daily. It is rarely necessary to give more than 10 dispersible tablets of Madopar 100mg/25mg (five capsules of Madopar 200mg/50mg) per day. Treatment should be continued for at least six months before failure is concluded from absence of clinical response.

Patients requiring a more rapid onset of action, e.g., patients suffering from early morning or afternoon akinesia, or who exhibit delayed on or wearing off phenomena, are more likely to benefit from Madopar Dispersible.

For patients previously treated with levodopa, levodopa alone should be discontinued and Madopar started on the following day. The patient should be initiated on a total of one less Madopar 100mg/25mg dispersible tablet daily than the total number of 500mg levodopa tablets or capsules previously taken. The patient should be observed for one week and then, if necessary, the dose as outlined for existing patients.

For patients previously treated with other levodopa/decarboxylase inhibitor combinations, the previous therapy should be withdrawn for 12 hours. In order to minimise the potential for any effects of levodopa withdrawal, it may be beneficial to discontinue previous therapy at night and institute Madopar therapy the following morning. The initial

Madopar dose should be one dispersible tablet of Madopar 50mg/12.5mg three or four times daily.

Mode of action

Levodopa, a naturally occurring amino acid, is the immediate precursor of the neurotransmitter dopamine. The actions of levodopa are mainly those of dopamine.

Unlike dopamine, levodopa readily enters the CNS and is used in the treatment of conditions such as Parkinson's disease that are associated with depletion of dopamine in the brain. Levodopa is rapidly decarboxylated by peripheral enzymes. Consequently, levodopa is usually given with a peripheral dopa-decarboxylase inhibitor, such as benserazide or carbidopa, to increase the proportion of levodopa that can enter the brain.

The majority of patients with Parkinson's disease benefit from levodopa therapy, but after two years or more, improvement in disability is gradually lost as the disease progresses and fluctuations in mobility emerge. Postencephalitic parkinsonism responds to levodopa, but a higher incidence of adverse effects has been reported than in the idiopathic form so smaller doses are generally used.

Absorption

Levodopa is rapidly absorbed from the gastrointestinal tract by an active transport system. Most absorption takes place in the small intestine; absorption is very limited from the stomach, and since decarboxylation to dopamine may take place in the stomach wall, delays in gastric emptying may reduce the amount of levodopa available for absorption.

Peak plasma concentrations occur within 1-2 hours of oral doses. Food intake reduces the rate and extent of levodopa absorption by approximately 30% and 15% respectively.

The transport of levodopa into the brain is subject to competition from chemically related amino acids. A high-protein diet has been shown to reduce the therapeutic effect of levodopa. Such alterations in the absorption and transport of levodopa may contribute to the fluctuating responses seen in Parkinson's disease, the so-called 'on-off' phenomenon.

Change to warning label

The previous version of the HPRA SPC for Madopar stated, 'Take with, or immediately after, meals'.

The warning label that was applied to Madopar tablets by us at the NHPC (National Health Products Catalogue), was therefore 'Take with or just after food, or a meal'.

We have now removed this warning label from the NHPC and IPU Product File.

It should be communicated to patients and their carers that, as per the new SPC and Package leaflet, where possible, Madopar should be taken in-between meals, to avoid the effect of dietary protein on levodopa and facilitate a more rapid onset of action. A delay between a meal and Madopar may be advisable to avoid delays in gastric emptying which may reduce the amount of levopdopa available for absorption.

References

HPRA Safety Notice *'Update in dosing information in the Madopar product information with respect to food'*, located at http://www.hpra.ie/docs/default-source/3rd-party-documents/product-information-update-(piu)/product-information-update-madopar-10-may-2021.pdf?sfvrsn=4

Madopar SPC access online 14 May 2021 at https://www.hpra.ie/homepage/medicines/medicines-information/find-a-medicine/results?query=madopar&field=

Martindale: The Complete Drug Reference, accessed at MedicinesComplete 14 May 2021 at https://www.medicinescomplete.com

Praluent Pre-filled Pens

Praluent 75mg and 150mg Pre-filled Pens were added to the High Tech Medicines Scheme in April.

Each single-use pre-filled pen contains 75mg or 150mg alirocumab in 1ml of solution. Alirocumab is a human IgG1 monoclonal antibody produced in Chinese Hamster Ovary cells by recombinant DNA technology.

