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irishpharmacist

for all that matters in pharmacy

SAFETY FIRST

EXCLUSIVE COVERAGE FROM THE RECENT IRISH MEDICATION SAFETY NETWORK ANNUAL CONFERENCE

ABOUT-TURN

WE LOOK AT WHAT MIGHT BE NEXT FOR PHARMACISTS FOLLOWING THE REVERSAL IN PROPOSED FEE CUTS

DUMB AND DUMBER?

ARE PHARMACISTS A LITTLE LACKING IN GREY MATTER WHEN IT COMES TO PRICING, ASKS FINTAN MOORE

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CCF:22656 Date of preparation: (10-19)

ABBREVIATED PRESCRIBING INFORMATION

Product Name: Emazole Control 20 mg Gastro-Resistant Tablets
Composition: Each tablet contains 20 mg esomeprazole (as magnesium dihydrate).
Description: Light pink oval film coated tablet.
Indication(s): Proton Pump Inhibitor (PPI): Short-term treatment of reflux symptoms (e.g. heartburn and acid regurgitation) in adults. **Dosage:** Swallow tablets whole with liquid, do not chew or crush. Disperse in half a glass of non-carbonated water if difficulty in swallowing. Stir until tablets disintegrate, drink liquid with pellets immediately or within 15 min, or administer through a gastric tube. Do not chew or crush pellets. **Adults:** The recommended dose is 20 mg esomeprazole (one tablet) per day. It might be necessary to take the tablets for 2-3 consecutive days to achieve improvement of symptoms. Duration of treatment is up to 2 weeks. Once complete relief of symptoms has occurred, treatment should be discontinued. If no symptom relief is obtained within 2 weeks of continuous treatment, the patient should be instructed to consult a doctor. **Elderly (≥ 65 years old):** As per adults. **Paediatric population (< 18 years):** Not recommended. No relevant use in this group in the indication: "short-term treatment of reflux symptoms (e.g., heartburn and acid regurgitation)". **Severe impaired renal function:** Caution. **Severe liver impairment:** 20 mg max daily dose.
Contraindications: Hypersensitivity to esomeprazole, substituted benzimidazoles or any of the excipients. Not with nelfinavir. **Warnings and Precautions for Use:** On demand treatment: Contact a physician if symptoms change in character. In the presence of any alarm symptom (e.g. significant unintentional weight loss, recurrent vomiting, dysphagia, haematemesis or melaena) and when gastric ulcer is suspected or present, malignancy should be excluded, as treatment with esomeprazole may alleviate symptoms and delay diagnosis. Treatment with proton pump inhibitors (PPIs) may lead to a slightly increased risk of gastrointestinal infections such as *Salmonella* and *Campylobacter* and in hospitalised patients, also possibly *Clostridium difficile*. Patients should consult their doctor before taking this medicinal product if they are due to have an endoscopy or urea breath test. Absorption of vitamin B12 may be reduced due to hypo- or achlorhydria. Not recommended for long-term use as the following may also occur: Hypomagnesaemia; Risk of fracture. Consider stopping Emazole Control in cases of Subacute cutaneous lupus erythematosus (SCLE) accompanied by arthralgia. Interference with laboratory tests: Increased Chromogranin A (CgA) level may interfere with investigations for neuroendocrine tumours. To avoid this interference, Emazole Control treatment should be stopped for at least 5 days before CgA measurements. If CgA and gastrin levels have not returned to reference range after initial measurement, measurements should be repeated 14 days after cessation of PPI treatment. Contains glucose and sucrose.
Interactions: Effect of esomeprazole on other drugs: Co-administration with atazanavir is not recommended. If the combination of atazanavir with a PPI is judged unavoidable, close clinical monitoring is recommended in combination with an increase in the dose of atazanavir to 400 mg with 100 mg of ritonavir; esomeprazole 20 mg should not be exceeded. Esomeprazole is a CYP2C19 inhibitor. When starting or ending treatment with esomeprazole, the potential for interactions with drugs metabolised through CYP2C19 should be considered. Serum levels of cilostazol, cisapride, tacrolimus, methotrexate may be increased. An interaction is observed between clopidogrel and esomeprazole, but the clinical relevance is uncertain. As a precaution, concomitant use of esomeprazole and clopidogrel should be discouraged. Gastric acid suppression by PPIs increase or decrease absorption of drugs with pH dependent absorption (decreased absorption of ketoconazole, itraconazole); esomeprazole inhibits CYP2C19 metabolising enzyme and could increase plasma concentrations of diazepam, citalopram, imipramine, clomipramine, phenytoin (monitor plasma levels of phenytoin), etc. resulting in need of a dose reduction; monitor INR when given with warfarin or similar. Caution as absorption of digoxin can increase. Effect of other drugs on esomeprazole: CYP2C19 and CYP3A4 inhibitors (clarithromycin, voriconazole) may increase the esomeprazole exposure. Dose adjustment not regularly required, except in severe hepatic impairment and long-term use. CYP2C19 and/or CYP3A4 inducers (rifampicin and St. John´s wort) may lead to decreased esomeprazole serum levels by increasing the esomeprazole metabolism.
Pregnancy and Lactation: Caution in pregnancy due to lack of clinical data. No studies in lactating women, therefore, not recommended during breast-feeding. **Ability to Drive and Use Machinery:** Minor influence on the ability to drive or use machines. Adverse reactions such as dizziness (uncommon) and blurred vision (rare) have been reported. If affected, patients should not drive or use machines. **Undesirable Effects:** Common: Headache, abdominal pain, constipation, diarrhoea, flatulence, nausea/vomiting, fundic gland polyps (benign). Uncommon: Peripheral oedema, insomnia, dizziness, paraesthesia, somnolence, vertigo, dry mouth, increased liver enzymes, dermatitis, pruritis, rash, urticaria, fracture of the hip, wrist or spine. For other side effects refer to the SPC.
Marketing Authorisation Holder: IQ Pharmatek Ltd., Gurtnafleur, Old Waterford Road, Clonmel, Co. Tipperary. **Marketing Authorisation Number:** PA 22777/001/001. Further information and SPC are available from: Rowex Ltd, Bantry, Co. Cork. Freephone: 1800 304 400 Fax: 027 50417. E-mail rowex@rowa-pharma.ie
Legal Category: Not subject to medical prescription.
Date of Preparation: September 2019

Adverse events should be reported. Reporting forms and information can be found on the HPRA website (www.hpra.ie) or by emailing medsafety@hpra.ie or by emailing Rowex pv@rowa-pharma.ie

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PHARMACIST PRESCRIBING

ICGP green-lights pharmacist prescribing model

A "highly-trained pharmacist prescriber" under the governance and supervision of a managing GP would be "an additional valuable resource in the community", the ICGP has stated.

Responding to questions on the future role of community pharmacists in Ireland, a College spokesperson said: "If care is shared with GPs and is guided and directed by the GP, then a pharmacist prescriber would add to the community support team for patients. Pharmacist prescribers would require extra training and thorough and comprehensive guidelines and protocols in order to ensure patient safety and wellbeing."

The College also issued a positive opinion on a potential minor ailments scheme in pharmacy, subject to certain conditions being met, which is a departure from a previous standpoint communicated in 2016.

"Community pharmacists already treat several minor ailments, such as minor coughs and respiratory infections and some skin infections, among other ailments, and this of course helps to reduce pressure on the hospital emergency services and on other parts of the health service," stated a College spokesperson last month.

"A community pharmacist-provided minor ailments scheme would require clear guidelines, protocols and governance structures, as well as training of pharmacy support staff."

See feature, p16 ▸

CLEAN SWEEP OF PRIZES FOR CENTRE FOR PAIN RESEARCH AT NUIG

Researchers from NUI Galway's Centre for Pain Research recently received prestigious prizes for their research at the Annual Scientific Meeting of the Irish Pain Society 2019, continuing an impressive track record of success in these competitions. Researchers from the Centre won prizes in every research category at the event. **Ms Orlaith Mannion** won Best Presentation at the Irish Pain Research Network short oral data blitz for her short presentation demonstrating that drugs which boost levels of the body's own marijuana-like cannabinoids have potential for effective treatment of postoperative pain following groin hernia repair. **Ms Rachel Humphrey** won the Irish Pain Society Preclinical Research Medal for her poster demonstrating that alterations in pain processing may be a feature of autism spectrum disorder symptomatology, and pinpointing brain regions that could be implicated. **Ms Mehnaz Ferdousi** won second prize in the Preclinical Poster category for her Science Foundation Ireland-funded research on the effects of novel opioid drugs on pain, anxiety and depression-related behaviour. **Ms Monika Pilch** won the Irish Pain Society Clinical Research Medal for Best Clinical Poster on how perspective-taking influences what we pay attention to when evaluating facial expressions of pain. **Ms Nessa Sweeney** won second prize in the clinical poster category for her work examining the experience of young Irish mentors supporting adolescents with juvenile idiopathic arthritis.

SAFETY INCIDENTS

Department of Health working on legislation for mandatory open disclosure

The recent Irish Medication Safety Network (IMSN) Annual Conference 2019, held in the RCSI, heard from Ms Marita Kinsella, Director of the National Patient Safety Office at the Department of Health, who told the attendees that the Department is currently working on the preparation of a bill that will require mandatory open disclosure of serious patient safety incidents and events.

Ms Kinsella told the conference, which was held under the theme 'Medication Without Harm: Responding to the Challenge': "As a health service, openness and honesty with patients must be at the heart of everything we do. Open disclosure must happen in the right way and in all circumstances — patients have to be informed.

"We have seen all too clearly arising from a number of serious patient safety incidents over recent years the impact that failure of open disclosure can have on patients. It's important that we're all committed to learning from these events and embedding a culture of ensuring that patients are treated in a way that they would most like to be treated when things go wrong, that they perceive a sincere and genuine apology, and to be sure that what has happened to them will not happen to anybody else," she continued.

"We need to ensure that the culture of trust and confidence between patients and clinicians prevails. Within the team at the National Patient Safety Office, we have been working on a new patient safety bill, which will focus on mandatory open disclosure of the most serious patient safety incidents. This will ensure that patients and their families affected by a serious incident will be assured of receiving appropriate and timely information in relation to an unintended or anticipated serious event that may have occurred in relation to their care."

Ms Kinsella added that the mandatory disclosure bill will also require notification of the most serious patient safety events and incidents to HIQA and the Mental Health Commission, as appropriate, to ensure system-wide improvements. However, she described the legislation as a "blunt tool" to embed a culture of openness and transparency in cases of serious incidents. "Ensuring that patients and their families are treated honestly and openly when things go wrong also requires personal commitment from all of us who work in the health service," she added.

Ms Marita Kinsella

See conference coverage on p10-15

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PHARMACY CONTRACT

IPU welcomes Minister's commitment to pharmacy contract talks in 2020

The Irish Pharmacy Union (IPU) welcomed what it called the "sensible" decision by the Minister for Health Simon Harris not to proceed with the proposed cuts in fees to pharmacies and, instead, to recommit to early talks on a new pharmacy contract and investment in pharmacy services.

Deep cuts to pharmacy fees were proposed by the Department of Health in October 2019 and, following a concerted effort by pharmacists to push back against these further fee cuts, Minister Harris met with the IPU late last year and announced his decision not to introduce the cuts, but to leave fees as they are and to start contract talks early in the New Year.

Speaking after the meeting, IPU Secretary General Mr Darragh O'Loughlin said: "While this reprieve is welcome, a significant increase in resources is urgently needed to meet the ever-increasing costs of providing the existing service, to ensure the viability of community pharmacy and to allow pharmacists to deliver on their commitment to ongoing service development and reform, which will have significant benefits for patients and the public."

Mr O'Loughlin continued: "When the proposed cuts were announced in October, Ireland's 2,300 community pharmacists were left deeply shocked and concerned and warned that these unfair and unjustifiable cuts would hit rural, disadvantaged and isolated pharmacies hardest. Any funding cuts would also go completely against the Government's Sláintecare strategy, which aims to keep health services in the local community.