Indications

- Praluent is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:
  - In combination with a statin or statin with other lipid-lowering therapies in patients unable to reach low density lipoprotein cholesterol (LDL-C) goals with the maximum tolerated dose of a statin; or
  - Alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.
- Praluent is indicated in adults with established atherosclerotic cardiovascular disease to reduce cardiovascular risk by lowering LDL-C levels, as an adjunct to correction of other risk factors:
  - In combination with the maximum tolerated dose of a statin with or without other lipid-lowering therapies; or
  - Alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.

A large body of epidemiological evidence exists demonstrating a strong positive correlation and causal relationship between serum LDL-C, and the risk of coronary heart disease (CHD). Other clinical manifestations of atherosclerosis also appear linked to plasma LDL-C levels such as cerebrovascular disease (i.e., stroke) or peripheral vascular disease.

Epidemiologic data indicates a continuously increasing risk from very low to normal and high levels of LDL-C. A number of interventions to achieve LDL-C control in patients with elevated LDL-C and with high cardiovascular risk are available, such as statins and other lipid-lowering therapies. Often, however, these are not sufficiently effective, or their use is limited by toxicity. Therefore, there is a medical need for new effective and well tolerated treatments of lipid disorders.

Posology and administration

The usual starting dose of alirocumab is 75mg administered subcutaneously once every two weeks.

Patients requiring larger LDL-C reduction (>60%) may be started on 150mg once every two weeks, or 300mg once every four weeks, administered subcutaneously.

The dose of alirocumab can be individualised based on patient characteristics such as baseline LDL-C level, goal of therapy, and response. Lipid levels can be assessed four to eight weeks after treatment initiation or titration, and dose adjusted accordingly.

Alirocumab is injected as a subcutaneous injection into the thigh, abdomen or upper arm. Each pre-filled pen is for single use only.

It is recommended to rotate the injection site with each injection. Alirocumab should not be injected into areas of active skin disease or injury such as sunburn, skin rashes, inflammation, or skin infections. It must not be co-administered with other injectable medicinal products at the same injection site. The patient may either self-inject alirocumab, or a caregiver may administer alirocumab, after guidance has been provided by a healthcare professional on proper subcutaneous injection technique. The solution should be allowed to warm to room temperature prior to use. In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Mode of action

Alirocumab is a fully human IgG1 monoclonal antibody that binds with high affinity and specificity to proprotein convertase subtilisin kexin type 9 (PCSK9). PCSK9 binds to the low-density lipoprotein receptors (LDLR) on the surface of hepatocytes to promote LDLR degradation within the liver. LDLR is the primary receptor that clears circulating LDL, therefore the decrease in LDLR levels by PCSK9 results in higher blood levels of LDL-C.

By inhibiting the binding of PCSK9 to LDLR, alirocumab increases the number of LDLR available to clear LDL, thereby lowering LDL-C levels.

Adverse reactions and drug interactions

General allergic reactions, including pruritus, as well as rare and sometimes serious allergic reactions such as hypersensitivity, nummular eczema, urticaria, and hypersensitivity vasculitis have been reported in clinical studies. If signs or symptoms of serious allergic reactions occur, treatment with alirocumab must be discontinued and appropriate symptomatic treatment initiated.

Alirocumab should be used with caution in patients with severe renal or severe impairment.

Since alirocumab is a biological medicinal product, no pharmacokinetic effects of alirocumab on other medicinal products and no effect on cytochrome P450 enzymes are anticipated.

Statins and other lipid-modifying therapy are known to increase production of PCSK9, the protein targeted by alirocumab. This leads to the increased target-mediated clearance and reduced systemic exposure of alirocumab. Compared to alirocumab monotherapy, the exposure to alirocumab is about 40%, 15%, and 35% lower when used concomitantly with statins, ezetimibe, and fenofibrate, respectively. However, reduction of LDL-C is maintained during the dosing interval when alirocumab is administered every two weeks.

The use of Praluent is not recommended during pregnancy unless the clinical condition of the woman requires treatment with alirocumab.

It is not known whether alirocumab is excreted in human milk. Human immunoglobulin G (IgG) is excreted in human milk, in particular in colostrum. The use of Praluent is not recommended in breast-feeding women during this period. For the remaining duration of breast-feeding, exposure is expected to be low. Since the effects of alirocumab on the breast-fed infant are unknown, a decision should be made whether to discontinue breast-feeding or to discontinue Praluent.

Praluent has no or negligible influence on the ability to drive and use machines.