"We are pleased that Minister Harris kept the promise he made at the National Pharmacy Conference in May this year, when he acknowledged the previous cuts to pharmacists' incomes that had been imposed during the financial crisis and the resulting financial pain felt by pharmacists and stated the Government's intention to unwind those cuts. He also committed to starting talks on a new pharmacy contract.

"New contract talks will also include discussions on an expansion of healthcare services in pharmacy," Mr O'Loughlin commented. "As we continue into the winter months and a rising trolley count, this will deliver real benefits for patients and will take pressure off the rest of the health system and in particular overstretched accident and emergency departments and GP clinics. We look forward to working with Minister Harris and his officials in the New Year, and ensuring Irish patients are able to fully benefit from the professional expertise of their local pharmacist."

PHARMACY BUSINESS

New scheme initiated to help pharmacists launch their own business

Irish pharmacy group totalhealth has launched a new scheme, which it says will "revitalise the local Irish pharmacy industry". The 'Pharmacy Assistance Purchase Scheme (PAPS)' aims to facilitate Irish pharmacists with the launch of their own business. The purpose of the scheme is to remove some of the barriers faced by pharmacists who wish to become pharmacy owners by providing financial assistance and business support.

The landscape for independent pharmacies is challenging and for pharmacists who wish to establish their own local operation and serve their local community, the task is becoming more difficult, said totalhealth. The scheme aims to support aspiring pharmacy owners through the PAPS initiative by assisting financially with the launch of the business, alongside an established Irish financial institution.

The scheme will also see the pharmacies open under the totalhealth symbol group, which currently has 80 pharmacies nationwide, and the PAPS initiative is part-funded by totalhealth member investors and will provide financial assistance to those wishing to purchase a pharmacy.

Mr John Arnold, Managing Director of totalhealth Pharmacy, commented: "We want to facilitate pharmacists with the PAPS scheme in achieving their goal of owning and operating their own pharmacy. I have seen the struggles faced by both current and potential pharmacy owners. Raising capital is a major barrier to entry, with financial institutions requiring a significant percentage of the purchase price up-front. Potential owners are also aware of the difficulties of running a pharmacy; operational costs can be daunting. By buying a pharmacy within an established symbol group such as totalhealth, owners have all the benefits of working with an overarching, recognisable brand, as well as an alleviation of the financial constraints, giving aspiring pharmacy owners a fair start on their business journey".

PAPS Chairperson Mr Rory O'Donnell added: "It's almost as difficult for a pharmacist to sell their business as it is for someone to buy it. With this new scheme, we're helping at both ends of the process, as well as offering our existing members a unique investment opportunity. Pharmacy owners wishing to retire or sell their businesses can be confident that their patients and customers will continue to receive a high standard of service and care when they do."

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Abbreviated Prescribing Information

Please refer to the Summary of Product Characteristics (SmPC) before prescribing **Pelgraz▼** (pegfilgrastim) **6 mg solution for injection in pre-filled syringe or pre-filled injector. Presentation: Pelgraz 6 mg solution for injection in pre-filled syringe:** Each pre-filled syringe contains 6 mg of pegfilgrastim* in 0.6 mL solution for injection. The concentration is 10 mg/mL based on protein only**. **Pelgraz 6 mg solution for injection in pre-filled injector:** Each pre-filled injector contains 6 mg of pegfilgrastim* in 0.6 mL solution for injection. The concentration is 10 mg/mL based on protein only**. *Produced in *Escherichia coli* cells by recombinant DNA technology followed by conjugation with polyethylene glycol (PEG). ** The concentration is 20 mg/mL if the PEG moiety is included. **Indications**: Reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes). **Dosage and Administration**: Pelgraz therapy should be initiated and supervised by physicians experienced in oncology and/or haematology. Posology: One 6 mg dose (a single pre-filled syringe or pre-filled injector) of Pelgraz is recommended for each chemotherapy cycle, given at least 24 hours after cytotoxic chemotherapy. Safety and efficacy of Pelgraz in children and adolescents has not yet been established. No dose change is recommended in patients with renal impairment, including those with end-stage renal disease. **Method of administration:** Pelgraz is for subcutaneous use. The injections should be given subcutaneously into the thigh, abdomen or upper arm. See SPC for instructions on handling of the medicinal product before administration. **Contraindications**: Hypersensitivity to pegfilgrastim or any of the excipients in Pelgraz. **Warnings and precautions**: In order to improve the traceability of biological medicinal products, the trade name of the administered product should be clearly recorded. The long-term effects of pegfilgrastim have not been established in acute myeloid leukaemia (AML); therefore, it should be used with caution in this patient population. Granulocyte-colony stimulating factor can promote growth of myeloid cells *in vitro* and similar effects may be seen on some non-myeloid cells *in vitro*. The safety and efficacy of pegfilgrastim have not been investigated in patients with myelodysplastic syndrome, chronic myelogenous leukaemia, and in patients with secondary AML; therefore, it should not be used in such patients. Particular care should be taken to distinguish the diagnosis of blast transformation of chronic myeloid leukaemia from AML. The safety and efficacy of pegfilgrastim administration in *de novo* AML patients aged < 55 years with cytogenetics t(15;17) have not been established. The safety and efficacy of pegfilgrastim have not been investigated in patients receiving high dose chemotherapy. This medicinal product should not be used to increase the dose of cytotoxic chemotherapy beyond established dose regimens. Pulmonary adverse reactions, in particular interstitial pneumonia, have been reported after G-CSF administration. Patients with a recent history of pulmonary infiltrates or pneumonia may be at higher risk. The onset of pulmonary signs such as cough, fever, and dyspnoea in association with radiological signs of pulmonary infiltrates, and deterioration in pulmonary function along with increased neutrophil count may be preliminary signs of Adult Respiratory Distress Syndrome (ARDS). In such circumstances pegfilgrastim should be discontinued at the discretion of the physician and the appropriate treatment given. Glomerulonephritis has been reported in patients receiving filgrastim and pegfilgrastim. Generally, events of glomerulonephritis resolved after dose reduction or withdrawal of filgrastim and pegfilgrastim. Urinalysis monitoring is recommended. Capillary leak syndrome has been reported after granulocyte-colony stimulating factor administration and is characterised by hypotension, hypoalbuminaemia, oedema and haemoconcentration. Patients who develop symptoms of capillary leak syndrome should be closely monitored and receive standard symptomatic treatment, which may include a need for intensive care. Generally asymptomatic cases of splenomegaly and cases of splenic rupture, including some fatal cases, have been reported following administration of pegfilgrastim. Therefore, spleen size should be carefully monitored (e.g. clinical examination, ultrasound). A diagnosis of splenic rupture should be considered in patients reporting left upper abdominal pain or shoulder tip pain. Treatment with pegfilgrastim alone does not preclude thrombocytopenia and anaemia because full dose myelosuppressive chemotherapy is maintained on the prescribed schedule. Regular monitoring of platelet count and haematocrit is recommended. Special care should be taken when administering single or combination chemotherapeutic medicinal products which are known to cause severe thrombocytopenia. Sickle cell crises have been associated with the use of pegfilgrastim in patients with sickle cell trait or sickle cell disease. Therefore, physicians should use caution when prescribing pegfilgrastim in patients with sickle cell trait or sickle cell disease, should monitor appropriate clinical parameters and laboratory status and be attentive to the possible association of this medicinal product with splenic enlargement and vasoocclusive crisis. White blood cell (WBC) counts of 100 x 10^9/L or greater have been observed in less than 1% of patients receiving pegfilgrastim. No adverse reactions directly attributable to this degree of leukocytosis have been reported. Such elevation in WBCs is transient, typically seen 24 to 48 hours after administration and is consistent with the pharmacodynamic effects of this medicinal product. Consistent with the clinical effects and the potential for leukocytosis, a WBC count should be performed at regular intervals during therapy. If leukocyte counts exceed 50 x 10^9/L after the expected nadir, this medicinal product should be discontinued immediately. Hypersensitivity, including anaphylactic reactions, occurring on initial or subsequent treatment have been reported in patients treated with pegfilgrastim. Permanently discontinue pegfilgrastim in patients with clinically significant hypersensitivity. Do not administer pegfilgrastim to patients with a history of hypersensitivity to pegfilgrastim or filgrastim. If a serious allergic reaction occurs, appropriate therapy should be administered, with close patient follow-up over several days. As with all therapeutic proteins, there is a potential for immunogenicity. Rates of generation of antibodies against pegfilgrastim is generally low. Binding antibodies do occur as expected with all biologics; however, they have not been associated with neutralising activity at present. Aortitis has been reported after filgrastim or pegfilgrastim administration in healthy subjects and in cancer patients. The symptoms experienced included fever, abdominal pain, malaise, back pain and increased inflammatory markers (e.g. C-reactive protein and WBC count). In most cases aortitis was diagnosed by CT scan and generally resolved after withdrawal of filgrastim or pegfilgrastim. The safety and efficacy of Pelgraz for the mobilisation of blood progenitor cells in patients or healthy donors has not been adequately evaluated. Increased haematopoietic activity of the bone marrow in response to growth factor therapy has been associated with transient positive bone-imaging findings. This should be considered when interpreting bone-imaging results. This medicinal product contains 50 mg sorbitol in each unit volume, which is equivalent to 30 mg per 6 mg dose. Pelgraz contains less than 1 mmol (23 mg) sodium per 6 mg dose, that is to say essentially 'sodium-free'. The needle cover contains dry natural rubber (a derivative of latex), which may cause allergic reactions. **Pregnancy and Lactation**: Pegfilgrastim is not recommended during pregnancy and in women of childbearing potential not using contraception. A decision must be made whether to discontinue breastfeeding or to discontinue/abstain from pegfilgrastim therapy taking into account the benefit of breastfeeding for the child and the benefit of therapy for the woman. **Adverse Events include: Adverse events which could be considered serious include: Common:** Thrombocytopenia. **Uncommon:** Sickle cell crisis, capillary leak syndrome, glomerulonephritis, hypersensitivity reactions (including angioedema, dyspnoea, anaphylaxis), splenic rupture (including some fatal cases), Sweet's syndrome (acute febrile dermatosis), pulmonary adverse reactions including interstitial pneumonia, pulmonary oedema and pulmonary fibrosis have been reported. Uncommonly cases have resulted in respiratory failure or ARDS which may be fatal. **Rare:** Aortitis, pulmonary haemorrhage. **Other Very Common adverse events:** Headache, nausea, bone pain. **Other Common adverse events:** Leukocytosis, musculoskeletal pain (myalgia, arthralgia, pain in extremity, back pain, musculoskeletal pain, neck pain), injection site pain, non-cardiac chest pain. See SPC for details of other adverse events. **Shelf Life:** 3 years. Store in a refrigerator (2°C – 8°C). Pelgraz may be exposed to room temperature (not above 25°C ± 2°C) for a maximum single period of up to 72 hours. Pelgraz left at room temperature for more than 72 hours should be discarded. Do not freeze. Accidental exposure to freezing temperatures for a single period of less than 24 hours does not adversely affect the stability of Pelgraz. Keep the container in the outer carton in order to protect from light. **Pack Size: Pelgraz 6 mg solution for injection in pre-filled syringe:** Each prefilled syringe contains 0.6 mL of solution for injection. Pack size of one prefilled syringe with one alcohol swab, in a blistered packaging. **Pelgraz 6 mg solution for injection in pre-filled injector:** Each prefilled syringe injector contains 0.6 mL of solution for injection. Pack size of one prefilled injector with one alcohol swab, in a blistered packaging. **Marketing Authorisation Numbers: Pre-filled syringe:** EU/1/18/1313/001, **Pre-filled injector:** EU/1/18/1313/002. **Marketing Authorisation Holder (MAH):** Accord Healthcare S.L.U, World Trade Center, Moll de Barcelona, s/n, Edifici Est, 6a planta, Barcelona, 08039 Spain. **Legal Category:** POM. Full prescribing information including the SPC is available on request from Accord Healthcare Ireland Ltd, Euro House, Little Island, Co. Cork, Tel: 021-4619040 or www.accord-healthcare.ie/products. **Adverse reactions can be reported to Medical Information at Accord Healthcare Ltd. via E-mail:** medinfo@accord-healthcare.com **or Tel:** +44(0)1271385257. **Date of Generation of API:** August 2019. IE-01426

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Adverse events should be reported. Reporting forms and information can be found on the HPRA website (www.hpra.ie), or by e-mailing medsafety@hpra.ie. Adverse events should also be reported to Medical Information via email; medinfo@accord-healthcare.com or tel:0044 (0) 1271 385257

October 2019. IE-01429

HIV PREP

One-in-five people unaware of HIV prevention methods

Ahead of World Aids Day 2019, research was published which showed one-in-five people are unaware of any HIV prevention methods. Specifically, 87 per cent of people had never heard of pre-exposure prophylaxis (PrEP), yet 36 per cent of people admitted that they would consider taking it.

The research was conducted with Irish adults over 18 years of age, with a national average sample size of 969 people.

Researchers examined several areas relating to HIV and PrEP, including the general public's understanding of HIV and anti-HIV drug PrEP, the role of HIV and STI clinics, and the awareness and use of HIV prevention methods.

The research followed the Government's recent announcement of a new PrEP public access programme, which began on 4 November 2019.

The survey found that 70 per cent of people believed PrEP should be available free of charge. A formal PrEP programme, as previously recommended by the Health Information and Quality Authority, would allow for a safe, effective and cost-saving environment.

PrEP, a HIV prevention medication, has been shown, in conjunction with safe sex practices, to significantly reduce the risk of HIV infection through sex, particularly for those deemed at risk, such as gay and bisexual men and transgender women, but also for heterosexual men and women.

The research was conducted by Core Research on behalf of Teva Pharmaceuticals Ireland.

KEY FINDINGS FROM THE RESEARCH INCLUDE:

65%
of Irish adults still believe that HIV is a sensitive subject.

93 per cent of people think there needs to be more information on HIV in Ireland.

79%
of people say that the first thing they would do if they found out they had HIV would be to visit a HIV clinic.

70%
of people feel that the risk of HIV is not taken into consideration before engaging in sexual activity.

One-in-five
are unaware of any HIV prevention methods but of those who did know, only 2 per cent mentioned PrEP.

87%
of people had never heard of PrEP, but 36 per cent of people admitted that they would consider taking it.

Seven-in-10
people believe PrEP should be available free of charge.

DRUG PATENTS

High Court rules in favour of Clonmel Healthcare on cholesterol-lowering therapy

Irish pharmaceutical company Clonmel Healthcare recently won a High Court case against Merck Sharp and Dohme (MSD) in a counter-claim over patent rights for the cholesterol-lowering drug Ezetimibe/Simvastatin. Previously, MSD took legal action against Clonmel Healthcare, claiming that Clonmel had breached MSD's supplementary protection certificate (SPC) for Inegy, a drug produced by MSD. However, Clonmel Healthcare lodged a counter-claim against MSD, stating that the combination of Ezetimibe and Simvastatin was in fact unprotected by patent and that the MSD SPC was in breach of a 2009 EU SPC regulation.

Further, Clonmel Healthcare maintained that only Ezetimibe was protected and because the combination of Ezetimibe and Simvastatin was previously authorised, MSD's 2005 SPC was not valid. In the High Court, Mr Justice McDonald ruled that the compound combination is not protected by patent and "there is nothing in the evidence or in the materials before the court to explain how the combination can be said to be an invention in itself". As a result, he said the combination of compounds is not protected within Article 3(a) of the 2009 SPC and the certificate must be revoked. Mr Justice McDonald also stated that there was no legal basis for him to refer the case on to the EU's Court of Justice.

PHARMACY WORKFORCE

Pharmacists highlighted in new OECD report

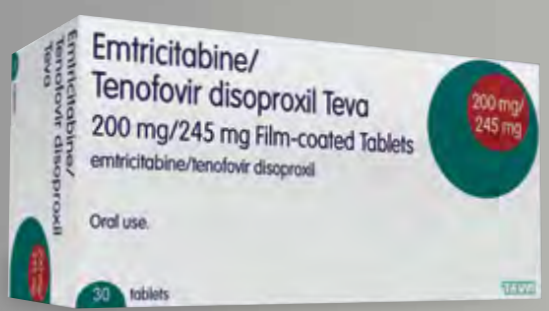
A report recently published by the Organisation for Economic Cooperation and Development (OECD), titled *Health at a Glance 2019*, has demonstrated how the health status and health-seeking behaviours of citizens across countries currently differ. Using 80 different indicators, it aimed to compare access to and quality of healthcare in OECD countries.

A chapter on pharmacists and pharmacies says that between 2000 and 2017, the density of practising pharmacists increased on average by 33 per cent in OECD countries, to 83 pharmacists per 100,000 inhabitants. The highest density is in Japan (181 pharmacists per 100,000 people), and the lowest in the Netherlands (21 per 100,000). Community pharmacists' role is changing, according to the report, as they increasingly provide care other than dispensing medicines to patients.

"The number of pharmacists per capita increased in all OECD countries for which time series are available," according to the report. "Pharmacist density increased most rapidly in Japan, Portugal and Slovenia. In Japan, increased numbers of pharmacists are largely attributable to the government's efforts to more clearly separate drug prescribing by doctors from drug dispensing by pharmacists (the 'Bungyo' system)." The report goes on to state: "The role of the community pharmacist has changed over recent years. Although their main role is to dispense medications, pharmacists are increasingly providing direct care to patients (ie, flu vaccinations in Australia, Ireland and New Zealand; medicine adherence support in Australia, Japan, New Zealand and the United Kingdom), both in community pharmacies and as part of integrated health care provider teams."

PrEP Love LiFE

PrEP (Pre-Exposure Prophylaxis) can protect against HIV and makes sex safer for adults at high risk of infection*.



Emtricitabine/Tenofovir disoproxil Teva 200/245mg Film-coated Tablets
Further information is available on request in the SmPC.

Teva Pharmaceuticals Ireland
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Prescription only medicine.
*when used in combination with safer sex practices

Date of preparation: December 2019. Job code: IE/GEN/19/0020(1)a

New research published finds **1 in 5 people are unaware** of any **HIV prevention methods.**

A survey conducted in September 2019 by Core Research on behalf of Teva Pharmaceuticals Ireland examined several areas relating to HIV and PrEP including the general public's understanding of HIV and the anti-HIV drug PrEP, the role of HIV and STI clinics, and the awareness and use of HIV prevention methods. The research was conducted with Irish adults over 18 years of age, with a national average sample size of 969 people.

65% of Irish adults still believe that **HIV is a sensitive subject**, yet **93%** of people think there needs to be **more information on HIV in Ireland**

79% of people say the first thing they would do if they found out they had HIV **would be to visit a HIV clinic**

70% feel that **the risk of HIV** is not taken into consideration before **engaging in sexual activity**

20% are unaware of any **HIV prevention methods**

87% of people had **never heard of PrEP,** but **36%** of people admitted that they will **consider taking it**

70% believe PrEP should be available **free of charge**

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INFANT CARE

Breast milk could help prevent heart disease caused by premature birth — RCSI study

Early use of breast milk could play a vital role in preventing heart disease in prematurely-born infants, according to a paper led by researchers at the RCSI and the Rotunda Hospital, Dublin.

One of the long-term health complications that young adults born prematurely may have is unique heart characteristics. These can include smaller heart chambers, relatively higher blood pressure, and a disproportionate increase in muscle mass in the heart.

One study cited in the article looked at 30 preterm-born adults who were assigned to receive exclusive human milk and 16 preterm-born adults who were assigned to receive an exclusive formula-based diet during their hospital stay at birth. They then underwent detailed cardiovascular assessment between 23 and 28 years of age, including an MRI of their hearts. As expected, all of the hearts of those born prematurely had smaller chambers than the hearts in people who were not born prematurely.

However, the study showed that the smaller heart chambers were less profound for the exclusively human milk-fed group in comparison to those who were exclusively formula fed, suggesting a potentially protective effect of human milk for heart structure.

The researchers then identified potential reasons for why breast milk results in a lower risk of heart disease. Breast milk could help prevent heart disease by better regulating hormones and growth factors, strengthening the infant's immune system, reducing inflammation and by possibly improving the metabolism of the child.

Identifying the key components within breast milk that result in improved heart health could pave the way for a more targeted approach to improve long-term cardiovascular wellbeing for those born prematurely.

"It is becoming increasingly clear that premature birth results in long-term adverse cardiovascular effects with important clinical consequences. There is a distinct lack of preventative and therapeutic interventions available to alleviate those effects," said Prof Afif EL-Khuffash, Honorary Clinical Professor of Paediatrics at the RCSI and Consultant Neonatologist at The Rotunda Hospital.

"The current evidence comes from observational studies and highlights the strong link between early breast milk administrations and improvement in long-term heart health, but it lacks concrete mechanistic explanations. More studies on the composition of breast milk could make clear exactly what causes these health benefits, which could in turn lead to better treatment options."

The collaborative research group is continuing to study the effects of human milk exposure on heart function in very premature infants by using novel scans to measure heart function. They hope to demonstrate that early human milk exposure in premature infants can lead to significant improvements in heart function over the first two years of age. The review article was published in the journal *Paediatric Research* and was written in collaboration with researchers from Harvard Medical School, the University of Oxford and University of Toronto. The full article is available at ***https://doi.org/10.1038/s41390-019-0648-5***.

OPIOIDS

Prenatal opioid exposure may alter brain function in babies

Connectivity in an area of the brain that regulates emotion may be altered in infants exposed to opioids while *in utero*, according to a new study presented at the annual meeting of the Radiological Society of North America (RSNA).

Opioid use in pregnancy has become a major public health crisis. Opioids can have a devastating effect on maternal, foetal and infant health. When babies who have been exposed to opioids *in utero* are born, they suffer from drug withdrawal, or a group of conditions known as neonatal abstinence syndrome (NAS). Exposure to opioids *in utero* is believed to have lasting consequences on brain development and behaviour.

According to the researchers, NAS requires prolonged hospital stays, monitoring and, in severe cases, additional treatment with opioids. Understanding how opioids affect the developing brain would be one of the important steps in early identification and management of NAS and in improving neurodevelopmental and behavioural outcomes in these children.

"Little is known about brain changes and their relationship to long-term neurological outcomes in infants who are exposed to opioids *in utero*," said Dr Rupa Radhakrishnan, Assistant Professor of Radiology and Imaging Sciences at Indiana University School of Medicine in Indianapolis, US. "Many studies have looked at the impact of long-term opioid use on the adult and adolescent brain, but it is not clear whether social and environmental factors may have influenced those outcomes."

A team of obstetricians, neonatologists, psychologists and imaging scientists collaborated to study the brains of 16 infants using resting state functional MRI (fMRI), which enables researchers to measure brain activity by detecting changes in blood flow. With resting-state fMRI, the connectivity between neural regions can be observed while the brain is at rest.

The research team investigated the functional connectivity of the amygdala, a region responsible for the perception and regulation of emotions such as anger, fear, sadness and aggression. The study group included 16 full-term infants, including eight exposed to opioids prenatally and eight who were not exposed to prenatal opioids, or opioid-naive. Imaging, including fMRI and anatomical MRI, was performed while the infants were naturally asleep.

To determine the participation of the amygdala in the resting state networks, the team created brain maps and applied regions of interest for the left and right amygdala.

"Our early results show significant differences in the way the amygdala connects to different brain regions between the infants exposed to opioids and the opioid-naive infants," Dr Radhakrishnan said. "We still need to study what the clinical implication of this finding may be."