Storage and pack details

Praluent must be stored in the pharmacy in a refrigerator (2°C to 8°C). Praluent can be stored outside the refrigerator (below 25°C) protected from light for a single period not exceeding 30 days. After removal from the refrigerator, the medicinal product must be used within 30 days or discarded.

The pre-filled pens are marketed in packs of two pens:

- *Praluent 75mg 2 x pre-filled pens, GMS number 89070*
- *Praluent 150mg 2 x pre-filled pens, GMS number 89071*

Praluent was first authorised by the EMA in 2015 and was added to the IPU Product File with the April 2021 update, following addition to the High Tech Scheme.

Further information on the assessment of Praluent can be found in the European Public Assessment Report and SmPC on the EMA website at https://www.ema.europa.eu/en/medicines/human/EPAR/praluent.

First of the summer wine

Brigid O'Hora of 'Virtual Vineyards' recommends some suitable wines to accompany the pandemic era outdoor Irish summer

So finally, it seems the restrictions are lifting, the clouds are parting, the sun cream is flying, albeit for a rainy start so far. But the gist is, summer is coming. Hurrah!

Indeed, we have so much to be thankful for. Gratitude is in full swing. But before we get carried away, we do have the minor issue of an outdoor summer. Now this ordinarily sounds like bliss, but when reality kicks in for us good hearted Irish, we know that summer is a mixed bag of all sorts. Forty seasons in one day. I was once at a wedding in Achill island in August and we were literally swept like drowned cats into the church. Not even 'Ellnet' could have tamed the Atlantic swept gruaig on everyone that day. We Irish though, are the absolute warriors of outdoor activities and now outdoor socialising. When planning those long lazy picnics, or glitzy summer garden parties, let's look at a few wines that have the accessible appeal to them.

The veritable 'bag of cans' is the handiest form of consuming your well-earned refreshments on your outdoor escapades. But Bulmers or Guinness don't really do it for me to match my beautifully curated charcuterie. I prefer wine.

Thankfully now, wine producers have broken the mould of the traditional glass bottle and we can grab ourselves a 'bag of cans' of a Pinot Grigio, or a Rosé or a Prosecco. Truthfully though, many of these cans that are available in the larger supermarkets are a little devoid of flavour or character. I recently tried **'Liberator'** in a can. This is a stunning Chenin Blanc from South Africa that has been created and perfected by the Master of Wine, Richard Kelley. He believes, like many others, that the future of sustainability in the wine industry lies with recyclable packaging. And why compromise on quality and taste for this aspect of innovation. He has managed to create smaller production wines with real zest and intrigue and 'can' them! We as consumers are now offered the experience to sip away on fine Chenin Blanc, that has a touch oak ageing and bracing notes of baked lemons and green apples on the palate to slice perfectly through your cured salty meats. If it is a choice between the wines in a can from the larger supermarkets and this sleek and succulent Chenin Blanc that is available online from Boutique Wines, I think I know where my choice would be. It is just the matter of being a little more organised, and pre-ordering your cans before your park date.

Maybe a Chenin is too serious for you. So now the innovative guys at Winelab Ireland have brought out **Ramona** in a can. This is a Sommelier-created spritz made with the highest quality organic ingredients, sustainable production methods, no added sugar, no gluten, basically no artificial anything. It is considered Ramona is one of the best fine wine options in a can. This gentle spritz make them ideal with creamy cheeses or even a country terrine. And how handy they are in terms of resting all your little picnic bits on the blanket, and the chilled can stays rock steady in its position. Can you imagine trying to achieve the same result, with your wine opener, propping the wine glasses up against your picnic box, squeezing the cork back into the bottle, one eye on the glasses and another on the neighbouring dog that is sniffing around and generally making a nuisance of himself. Eh . . . cans please!

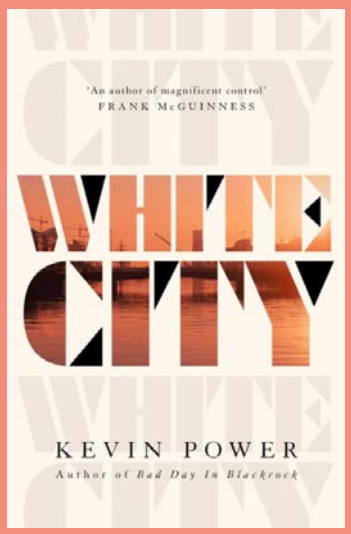
In the interest of sustainability, but primarily our outdoor enjoyment also, Winelab has released a **'Bagnum'** for the summer. This is a double bottle wine bag that sits ideally into your tote bag for any summer garden party or indeed an evening bbq. The Bagnum is available in Sauvignon Blanc, Pinot Grigio and Refresco (Red). These sleek 15-litre bags stay fresh once opened for six weeks. So perhaps you enjoy a glass on a Monday or early week, but just the one, this is the option that allows you to have your favourite wine in the fridge fresher for longer. These wines

are produced in the Fruili region of Northern Italy. This is one of the top-quality regions in Italy that consistently produces aromatic well-balanced wines, that far exceed expectations of 'wine in a bag'. Again, giving us the option to pop this pre-chilled bag into your cool box of goodies and off we go to our picnic or garden party with serious quality and accessibility for our wine pleasure.

If you are a traditionalist at heart and are still swayed towards the bottle and glasses for your outdoor escapades, then I would highly recommend a compact picnic table from the inventive guys at Flying Elephant. Here you can source a picnic table that will hold your bottle and four wine glasses also, out of the way of preying dogs or cats or your own busy wobbly hands that are destined to knock things over. These flatpack tables come with a laminate easy wipe top, bottle, and glass holders. They are small enough to repack back into your tote bag and leave no major lugging around. If this is the case, a bottle of **Cremant Rosé** is a must. Cremant is the affordable style bubbles produced in regions all over France minus the Champagne price tag. These styles of wines are some of the most food friendly in the world. The tiny persistent bubbles slice right through any fatty meats and refreshen the palate. The abundant strawberries and raspberries are perfect at contrasting with salty cheese and cured meats. Plus, the addition of pink bubbles from a proper champagne glass in the sun is a little bit special. This Cremant from the Loire produced by the Bollinger owned Langlois is a gorgeous example of summer in a glass. And in truth I would probably rather this is in a flute glass poured from the bottle itself. Horses for courses eh . . .

The Village Bookshelf

The Village Bookshop in Terenure, Dublin, picks out some new and interesting titles from their shelves. An independent, family-run bookstore since 2013, they carry new, used, rare and out-of-print books and offer special nationwide postal rates.



White City

Kevin Power

From the author of *Bad Day in Blackrock* (inspiration for award-winning film *What Richard Did*, by Lenny Abrahamson), this is a darkly funny, gripping novel about a life spinning out of control. Abruptly cut off, at the age of 27, from a life of heedless privilege, Ben (only son of a rich South Dublin banker) flounders through a world of drugs and dead-end jobs, his self-esteem at rock bottom. Then he gets involved with a shady property deal in the Balkans which can deliver him from all his troubles: his addictions, his father's very public disgrace, and his own self-loathing and regret. Problem solved. Except his problems have only begun! Very entertaining with story twists that keep you turning the page.

First Person Singular

Haruki Murakami

Eight stories told in the first person by a classic Murakami 'magic-realist' narrator. From nostalgic memories of youth, meditations on music and an ardent love of baseball to dreamlike scenarios, an encounter with a talking monkey and invented jazz albums, together these stories challenge the boundaries between our minds and the exterior world. Occasionally, a narrator who may or may not be Murakami himself is present. Is it memoir or fiction? You can decide! Philosophical and mysterious, the stories touch on love and solitude, childhood and memory. Murakami may not be to everybody's taste, but certainly worth trying!

The Best Catholics in the World

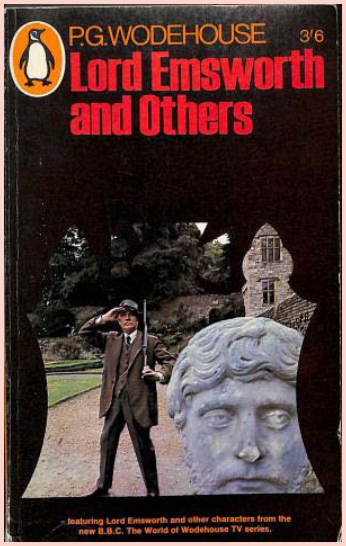
Derek Scally

On a visit home from Berlin, Dublin journalist Derek Scally finds more memories than congregants in the church where he was once an altar boy. This book is his resulting quest to unravel what happened to the remarkable hold the Catholic Church had on the Irish people. He spent three years travelling Ireland and Europe, talking to those who have abandoned the Church and those who have held on, to survivors and campaigners, to writers, historians, psychologists and many more. A great work of reporting and a lively read. Colm Toibin called it 'a great achievement - brilliant, engaging and essential'.