He said larger and long-term outcome studies are underway to better understand the functional brain changes in prenatal opioid exposure and their associated long-term developmental outcomes.

RESEARCH

New cell models developed for ocular drug discovery

Researchers at the University of Eastern Finland have developed two new cell models that can open up new avenues for ocular drug discovery. The new cell models are continuously growing retinal pigment epithelial cells, which have many benefits over the models currently used by researchers and pharmaceutical companies. The models were developed by Professor Arto Urtti's Ocular Drug Delivery group at the University of Eastern Finland.

Pigment epithelial cells play a key role in, ie, age-related macular degeneration, which makes them an interesting target for drug therapy. The retinal pigment epithelium also regulates the access of drugs from the blood stream into the eye and vice-versa, further highlighting the importance of this cell type for drug discovery.

Until now, cultivated retinal pigment epithelial cell lines have lacked both pigmentation and the blood-retinal barrier, which has complicated their use.

The retinal pigment epithelium (RPE) is characterised by strong pigmentation. Many drugs bind to cellular pigment and, consequently, can accumulate in RPE cells. The new cell model makes it possible to study this accumulation in greater detail than before.

In the new model, non-pigmented RPE cells can be re-pigmented by feeding them with melanin pigment.

Published in *Scientific Reports*, the study also described the uptake of different drugs in melanosomes. According to the researchers, most drugs that bind to melanin at high levels were taken up by the melanosomes, whereas the same was true only for a small number of drugs that bind to melanin at low levels.

"By using non-pigmented cells as controls, we were able to study how much of a drug given to the cells eventually ends up in the melanosomes. Next, we need to find out for how long the melanosomes can hold on to a drug, and whether this causes any harm. The accumulation of drugs in the melanosomes can, on the other hand, make it possible to target drugs at specific tissues," postdoctoral researcher Ms Mika Reinisalo of the University of Eastern Finland said.

Medication safety 'now a global goal'

Late last year, the RCSI played host to the Irish Medication Safety Network (IMSN) Annual Conference 2019, the 10th year in which the event has been held. The conference, which was held under the theme 'Medication Without Harm: Responding to the Challenge', was chaired by Ms Pat O'Brien, IMSN member and Medication Safety Co-Ordinator at Galway University Hospitals.

Ms O'Brien introduced Ms Marita Kinsella, Director of the National Patient Safety Office at the Department of Health. Ms Kinsella referred to the "shared goal, which is indeed a global goal now, of ensuring the safety of medications" and in keeping with the range of healthcare professionals attending the conference, she emphasised the need for a multidisciplinary approach to medication safety.

"Collaboration between healthcare professionals, patients, policy-makers, regulatory bodies and everybody else involved in the medication process is vital in promoting patient safety and responding to the global challenge that is medication without harm," said Ms Kinsella. "The IMSN demonstrates the importance of that collaboration by promoting the exchange of information on medication safety and facilitating national initiatives to help minimise risks to patients.

"Over the years, we have seen the benefits of IMSN collaborations, with the publication of medication safety briefings and alerts, development of guidance on the management of identified high-alert drugs, and 'sound-alike' and look-alike' medicines," she told the conference. "The IMSN has led on a number of really important safety initiatives over the past year, but I particularly want to commend the IMSN on [the initiative] 'Building a Medication Safety Programme in a Hospital in Ireland — Fundamental Steps'.. I want to recognise the IMSN's leadership in building a guidance document that provides hospitals with the building blocks to design a safety programme and thereby give practical advice in addressing HIQA's medication safety recommendations.

Ms Marita Kinsella, Department of Health

"It is this kind of collegiality and collaboration that is essential in our health service to embedding a culture of patient safety and quality."

Ms Kinsella told the attendees that the Department of Health is contributing to EU-level efforts to "consider initiatives" to minimise the risks to patients and also the impact on healthcare professionals of medicines [supply], the most serious issue facing the health service arising from Brexit," she said. "Brexit will affect all of us, but in relation to medicines and medical devices, the Department is confident that people will continue to have access to high-quality, safe and effective medicines and medical devices. In some limited circumstances, we may need to use therapeutic alternatives but if this is necessary, it will be informed by expert clinicians in their respective medical specialties and the expert role of pharmacists and those of you with expertise in the safe use of medicines will be critical in ensuring that we minimise the impact of Brexit for Irish patients."

Ms Kinsella also addressed the increasing importance of open disclosure and told the attendees: "It's very heartening to see that the IMSN is engaging in a very real way on open disclosure and what it means with regard to the safety of medicines," she said. "As a health service, openness and honesty with patients must be at the heart of everything we do. Open disclosure must happen in the right way and in all circumstances — patients have to be informed.

"We have seen all too clearly arising from a number of serious patient safety incidents over recent years the impact that failure of open disclosure can have on patients. It's important that we're all committed to learning from these events and embedding a culture of ensuring that patients are treated in a way that they would most like to be treated when things go wrong, that they perceive a sincere and genuine apology, and to be sure that what has happened to them will not happen to anybody else," she continued.

"We need to ensure that the culture of trust and confidence between patients and clinicians prevails. Within the team at the National Patient Safety Office, we have been working on a new patient safety bill, which will focus on mandatory open disclosure of the most serious patient safety incidents. This will ensure that patients and their families affected by a serious incident will be assured of receiving appropriate and timely information in relation to an unintended or anticipated serious event that may have occurred in relation to their care."

Ms Kinsella added that the mandatory disclosure bill will also require notification of the most serious patient safety events and incidents to HIQA and the Mental Health Commission, as appropriate, to ensure system-wide improve-

ments. However, she described the legislation as a "blunt tool" to embed a culture of openness and transparency in cases of serious incidents.

"Ensuring that patients and their families are treated honestly and openly when things go wrong also requires personal commitment from all of us who work in the health service," she said.

Electric dreams in medications prescribing

The IMSN Annual Conference 2019 heard from Mr Paul Tighe, IMSN Chair and Head of Pharmacy at St Vincent's University Hospital, Dublin. Mr Tighe provided an overview of the IMSN and its activities during 2019 and told the attendees: "The IMSN is an entirely voluntary network and people are surprised when they hear that," he said. "Our full-time roles are in the hospitals in which we work — this is a collection of hospital pharmacy-based specialists from all the hospitals, not just the public ones, but also private ones. That's very important, that we are very representative of all of the hospitals."

The Network promotes medication safety through the exchange of information, as well as national and international initiatives and during 2019, the Network published safety alerts on medication safety in pregnancy; tamoxifen and the potential for drug-drug interactions; medications for Parkinson's disease; and a fresh review of intravenous (IV) paracetamol. "We were particularly keen to review IV paracetamol and look at risks relating to dose-adjustment and risks around IV paracetamol use in children," said Mr Tighe.

For the start of this year, there is a working group focused on medication safety in operating theatres and another group focused on medication safety in the Electronic Health Record (EHR). "That's very relevant when you take into account the number of hospitals that are moving towards using an EHR, particularly in the maternity sector," he explained.


Mr Paul Tighe, IMSN Chair

Mr Tighe presented national State Claims Agency data to show that of the clinical incidents that were reported to NIMS during 2018, one-in-four were incidents that related to medication errors. Citing more data from the NIMS *Clinical Insights* report, Mr Tighe told the conference that regarding the areas in which medication errors were occurring during the medications use process, one-in-two such incidents happened at the prescribing stage. "That's highly relevant, considering that prescribers traditionally report the least amount of incidents, but it's also important when you consider where we are going with medication safety," said Mr Tighe.

"We have spoken at previous conferences about the hierarchy of intervention and about telling people to be more careful, to introduce some policy in practice, but the more we can engineer things out of the system, the safer they will be," he said. "Every time we get a new recruit of medics, pharmacists or nurses in our hospital, we have to go through the same processes."

Mr Tighe told the attendees that the most important development in the past three years in Ireland in medication safety has been the strategic decision by HIQA to commence medication safety inspections and monitoring visits in public hospitals. "This has been a significant programme that has really shone a light on all of the issues around not only medication safety, but also clinical pharmacy," he said. "At the moment, I believe there have been approximately 60 inspections, 54 of which are on the HIQA website. We have been given a gift from HIQA; 12 recommendations, seven of which are hospital-level and five that are national.

"We are quite good at some of these [recommendations] and we have made some progress on the national recommendations, particularly in sharing and learning from medication incidents, and also in trying to use electronic solutions where we can," he continued. "But there are two that I would like to flag. The medication safety monitoring visits were as much about medication safety as they were about clinical pharmacy. Another recommendation that we have is to develop a national plan for comprehensive clinical pharmacy services — it's a huge task to do that, but it is also a huge opportunity in terms of the benefit that we will have if we can standardise some of the clinical pharmacy across all of our hospitals, regardless of the size of the hospital, and also the different types of scale that we deal with."

Regarding one-in-two errors being at the prescribing stage of the medicine process, Mr Tighe spoke to the attendees

about electronic prescribing. "We have seen significant progress with the NCIS [National Cancer Information System] and in maternity, and I think now is the time for all the hospitals to make a huge effort to move towards EPMA [electronic prescribing and medicines information] and to try to push the EPMA agenda as much as we can," he stressed.

"There are only so many times we can train our prescribers and encourage people around medication safety but if we have EPMA, we can introduce decision support, we can introduce 'forcing functions', and we can try to encourage safer prescribing." In this regard, Mr Tighe offered St James's Hospital in Dublin as an example that other hospitals could follow.

Unpublished data shows significant improvements in hospital medication safety

The IMSN Annual Conference 2019 also saw a joint presentation titled 'Collaborative Approach to Reducing Hospital-Acquired Venous Thromboembolism from a Patient, Clinician and Group Hospital Manager Perspective'. The attendees were given different perspectives on this topic from Ms Annemarie O'Neill of Thrombosis Ireland, Prof Fionnuala Ni Ainle, Consultant Haematologist at the Mater Misericordiae University Hospital and Rotunda Hospital in Dublin, and Prof Mary Day, CEO of the Ireland East Hospital Group.

This was followed by a presentation by Ms Aoife Lenihan, Regional Manager of Healthcare Regulation with HIQA, who spoke on the theme 'HIQA Phase II Medication Safety Monitoring in Hospitals'. Ms Lenihan provided an overview of this phase of the programme, which has been running for four years, and said the public must be fully assured that national standards in medication safety are being met. For pharmacists who seek details of the programme, Ms Lenihan urged them to consult a guidance document published by HIQA on its website.

Ms Lenihan presented some previously-unpublished information on some findings from the past two years and told the seminar: "In that time, we have conducted 20 inspections in 19 hospitals, visiting one hospital twice in that time-frame," she explained. "Comparing what we found in 2016 and 2017 in relation to governance, in the first two years of the programme, we estimated that approximately 60 per cent of the hospitals that we inspected had a functioning drug and therapeutics committee. When we went back out in 2018 and 2019, this had significantly improved, in that all 19 hospitals had these functioning committees.

"In the first two years, we found very few hospitals had a formal medication safety strategy to be very clear on what the short-, medium- and long-term goals were for a particular hospital," said Ms Lenihan. "This had improved to 10 hospitals having a very structured and clear strategy in the past two years and it's fair to say the hospitals that had not formally developed a strategy had ways whereby they could identify their priorities, articulate them, and they had action plans to track improvement to ensure they were working in a systematic way to achieve those goals."

Quality of risk management system was shown to be "very solid" across all hospitals over the past two years, Ms Lenihan said, including risk registers to escalate high-risk issues in medication safety and analysis of incident reports, however she revealed that proactive risk assessments were quite rare.

Ms Aoife Lenihan, HIQA

"These were more common in the 'leading' hospitals, where instead of focusing on just incident reporting, there was a focus on what could potentially go wrong and taking proactive measures. This is an area that could potentially be improved."

Most of the hospitals showed increases in incident reporting, but the culture of reporting can always be improved, said Ms Lenihan, who pointed out that pharmacists and nurses most often reported safety incidents. On the day of inspection, samples would be looked at from eight high-risk medications identified by HIQA, including anticoagulants. "These are the highest-risk medications that perennially come up in incidents and the only medications that we identified in very serious events," she explained. In this regard, policies and protocols were designed to guide staff and avoid inadvertent double-dosing.

It was also decided that for the first time, the inspection team would visit operating theatres, said Ms Lenihan, and areas that provide procedural sedation outside of the theatre. "In-theatre is a unique situation, where there are multiple high-risk medications, high patient throughput and complex procedures, which makes it a very high-risk area," she said. "In general, the drawing-up and

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labelling of syringes was in line with best practice… hospitals were using internationally-recognised labelling systems and in general, practitioners were drawing-up drugs and using them themselves, rather than leaving them for another practitioner, and they were maintaining custody of those drugs and disposing of them at the end of a procedure."

However, while a limited number of sites were inspected for procedural sedation, the inspection team found variations in governance and oversight, with only two hospitals having a specific procedural sedation safety committee. Procedural sedation in endoscopy is generally "very well done," Ms Lenihan added. Overall, the inspections also revealed increases in medications reconciliation and "where there is a clinical pharmacy service, medication safety is greatly improved," she said. Five of the 19 hospitals inspected had a very limited or purely dispensing pharmacy service and hospitals that did not have a formulary are working on developing local formularies, while most hospitals had access to information for staff at the point of care, she said.

However, some hospitals' medication safety monitoring was limited to using nursing metrics and Ms Lenihan told the conference in conclusion: "I'm sad to say that the medication safety monitoring in its current guise will conclude in 2020, when we will have done more than three years of work," she said. "But on a positive note, it's not something that we will leave behind. We plan to work on and develop our approach to monitoring and this is something we will maintain; whatever way our monitoring approach changes… there will need to be a lot of communication with stakeholders, including yourselves, and stakeholder engagement in changing the way we monitor hospitals."

At the heart of anticoagulation

The IMSN Annual Conference 2019 also heard from Mr Sotiris Antoniou, Consultant Pharmacist in Cardiovascular Medicine and Chair of the International Pharmacists Anticoagulation Taskforce (iPACT), UK. Mr Antoniou provided an overview of collaborative care in anticoagulation and provided a number of case studies to illustrate how collaborative work can help to improve patient outcomes.

"With the NOACs, there is some good data to show that even after one year of treatment, the discontinuation rate is between 33 and 50 per cent," said Mr Antoniou. "In fact, if you look at the trials on NOACs in stroke prevention and atrial fibrillation (AF)… the discontinuation rate due to adverse events is approximately 20-to-25 per cent in a randomised, clinical trial. So we are not surprised that these figures are replicated in the general population."

Mr Sotiris Antoniou, iPACT

Regarding in medicines that cause hospitalisations due to an adverse event, he told the attendees that anticoagulants "will always be seen in the top-three, if not the number-one… warfarin is the number-one drug associated with hospitalisations in US hospitals. As you might expect, the majority of the reasons for this related to bleeding and the number-one concern was around intracranial haemorrhage." The average INR for a person taking warfarin and admitted to hospital with an intracranial haemorrhage is typically 2-to-3, he said.

Along with the ageing population, rates of AF are increasing and Mr Antoniou referred to international guidelines, which state that opportunistic screening for AF in patients aged over 65 years, involving pulse-taking followed by an ECG, is recommended to allow timely detection of the condition. In 2016, iPACT organised for hospitals and community pharmacies in five countries to run pulse awareness initiatives, he added.

One challenge for hospital pharmacists is that patients are rarely on the same medicines they end up taking on discharge, said Mr Antoniou, who spoke about the iPACT interprofessional guidelines on anticoagulation.

"Among the top recommendations are the importance of communication in the transfer-of-care between healthcare settings; ongoing medications adherence; medicines reconciliation; and medications review. We know that transfer of care is a particularly high-risk area because of lack of communication or inconsistent communication."

Healthcare staff often the 'second victims' in adverse incidents

The IMSN Annual Conference 2019 heard presentations from Mr Dan Burns, Pharmacy Director at Pharmapod, on the theme 'Advancing the Global Patient Safety Agenda' and Ms Ciara Kirke, Clinical Lead at the National Medication Safety Programme at the HSE, who delivered an overview of 'The Know Check Ask Campaign — Mobilising People Power for Medica-

tion Safety'.

Attendees also heard a presentation from Ms Ann Duffy, Senior Clinical Risk Advisor at the State Claims Agency (SCA), who spoke on the topic 'Medication Safety and Open Disclosure — An Evolving Landscape'. Ms Duffy told the conference that staff often do not get the supports they need following an adverse event, leading to them sometimes being described as "the second victim". She told the attendees: "Medicine is dynamic, it is evolving, it's complex. We are always going to have incidents and we are always going to have claims. What we need to focus on is how we react to those incidents and claims and how we manage our staff following those events."

A lot of the SCA's work revolves around data and the National Incident Management System (NIMS) to identify trends and mitigate potential risks, as well as the nature of claims and how they came about and a recurring theme is poor communication or lack of communications. In pharmacy, incorrect prescriptions and errors around drug dosage are also recurring themes, said Ms Duffy.

She described the "domino effect" adverse events can have on staff and she outlined the top-10 injuries in acute services, such as cuts, lacerations and postpartum haemorrhages. In terms of medication incidents, she told the attendees: "There were only 10,000 reported in 2018 and it will be similar for 2019, so we are well aware that the 'iceberg' is there and we are only seeing the very tip of it."

On the topic of who reports incidents most, Ms Duffy said: "Clinical pharmacists are picking up a lot of these medication incidents at ward level, followed by nursing and midwives and doctors… " She outlined 48 claims made between 2011 and 2016 and estimated the costs of these to be around €3 million, however the legal and expert costs often equal or exceed the amount a plaintiff will receive.

Ms Duffy presented a case study to illustrate a claim of negligence, pointing out that for negligence to be proven, it must be established whether a duty of care existed in the first place. She also outlined a definition of actions to be taken on adverse incidents from Australian authorities, which includes "expressing regret for what happened, keeping the patient informed, providing feedback and taking steps to prevent recurrence.


Ms Ann Duffy, State Claims Agency

"Open disclosure is about good, effective communication with patients and their families." Patients should be told quickly about medication errors rather than waiting for a process to begin, which could take days or weeks, she said.

"Medicine is complex and incidents will continue to happen," Ms Duffy concluded. "When things go wrong, we have to know how to look after our staff and help them. I say this to a lot of students — no-one is immune to being involved in an incident. Practical and timely support are important — there is the ASSIST model, which I myself used recently, and confidential settings are important for staff to discuss an incident and how it affected them… debriefing is also important and occupational health has a role in this area, as do employee assistance programmes."

Pharmacists front-and-centre in medication safety

Regional Manager of Healthcare Regulation at HIQA Ms Aoife Lenihan has said that pharmacists are leading the way in striving for medication safety in Irish hospitals. Ms Lenihan was speaking with ***Irish Pharmacist*** (***IP***) following her presentation at the IMSN Annual Conference 2019, which was titled 'HIQA Phase II Medication Safety Monitoring in Hospitals'.

Ms Lenihan commented: "From what we see on inspection, pharmacists [as part of the multidisciplinary team] are leading the way and are very often the drivers for medication safety. We also made the point in our overview report in 2018 that there are gaps in clinical pharmacy services and we have included this as a national recommendation."

Ms Lenihan also touched on the general public awareness of the importance of hospital pharmacists in patient care in comparison to the high level of awareness that exists around the value of community pharmacists. "There is definitely potential to raise awareness in this regard," she said. "Anything in the public domain that raises awareness of the role, and promotes the role of clinical pharmacists within a hospital setting, and to educate them about the evolving role of pharmacists over the years within hospital care is good, as well as highlighting their important role in ensuring medication safety."

Ms Lenihan was also asked about the fact that medication safety monitoring in its current guise will conclude in 2020, and what her hopes and aspirations may be when that happens in terms of the continued drive for medication safety. "Back in 2016, this was identified as a key area for HIQA to focus its monitoring programmes on," she told ***IP***, "so future monitoring of healthcare by the healthcare team will include aspects of medication safety."

WHERE TO NOW FOR PHARMACY?

Threatened fee cuts to community pharmacists will not now proceed, but it remains unclear when and how their role will be expanded in the future. ***Catherine Reilly*** *interviews representatives from the pharmacy and medical professions and finds there are differences of opinion*

In December 2019, the Irish Pharmacy Union (IPU) welcomed the "sensible decision" by Minister for Health Simon Harris not to proceed with proposed "savage cuts in fees" to pharmacies and, instead, to recommit to early talks on a new pharmacy contract and investment in pharmacy services.

When the proposed cuts were announced in October, Ireland's 2,300 community pharmacists were left "deeply shocked and concerned", according to the IPU.

Any funding cuts would "go completely against" the Government's Sláintecare strategy, which aims to keep health services in the local community, it added.

With this controversy now seemingly put to bed, pharmacists can return their attention to the development of a new contract that will facilitate an expansion of healthcare services within pharmacies.

"The contract we have for pharmacies has been in place since 1996," IPU Secretary General Mr Darragh O'Loughlin explained. in late November. "The Internet didn't even exist when this contract was signed. It was a modern contract back then, but it is completely outdated now and not fit-for-purpose anymore and pharmacists and the public need a new pharmacy contract that reflects how pharmacy should be practised in the 21st Century."

MINOR AILMENTS

What should 21st Century pharmacy look like? A document published in 2016 by the Pharmaceutical Society of Ireland (PSI), provided a comprehensive overview of the healthcare services that may become available in pharmacies in the future (see panel overleaf). One such service is a minor ailments scheme.

A feasibility trial into a minor ailments service in Irish pharmacies was conducted in 2016. It was piloted across 19 pharmacies in four towns (Kells, Roscommon, Macroom and Edenderry) for three months.

The medical conditions included in the trial were dry eye, dry skin, scabies, threadworms and vaginal thrush. In a response to a parliamentary question in November 2018, Minister Harris said the study successfully tested operational and administrative procedures, but the patient take-up was small (121 consultations) and no meaningful clinical or outcome data emerged.

More extensive trialling would be required if this was to be progressed, he said.

The Irish Medical Organisation (IMO) has expressed concern over a minor ailments scheme in pharmacies and about some other potential extensions to pharmacists' scope of practice. It has also frequently pointed to the importance of a clear distinction between the prescriber and dispenser of medicines.

Dr Denis McCauley, Chair of the IMO GP committee, said there is a substantial training requirement in order to become skilled in differentiating minor from non-minor ailments.

"You would almost have to do a casualty job for six months to be able to identify a minor ailment as opposed to a non-minor ailment. You can't just become a minor ailment 'superstar' overnight; it would take quite a lot of training to actually do it. Now, that is not being facetious or arrogant. Invariably, you will find they will still be referred to the doctor," he stated.

But according to Mr O'Loughlin of the IPU, such schemes have been operating well in other countries.

"And the pharmacists all have protocols they follow in order to ensure they have correctly identified what the ailment is, and that they are providing the correct treatment. This is happening in Scotland and it's happening in Wales," stated the IPU Secretary General.

"In Scotland, it was originally only for certain citizens, the ones who had eligibility for free prescriptions and the elderly, and now they are expanding it out to the whole population because it has been a success. They have found that symptom resolution rates, in other words appropriate and successful treatment rates, for minor ailments in pharmacies can be up in the 90s in terms of percentage.

"The *British Journal of General Practice* found the pharmacies were treating them as successfully as GPs but that it was done at a lower cost to the health system. So while I respect the view of the IMO, and we don't claim to be doctors — no pharmacist out there is pretending to be a doctor — I am a pharmacist, I want to be a pharmacist, but I want to practise pharmacy to the top of the scope of pharmacy practice."