Lord Emsworth and Others

P.G Wodehouse

From our secondhand corner. Wodehouse is renowned for his limitless powers of comic invention. In the title story – one of his longest and best shorter fictions – Lord Emsworth takes his revenge on his ghastly secretary, the Efficient Baxter, setting off a wave of similar reprisals at Blandings Castle with amazing results. In other tales we meet several members of the Drones Club, the ineffable Ukridge, and Clarice Fitch, 'the girl who used to fly oceans and things'. A delightful meeting with old friends for some readers, a superb introduction to the idyllic world of Wodehouse for others.



What White People Can Do Next

Emma Dabiri

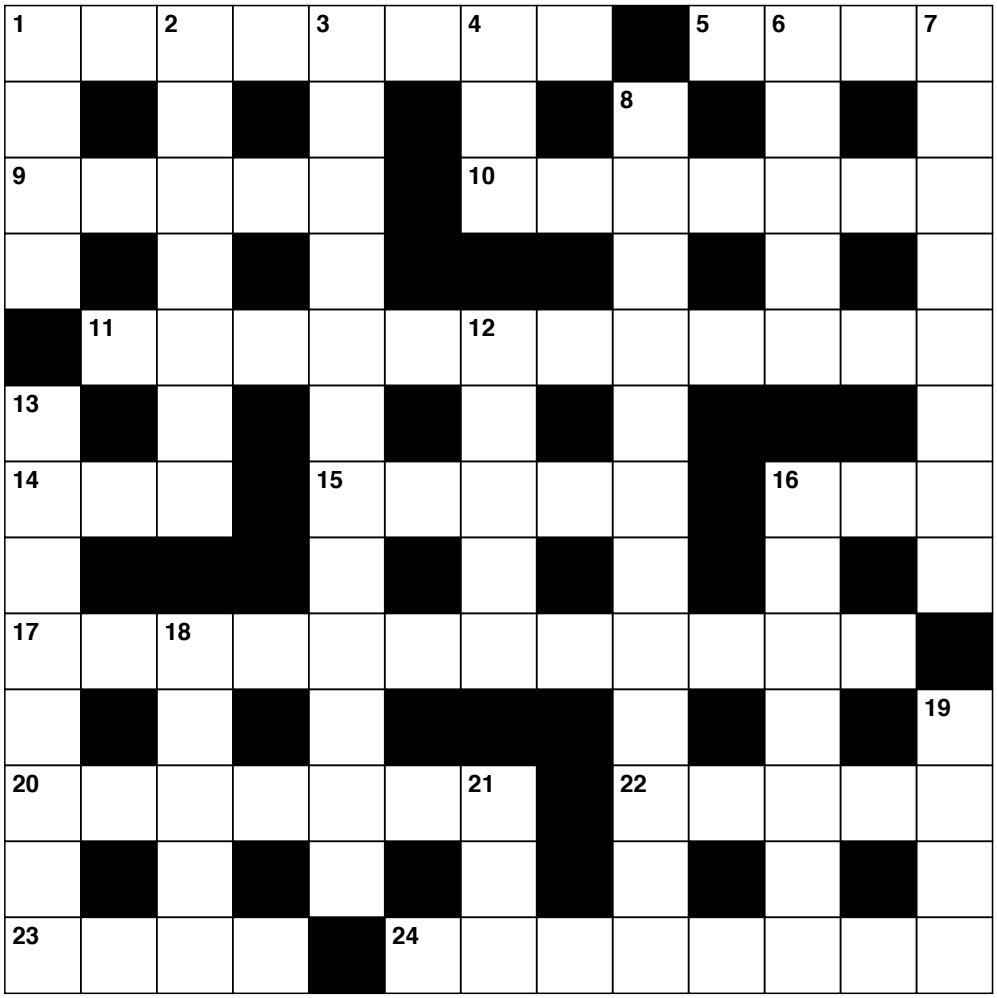
Emma Dabiri, acclaimed author of *Don't Touch My Hair*, grew up mixed-race in Dublin and is now a teaching fellow in the Africa department at School of Oriental & African Studies in London. She's a regular media contributer with a distinct perspective and in this short book she reviews current attitudes to race and how they might be improved. When it comes to racial justice, how do we transform demonstrations of support into real and meaningful change? With intellectual rigour and razor-sharp wit, she manages to cut through the haze of online discourse to offer clear advice. An incisive and practical book.