A minor ailments scheme is essentially operating for private patients, according to Mr O'Loughlin. He said people without a medical card often call into a community pharmacist with symptoms and receive an over-the-counter (OTC) medicine as treatment.

"They don't go to a doctor. So if a private patient has indigestion, or a headache, or

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constipation, nausea, hay fever, skin allergies, anything like that — they will invariably go to a pharmacy first. If it looks like it requires a doctor, the pharmacist will say 'you actually need to see your GP about that."

In contrast, public patients often present to their GP with a minor ailment as they need a prescription to avail of the OTC medication free of charge.

"We are just saying that public patients or medical card-holders should have the same access level to treatment as private patients have. In one year in Ireland, we have almost a million medical card prescriptions written, where there is just medicine on it and the medicine could have been bought without a prescription.

"So that suggests those are minor ailments which, if you were a private patient, you probably would have just gone to the pharmacy and got your treatment there and then. I can see what the IMO is saying but I don't agree with their suggestion that there is some risk inherent in pharmacists providing treatments to medical card-holders who have minor ailments because those risks have not manifested in pharmacists prescribing non-prescription medicines to private patients."

'FRAGMENTATION OF CARE'

Dr McCauley told this publication objections within his profession were not about "a 'greedy GP' keeping everything to himself", as some might perceive it.

He said GPs were concerned about "fragmentation of care, cherry-picking; various things like that".

Dr McCauley gave the example of pharmacists potentially being allowed to provide the oral contraceptive pill without a doctor's prescription. He said pharmacists would not be in a position to give a full range of contraceptive options, principally long-acting reversible contraceptives (LARCs), which are recommended for many women in terms of health and effectiveness.

"So giving a pharmacist one function, or one ability to do one thing — guess what happens; that pharmacist will only do that thing. Whereas if a GP has five options, they will choose what is best for the patients."

Again, Mr O'Loughlin viewed matters differently.

"The pharmacist is perfectly capable of talking through all the options with a woman looking for contraception, telling her about LARCs in addition to the pill and other methods, and explaining the benefits," he said.

"And then a woman will decide, 'I want to get the LARC as that sounds like it will suit me,' and we will refer them to a GP who does it because not all GPs, for example, fit the coil or fit Mirenas. So you'd refer them to a doctor who does that.

"We already know how to refer people to a doctor to provide a service to them. But last year in Ireland, there were two million packs of [contraceptive] pills dispensed in pharmacies on prescription; those prescriptions were written by doctors. So doctors are prescribing that level of oral contraceptive pill out there, to women who choose to use that method of contraception.

"What we are talking about is giving women the choice, so they wouldn't be obliged to go to a pharmacy; they could still go to a doctor. We are not going to oblige them to take the pill; they can still choose to have a LARC. But women who choose to go to a pharmacy to get the pill should be able to get it.

"They are already doing this in New Zealand, many states across the US, and parts of Canada. They have actually done a study in Oregon state, which was the first US state to introduce pharmacists' prescribing of the pill, and they were able to quantify the number of unwanted pregnancies that had been avoided and the consequent financial saving to the health system and the social care system as a result of those pregnancies not happening."

E-HEALTH

On a broader note, Ireland's poor e-health infrastructure remains a barrier to extending pharmacists' practice, according to Mr O'Loughlin.

"In Ireland, we don't have a proper e-health infrastructure, we don't have [system-wide] online health records, GPs can't see records in a hospital, the hospital can't see GP records, nobody can see pharmacy

PSI REPORT PROVIDED VISION FOR FUTURE PHARMACY PRACTICE

The existing role that community pharmacists play in "supporting patients treating minor and self-limiting conditions" should be further expanded, according to a document published by the regulator of pharmacists and pharmacies.

Future Pharmacy Practice in Ireland, published by the PSI in 2016, noted that an increase in the reclassification of medicines from prescription to non-prescription status had occurred in recent years.

"There has been successful implementation of the reclassification of some medicines, such as the emergency hormonal contraception (EHC), which is now available for patients directly from the pharmacist.

"In addition, recent legislation has enabled appropriately-trained pharmacists to supply and administer certain prescription-only medicines to patients in the event of an emergency, including epinephrine (adrenaline), salbutamol, glyceryl trinitrate, glucagon, and naloxone.

"Both of these initiatives demonstrate the role that pharmacists can play in directly treating patients in the community. These initiatives, combined with the availability of a private patient consultation area within community pharmacy, creates the potential for further development of this role. Other jurisdictions have introduced structured schemes for pharmacists to provide advice and treatment if required to patients for specified minor illnesses and complaints, ie, minor ailments scheme."

According to the report, "our research has confirmed that in other jurisdictions, while referral to the GP or acute setting is extremely important, it can also work in the opposite way and reduce pressure on the health system".

The report cited data from one large emergency department (ED) and two general practices in Scotland, which showed that at least 5 per cent of ED and 13 per cent of GP attendances were for common ailments "that could have been managed in a community pharmacy".

The document also stated that mechanisms should be explored to enable pharmacists and GPs to work more closely together to support patients in chronic disease management. "This could include supplementary prescribing activities, such as dosage adjustment or therapy continuation by the pharmacist in line with agreed protocols," according to the document.

The steering group for the report included Department of Health and HSE officials, a patient representative, pharmacists and pharmacy representatives, and a Medical Council representative (GP Dr Ruairi Hanley).

"The report is the result of a research project that included an extensive consultation process involving patients, pharmacists and other healthcare professionals, other regulatory bodies, and engagement with policy-makers," a PSI spokesperson said.

The PSI has met with stakeholders and organisations "to share the findings and recommendations and inform policy development and healthcare reform".

records, and so on…

"So look at Canada; patients are diagnosed by their physician there with high blood pressure — hypertension — the physician does out the care plan, 'these are the medications you are going to use, the pharmacist is going to monitor your blood pressure, the pharmacist is going to adjust the dose of these medicines up or down as appropriate, and put that information onto your electronic health record and I will see it here'.

"'And if your blood pressure is not controlled, you are going to be referred back here [to the doctor] and we're going to take control of it'. But for the majority of the population for whom the medication the doctor prescribes actually works, the pharmacist is doing the monitoring, and can even extend the prescription out if it is working and refer people back to the doctor where the medicine isn't working.

"Whereas today in Ireland… private patients get a six-month prescription, they go away and take the medicine and nobody is checking whether it is working or not, and nobody is checking that they are getting the right dose, and if they have achieved their target blood pressure. And there is international evidence that shows that blood pressure control in Ireland, particularly for male patients, is one of the poorest in the countries they looked at, whereas Canada is one of the best. That saves lives in Canada."

There would be additional training requirements for pharmacists if their role developed, as had occurred when the national influenza vaccination programme commenced in pharmacies. "There are some services where if they were to be rolled-out in pharmacy, they would require additional training, there is no doubt about that," said Mr O'Loughlin.

Both Dr McCauley and Mr O'Loughlin emphasise that the relationship between GPs and pharmacists on-the-ground is positive. But clearly, the two unions strongly disagree on how the relationship will develop.

Dr McCauley welcomed the inclusion in the recent agreement between the IMO and Department of a pharmacist-supported medicines usage review process in primary care. It will aim to support GPs in safe prescribing and reduce high-risk prescribing, arising due to the age of the patient, and potential comorbidities and co-prescription. This will be introduced and targeted at medical card/GP visit card patients aged over 75 years resident in the community.

The pharmacists, employed by the HSE and based regionally, will be able to visit GP practices and make suggestions on safer prescription.

It is these traditional areas of practice where the IMO believes the profession should focus their efforts.

Mr O'Loughlin considers it possible there is "a fear in one profession that if a new service is provided by a different profession, and funding goes into it, that they will somehow be at a loss".

"GPs should be paid for what they do and should be paid properly," Mr O'Loughlin emphasised, "but they should be given the level of support that allows them to spend meaningful amounts of time with patients who need meaningful amounts of time and not be rushed, having to get through a waiting room of people who could have been dealt with in a pharmacy."

ICGP

Meanwhile, the ICGP issued a statement to this publication conveying a much more open position on expanding the pharmacists' role, when compared with the IMO. The College will have a particular insight into developments in pharmacy through CEO Mr Fintan Foy, who is currently serving his second term on the Council of the PSI.

In regard to a minor ailments scheme, an ICGP spokesperson said community pharmacists already treat several minor ailments "such as minor coughs and respiratory infections and some skin infections, among other ailments, and this of course helps to reduce pressure on the hospital emergency services and on other parts of the health service.

"A community pharmacist-provided minor ailments scheme would require clear guidelines, protocols and governance structures, as well as training of pharmacy support staff."

As to the potential future introduction of independent pharmacist prescribers, as well as pharmacist supplementary prescribing as part of shared care with a GP, the spokesperson said: "Pharmacists and GPs already enjoy a close working relationship and a good level of trust and mutual respect has been established through years of working together. A highly-trained pharmacist prescriber under the governance and supervision of the managing GP would be an additional valuable resource in the community.

"If care is shared with GPs and is guided and directed by the GP, then a pharmacist prescriber would add to the community support team for patients. Pharmacist prescribers would require extra training and thorough and comprehensive guidelines and protocols in order to ensure patient safety and wellbeing."

On whether the College could have any future role in the training of community pharmacists, the spokesperson said pharmacists and GPs have their own separate education and professional competence schemes.

"However, the ICGP would be very happy to meet with the PSI and the Irish Institute of Pharmacy to discuss areas of mutual interest in the areas of education and service provision."

The Department of Health is clear that it sees the role of pharmacists in Irish healthcare as evolving. But it is providing limited detail on what this new model may look like.

"The Minister will be seeking to put in place a contractual agreement that is fit-for-purpose in a healthcare system that is increasingly seeking to tilt the balance of care towards a strengthened primary care system," according to a Department spokesperson.

"The intention would be that the vision and approach which underpins Sláintecare would be mapped-out for community pharmacy; a primary care model, integrated with other health policies as part of a multidisciplinary approach to healthcare. The way forward will require the expansion of both the scope of practice and the range of public services provided in community pharmacy.

"An overriding principle in that proposed engagement with pharmacy representatives has to be value for money, ensuring that any new service delivery actually improves health outcomes and benefits for patients. All proposals, including treatments for minor ailments, will be for discussion under the proposed contract reform."

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Road-blocks, U-turns and whiplash

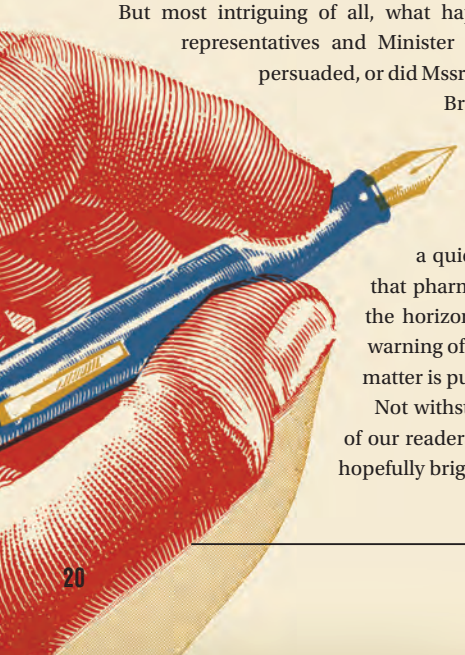
At the National Pharmacy Conference last May, it was with guarded optimism that I listened to the Minister for Health paint a picture of a rosy immediate future for Irish pharmacists, with gushing enthusiasm for the role pharmacists play in healthcare and a commitment, if somewhat vague, to new contract talks. With a forest of hands ready to shoot up towards the ceiling, the Minister had a clearly 'pressing commitment' and wasn't around for the Q&A after his address. The optimist in me imagined that he was rushing back to his office to work on drafting a new contract.

Fast-forward to October, when the bombshell dropped that new, savage cuts were to be imposed on pharmacy fees. There was a collective 'thud' as around 2,300 jaws hit the floor in community pharmacies nationwide — 2,301, if you include the offices of *Irish Pharmacist*. I took no pleasure in having my cynicism confirmed.

Taking another time-jump to December — having already penned the most scathing editorial I've ever written — and it was abruptly announced that the proposed fee cuts were not going ahead and the Minister had re-committed to new contract talks. The proposed cuts were confusing, but no less so than the Minister's reversal. The editorial found its new home in the recycle bin.

As the old saying goes, that kind of raised more questions than it answered. Who proposed these cuts in the first place before they were announced? Was it a decision by the Minister himself, or was he influenced by some clueless advisors who foolishly thought hammering pharmacists further would be a good idea? What happened in between the announcement that cuts would be imposed and the press release stating that they would not in fact go ahead? And even if he was badly advised on imposing further cuts, what the hell was Minister Harris thinking in going along with it? Was he not concerned about being perceived as something of a hypocrite, given the contents of his address at the National Pharmacy Conference?

But most intriguing of all, what happened at the meeting between the IPU representatives and Minister Harris on 5 December? Was he cajoled, persuaded, or did Mssrs Connolly and O'Loughlin bring along Luca Brasi to make the Minister an 'offer he couldn't refuse'? Whatever they did, it clearly worked and the Minister must have required treatment for whiplash injury.



Perhaps a Sir Humphrey-type figure had a quiet word in the Minister's ear to remind him that pharmacists vote too. With a general election on the horizon, the cynic in me is tugging at my sleeve, warning of another potential *volte face* when that small matter is put to bed.

Not withstanding all of the above, I sincerely wish all of our readers a smooth ride in 2020 along the road to a hopefully bright future for the profession.

THAR AN GCUNTAR AS GAEILGE

Prionsabal a hAon: Cuir an t-othar chun tosaigh i gcónaí. Is é an prionsabal seo an ceann is tábhachtaí i mo thuairimse, ós rud é go bhfuil sé mar bhunchloch an Chóid Iompair. Coinnigh an t- othar i gcroílár an chúraim a sholáthraíonn tú; Bíodh a bpríomhfhócas ar a sláinte, a bhfolláine agus a sábháilteacht i gcónaí; Agus é sin á dhéanamh agat, tá tú ag cinntiú go n-aithnítear riachtanais an othair agus go bhfreagraíonn tú ar bhealach díniteach agus gairmiúil. Coinníonn sé seo luachanna an othair chun tosaigh san idirghníomhaíocht. Feabhsaíonn sé seo eispéireas an othair. Tríd do scileanna agus eolas gairmiúil a chur i bhfeidhm, cinntíonn tú arís go bhfaigheann an t- othar cúram sábháilte agus éifeachtach. Mar fhocal scoir, ag aithint go mbíonn tionchar díreach ag do chinntí agus do ghníomhartha mar Chógaiseoir ar an gcúram a bhíonn ann, fiú i gcúinsí nach raibh tú ag obair go díreach leis an othar. Cén chaoi a gcinntíonn Cógaiseoir go bhfuil siad ag cur an chéad Phrionsabal Cleachtais i bhfeidhm sa Chód Iompair nua-athbhreithnithe?

1. Mar a luadh thuas, tá cur i bhfeidhm eolais, cur i bhfeidhm scileanna agus úsáid chinnteoireachta bunaithe ar fhianaise mar chuid lárnach de Phrionsabal a hAon agus, rud is tábhachtaí, cinntíonn sé go bhfuil an t-othar ag fáil an chaighdeáin is airde cúraim is féidir.

2. Tréith; ardchaighdeán, tá go leor cógais ag cógaiseoirí, ag feidhmiú a gcumas chun cóir leighis a chur ar gach othar ar bhealach measúil, díniteach agus cúirtéiseach.

3. Ní mór úsáid a bhaint as d'aitheantas ár luachanna, creidimh, éagsúlacht agus féiniúlacht chultúrtha na n-othar a dtéann tú i dteagmháil leo. Tá poitéinseal éagsúil cultúrtha in Éirinn, agus de réir, tá tionchar ag roinnt creidimh ar shláinte agus ar an dóigh a mbítear ag súil le sláinte nó ag teacht léi.

4. Prionsabal an toil nó an cead a urramú. Cinnte go bhfuil tú ag cloí leis na rialacháin reachtúla go léir.

5. Bheith ábalta cinntí othar a aithint agus a urramú, go háirithe i gcásanna inár féidir leo cóireáil nó seirbhísí a dhiúltú.

6. Cosc a chur ar aon cheann de do thuairimí pearsanta ó chúram an othair a chur i mbaol.

7. Déileálfaidh Cógaiseoir a chloíonn leis an gCód nua-athbhreithnithe le gach duine go cothrom lena n-áirítear daoine leochaileach, daoine faoi mhíchumas intleachta agus aon mhíchumas eile, a n-aithnítear go minic mar Chógaiseoirí in Éirinn.

8. Bheith muiníneach maidir le hábhair imní a ardú leis na húdaráis ábhartha más rud é go bhfuil baol tionchar a bheith acu ar shláinte an othair, nó a d'fhéadfadh tionchar diúltach a imirt ar chúram othar mura dtugtar aghaidh orthu.

Mar nóta scaradh, is é an t-othar a choinneáil chun tosaigh an rud is tábhachtaí i gcónaí. Mar sin féin, tá luach agat féin mar dhuine agus mar dhuine oiliúint ghairmiúil. Ná déan dearmad ar an méid sin.

MARK JORDAN is a community pharmacist based in Castlebar, Co Mayo. He is an elected member of the PSI Council, author of **The Weekly Nugget** on PharmaBuddy and host to the PharmaBuddy Podcast.

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TIME TO GET SMART

As a profession, are pharmacists dim-witted or do we just do a good impression of stupid people when it comes to pricing, asks ***Fintan Moore***

There's a great line in the 1990s movie, *Dangerous Liaisons*, spoken by the scheming and manipulative Marquise de Merteuil, played by Glenn Close, in which she contemptuously refers to a young man, saying: "He is an intellectual, and like most intellectuals, intensely stupid." I sometimes wonder if that description could be fairly applied to pharmacists. It's a pretty safe bet that a lot of us are intellectual, or at the very least have an exam-measurable intelligence. The open question is whether or not we are stupid, or continually behave like we might be.

When it comes down to it, pharmacy is a service industry. The same can be said of most professions — there's no fundamental difference between a GP and a window-cleaner. So let's take a look at the street-smarts used by barbers back when the VAT rate on

haircuts changed from 9 per cent to 13.5 per cent. My haircuts before the VAT change used to cost about €11. Given that cutting my hair just involves running a number 3 blade over the few relevant parts of my skull, the barber was doing pretty well on €11. When the Government changed the VAT rate up by 4.5 per cent, the cost of a haircut should have gone up by less than 50 cent, but instead it jumped to €14. Coincidentally, other barbers in the area also hiked prices by similar amounts. So the cover story provided by the Government let them all become more profitable.

In theory, pharmacists are more intelligent than barbers. If you wanted a Sudoku solved or a cryptic crossword filled in, I reckon the average pharmacist would be quicker than the average scissor-snipper. But would we have the brains to pull off a comparable stroke to make us more money for the same amount of work? Not likely, based on performance to date, especially given our willingness to do ever-increasing amounts of work while reducing prices. Look at our track record on FMD scanning. We've had to fork-out money on hardware, as well as the ongoing cost to the various companies we register with. But that's actually the least of it, when you measure the workload cost.

Let's do a back-of-envelope calculation, assuming a pharmacy is doing 4,000 items a month. Each scan takes probably a minimum of 10 seconds when you factor-in bringing every pack to the scanner, twirling the box to find the bar-code, etc. That's 40,000 seconds a month, or 480,000 seconds a year. That is 133 hours, which is more than three working weeks of productivity lost per annum. You can do your own maths on how you put a financial price on that loss, but I reckon that to get back to break-even would require a 30 cent increase on every private prescription. Yet instead of price increases, whenever I look around, all I see are more pharmacies advertising ever-decreasing prices in some kind of frenzy to presumably gain 'volume'. Maybe I'm the stupid one, but you can be the busiest person in town if you work for nothing. At least my local barber is smart enough to cut hair instead of prices.

BLISTERING COMMENTARY

Notwithstanding our profession absorbing the cost of FMD compliance rather than having the sense to pass it on to the public, there may be glimmers of hope that we are starting to realise that any proper service needs to be paid for by somebody. I'm reliably informed that the Joe Duffy show recently had callers complaining about having to pay to for their medication to be blister-packed. Nothing could induce me to listen to the show, but apparently the usual confusion reigned as to what could, would or should be paid by the HSE when it comes to phased dispensing and/or blister-packing. The good news about all this is the fact that enough pharmacists are charging for a service instead of doing it for nothing, in sufficient numbers to be a Joe Duffy item. So the question for the pharmacists who still aren't charging is, 'why not?' If the guy down the road from you is doing it, then you might as well too. If you lose the odd patient, you'll still be making the same money overall, with less of a workload. And the people you are still serving will be the ones who appreciate what you're doing enough to respect it by paying for it.

YELLOW-PACK HEALTH SERVICE

Has anybody ever told the HSE employees who work in the PCRS that there are only 12 months in a year? I merely ask because another envelope containing 12 yellow bags for paperwork was delivered by courier recently, which means that I now have enough bags for about the next four years. If even half of the pharmacies in the country got the same unnecessary delivery, then the expense to the HSE was probably about €10,000. The waste involved in this may be relatively minor in the greater scheme of things, but it is symptomatic of a bureaucracy that is unreformed, despite supposed improved productivity and reform. The shelving of proposed recent cuts to pharmacy was welcome, but it doesn't look like the HSE will react by using its existing funds any more efficiently.

CONTRIBUTOR INFORMATION

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LET'S TALK ABOUT DYING

The subject of death and dying should not be taboo and there needs to be more honesty around the topic from healthcare professionals, writes ***Terry Maguire***

People seldom, if ever, die at convenient times. Edith was no exception, yet she would have been annoyed had she thought her demise, when it eventually happened, would inconvenience anyone, never mind me, whom she didn't know. Her daughter, a close work colleague, meant I was duty-bound to attend her memorial service at the crematorium and it was an irony that the largely unplanned memorial at mid-day on Wednesday clashed with a long-planned training event on palliative care. Edith, diagnosed with cancer, was spared a prolonged debilitating illness, dying precisely one week later, having refused all interventions. The benefits of a swift death, painful as it was for the family, soothed their loss. At the Humanist ceremony before the coffin was lowered into the furnace, her daughter bravely recounted stories of her many stunning talents but accepted that she was now gone, sad as it was.

Edith's commendable stoicism, and that of her family, was in complete contrast to a family I dealt with the previous day. They had been told, in what seemed a masterfully ambiguous and roundabout way, that their 84-year-old mother, let's call her 'Mary', was dying. Such was the confusion that the GP spread, the family were convinced mother was on the road to recovery. The GP's conversation was nuanced and conditional to the point of being pointless. The GP's aim, as was his professional responsibility, was to inform the family at this most poignant and important of times that their mother was finished but in his timidity, he failed miserably.

When the eldest sibling told me the good news that mother was on the mend, I cautioned her enthusiasm, only to be strictly admonished. When she started palliative care treatment two weeks later, I received a tearful apology that was accepted with a caring hug — not politically correct but justified, given my service of over 30 years to Mary.

Death, for most, remains such a taboo. We just cannot have that conversation, so impressed are we that all can be fixed by the miracles of modern medicine. So heavily invested have national health services and politicians become in addressing sickness that it seems almost heresy to suggest that we can't cure everything, which of course we can't — unless we use cannabis oil!

In the modern era, we live such safe lives that most of us live long enough to reach the end of our natural lives, rather than get eaten by a wolf, speared by a savage or killed by an exploding shell. We are so good at avoiding sudden death that eventually our batteries run down, the wheels come off and the plumbing leaks dangerously. We transform from productive, sentient individuals to hopeless and helpless masses of bones and flesh.