Kindness Grows

Britta Teckentrup

A peek-through picture book for 2-5 year olds. Angry words can ruin friendships, but a gesture as simple as a smile can cause kindness to bloom and friendships to mend. Die-cut pages feature a sapling that grows into a flowering tree with each turn of the page as kindness is spread. Friends are sad when they're left out, and once a mean word is spoken, it's impossible to take it back. But what if we were to spread kindness instead? A sweet book, great for teaching the importance and relevance of being kind to others, especially our new friends.

CROSSWORD



The answers to the *IPU Review* crossword will be published in next months' edition.

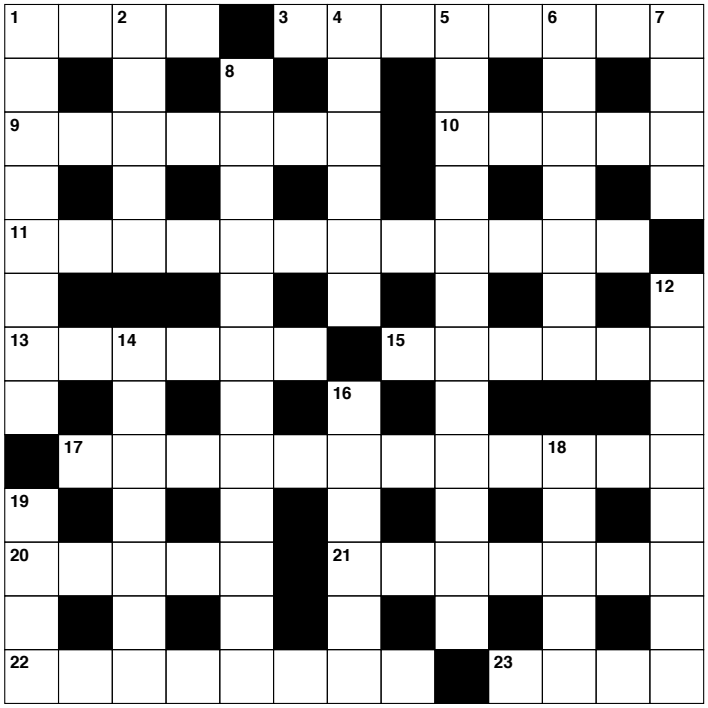
Across

1. Inducing sleep (8)
5. Unravel (4)
9. Reproductive unit of fungi (5)
10. Makes certain of (7)
11. Large grocery stores (12)
14. Stimulus (3)
15. Danger (5)
16. Great distress (3)
17. Inflexible (12)
20. Vague understanding; hint (7)
22. Verify (5)
23. Church service (4)
24. Hairdressers (8)

Down

1. Sound of a snake (4)
2. Give rise to (7)
3. Excessive stress (12)
4. Anger (3)
6. The Norwegian language (5)
7. Completely preoccupied with (8)
8. Relating to horoscopes (12)
12. Scores an exam paper (5)
13. Policy of direct action (8)
16. Is curious about (7)
18. Gains possession of (5)
19. Seek (anag) (4)
21. Acquire; obtain (3)

Last month's solution *(May 2021 issue)*



Anti-Hist ALLERGY

10mg Film-coated Tablets AND 1mg/ml oral solution

CETIRIZINE DIHYDROCHLORIDE

All Day Allergy Relief

For the relief of allergic rhinitis and urticaria

For the relief of symptoms of hay fever and other allergic conditions, skin rashes or itchy, watery eyes.

ORAL SOLUTION

ADULTS & CHILDREN AGED 2 YEARS AND OVER

1mg/ml oral solution

Available in 200ml bottle.

ADULT DOSE

ONE-A-DAY

Anti-Hist Allergy 10mg Film-coated Tablets

Available in 30 pack and 7 pack.

Contraindications: Hypersensitivity to the active ingredient, any of the excipients, hydroxyzine or to any piperazine derivatives. Patients with severe renal impairment at less than 10ml/minute creatinine clearance.

Medicinal product not subject to medical prescription. A copy of the summary of product characteristics is available upon request.

PA 126/267/1-2. PA Holder: Clonmel Healthcare, Waterford Road, Clonmel, Co. Tipperary.
Date prepared: May 2018. 2018/ADV/ANT/057.

CLONMEL HEALTHCARE