> *"Palliative care is not new and has been used for terminal cancer patients for decades*

Palliative care is not new and has been used for terminal cancer patient for decades. What is newer is its application to those with terminal conditions — heart failure, COPD, renal failure, dementia and neurological conditions.

Unlike cancers, these conditions do not have the cliff off which most cancer patients fall and death's timeline is easily predicable. Rather, the journey to death is a slog of minimal gradient, with pot-holes of more rapid decline from which the patient emerges to rally, to the amazement of family and physicians. This is never the road to recovery and there needs to be wider recognition of this natural fact.

Of the 15,000 deaths in Northern Ireland each year, 11,000 have palliative care needs. Where most individuals and families want deaths to happen at home, the vast majority happen in hospital, and in spite of efforts to support more home deaths, in our 'End-of-Life Strategy', little has changed since 2006 in terms of the place we make our appointments with death.

To support our final journey, most of the UK regions initially adopted the 'Liverpool Pathway', which defined what should be done and when. There was a backlash from families who felt that this approach was too callous and perhaps there was too much focus on death, so it was abandoned.

Medicines for most chronic long-term conditions need to be withdrawn when death is imminent, but there is little evidence that this is happening. Certainly most drugs, statins, endocrines, respiratory, etc, can and should be withdrawn, administering only those that specifically support palliative care. Antibiotics are a cause of particular passion. Giving an antibiotic while the patient is clearly dying may stop or delay the process of dying, leaving the end to another time but with no other material benefit to the patient.

Above all, when death is a few days away, there is a need to withdraw food, then fluids, and provide support and comfort only as-needed. Too many family members intervene and insist on oxygen therapy, PEG tube feeding and then saline drips. While these interventions are largely pointless, they are not sufficiently challenged by medical staff who seem to go with the notion that something positive should be done.

Both Edith and Mary are now gone. Each family has a different view of the palliative care process. Edith's family were spared a long, lingering death, but Mary's was not and the longer it went on, the more futile the interventions being tried were and rather than being caring were, in a distorted and unintentional way, cruel.

As a society, we need to talk more about death and dying and we need to do it more generally, so that when a family is faced with the huge challenges of the last few weeks of someone's life, they can make decisions from a position of caring, informed understanding, rather than cruel emotional ignorance. ●

CONTRIBUTOR INFORMATION

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VAPE LUNG INJURY

AND ITS LINK TO 'EARWAX', 'BHO' AND 'DABBING'

Dr Des Corrigan *writes on the current controversy in e-cigarettes and breaks down some of the terminology in 'cannavaping'*

Controversy has surrounded e-cigarettes since they were first appeared in 2006. Are they a valuable aid for those trying to quit smoking, or are they just another way of hooking young people on nicotine? These are just two of the questions this new technology has posed. Some believe they should be regulated as medical devices by the HPRA, while others favour the present unregulated free-for-all, on commercial grounds.

The range of products is bewildering, as is the terminology used. A variety of names exist, including 'e-cigarettes', 'e-cigs', 'mods', 'vape pens', 'vapes', and even 'electronic nicotine delivery systems'. Some look like cigarettes, cigars and pipes, while others resemble pens and USB sticks with refillable cartridges or pods. The latter are the dominant product in the States, accounting for 70 per cent of sales. They work by using a battery-powered metal resistance coil to heat nicotine, flavourings, propylene glycol and

vegetable glycerine in liquid form to produce an aerosol that users inhale into their lungs. That aerosol can contain (apart from the nicotine) volatile carbonyls, furans and reactive oxygen species, carcinogens, heavy metals (nickel, tin and lead), as well as ultrafine particulate matter. A key flavouring is diacetyl, the inhalation of which is known to cause a form of bronchiolitis called 'popcorn worker's lung'. Since plant tissue is not being burned, as in a cigarette, many of the harmful pyrolysis products from either tobacco leaf or cannabis herb will not be produced. Therefore, a case can be made that e-cigarettes may be less harmful to the lung than conventional cigarettes and certainly Public Health England is of that view.

However, proponents of these devices may lose sight of the fact that nicotine is still a highly-addictive compound that can be embryotoxic, may harm adolescent brain development and is a recognised poison. Two RCTs found that nicotine-containing e-cigarettes can help smokers quit over the long term when compared to placebo non-nicotine-containing devices. It is vital, however, that those quitting use e-cigarettes alone and that they do not fall into the trap of becoming 'dual users', ie, smoking regular cigarettes and also using e-cigarettes. In the US, electronic cigarettes are most commonly used by high-school students, raising concerns about the impact on their developing brains and the risk of their becoming addicted to nicotine. The high level of vaping by young people has reversed progress in the decline in tobacco use by that age cohort.

The controversy over these devices has intensified in recent months because of the emergence of what is now called EVALI in the US. The acronym stands for E Vaping Associated Lung Injury. At the time of writing, the Centres for Disease Control and Prevention (CDC) has reported 2,290 cases of 'vape lung injury', including 47 deaths. Cases have been reported from 49 states (Alaska is the exception) and involve mostly young white males, all with a history of vaping. Out of 867 patients for whom data is available, 86 per cent reported use of THC, 64 per cent nicotine, 52 per cent both THC and nicotine, 34 per cent only THC, and 11 per cent only nicotine. The THC-containing products were obtained particularly from street sources, friends, family members or illicit dealers. When samples were available for testing by the FDA, most were positive for THC but until recently, no one compound or ingredient had emerged as the cause of the injury to the lungs. Bronchoscopy samples from 29 patients were examined and vitamin E acetate identified in all samples. This is used in some THC-containing products to thicken the oil. Obviously, vitamin E acetate does not cause respiratory problems if taken orally or applied topically, but it is known that if it is inhaled, it may affect the lungs. Frantic efforts are underway to establish the exact cause of 'vape lung' and there has been a huge drop in sales and calls by politicians and health professionals, including the American Medical Association for bans on the advertising and sale of e-cigarettes. Not surprisingly, these calls have been matched by industry lobbying to prevent any attempt to curtail their profiteering.

Much of the THC consumed in what is called 'cannavaping' is in the form of oily solutions in refillable cartridges, although some was used by 'dabbing' or 'dripping' of a THC-rich cannabis concentrate directly onto the heated coil of the e-cigarette. 'Dabbing' is a relatively new method of drug use that emerged from the development of 'concentrates' by the now-legal cannabis industry. These concentrates were originally supposed to be used to manufacture 'edibles' — cannabis products for medicinal use designed to be eaten as confectionery or drunk in beverages (beers or soft drinks) by those wishing to avoid smoking the drug. Some concentrates are made using dry processing methods, such as dry ice.

Water-based methods provide what is known as 'bubble hash'. Although organic solvents such as ethanol or acetone can be used, most commercial and indeed amateur concentrates are processed using a liquid gas, such as pressurised butane. Some pharmaceutical-grade extracts use supercritical fluid extraction technology with liquid carbon dioxide because no solvent resides remain after it evaporates off.

Butane is particularly popular, giving rise to what is termed BHO (butane hash oil). Evaporation of the gas leaves a brown or yellowy-white solid with a low melting point. In slang terms, this is called 'ear wax', 'crumble', 'honeycomb', 'shatter' or 'budder', depending on its consistency and physical appearance. Such concentrates can have a THC content ranging from 69-to-95 per cent, depending on the potency of the starting cannabis plant material. Samples of BHO tested in the UK in 2016 gave THC contents ranging from 73-to-83 per cent with less than 1 per cent of CBD. To put that into context, herbal cannabis from the 1960s through to the late 1990s had between 1-and-3 per cent THC and hash had between 3 and 10 per cent.

Until the emergence of 'cannavaping', dabbing involved the application of a small amount of concentrate (a 'dab') to a nail made of titanium, which was then flash-vapourised with a butane flame, such as the popular crème brûlée torch. The vapour was then inhaled in a single puff through a water pipe. More THC is absorbed by 'dabbing' than by smoking marijuana flower buds (76 per cent vs 27 per cent). It is also absorbed much more quickly (seconds vs minutes), producing a more intense euphoric high. Swiss researchers noted that as a result, dabbing provides an easier way of quickly consuming massive doses of THC that is more likely to lead to tolerance and withdrawal symptoms. A 2017 study in *Drug and Alcohol Dependence* of 121 recent BHO users reported higher levels of physical dependence, impaired control, academic and occupational problems.

In the meantime, the CDC in the States has advised against any vaping of THC-containing products at present. Even for those who are vaping only nicotine, caution is advised because stronger evidence is needed before any definitive statement can be made as to whether e-cigarettes are effective in helping smokers quit. ●

CONTRIBUTOR INFORMATION

Dr Des Corrigan, Best Contribution in Pharmacy Award (winner), GSK Medical Media Awards 2014, is a former Director of the School of Pharmacy at TCD and won the Lifetime Achievement Award at the 2009 Pharmacist Awards. He was chair of the Government's National Advisory Committee on Drugs from 2000 to 2011. He currently chairs the Advisory Subcommittee on Herbal Medicines and is a member of the Advisory Committee on Human Medicines at the IMB. He is a National Expert on Committee 13B (Phytochemistry) at the European Pharmacopoeia in Strasbourg and he is an editorial board member of the Journal of Herbal Medicine and of FACT — Focus on Alternative and Complementary Therapy.

A vision for the future

***Ultan Molloy** looks at the factors that will be necessary in 2020 to bring the profession forward and reviews his correspondence with the office of the Minister for Health*

I am writing this noting that my previous open letter to our Minister for Health was somewhat redundant by the time it was published. I did send it to him; incidentally, he chose to acknowledge its receipt on the day I write this. About a 75 per cent acknowledgement of correspondence rate from public representatives is perhaps reasonable. I have come to the conclusion, having been on the receiving end of an occasional snubbing, or having been ignored, that it is kinder to acknowledge, making a modest allowance for occasionally forgetting to, of course.

Too many *curricula vitae* have ended up in the bin over the years without me acknowledging their receipt and thanking the person for their interest in our company. Too many company representatives and sales people have got a response that was curt and ignorant, perhaps on foot of my own stress levels and energy resources. I understand, since 'it's business' and all that, but there really is no need to be so rude in most cases.

Is it the Buddhists who suggest that kindness and compassion are everything. Now, that's a noble aspiration for the new year ahead. I know that I, for one, will struggle.

A VISION FOR THE FUTURE

We didn't receive the cuts that we could have before Christmas under FEMPI regulations, with the promise of a new "fit-for-purpose" pharmacy contract being developed this year. We had, however, circa €28,000 in phased prescription fees cut in our pharmacy business, which is highly significant on our modest turnover. This unexplained cancelling of patient eligibility without engagement or explanation appears to have gone under the radar completely for our politicians and our Minister.

"We have the people to deliver this", one colleague had posted on a pharmacist social medium in relation to new contract negotiations, and this got me thinking. Credit whom or what you will for this pre-Christmas achievement, or rather a preven-

tion of a further drain on community pharmacy resources, but we have little to show in terms of successes in the sector over the last 10-year period. A flu vaccination service as a professional service offers a glimmer of hope, although it continues to be a financial loss-leader given the cost of training, the cost of providing the service, and the poor remuneration paid following negotiations with the PCRS. Professional services should not be a loss-leader, so don't even go there with me, in case that's your retort. If nothing is sacred, then the sector is destined to the same fate as fast-moving consumer goods. As much (medicine) as you can, as cheap as you can and as fast as you can.

Have we a situation where the profession is represented at the most senior executive levels in the Government? The absence of a Chief Pharmacy Officer representing the interests of pharmacists daily at Government level speaks volumes about the value seen in having that position.

We have a single representative body for community pharmacists at present. Noting that previous behaviour is the best predictor of future behaviour, we can ask, does it have the capability, capacity and culture to deliver a robust new fit-for-purpose contract for community pharmacy, and the patients and customers it serves? We can ask, thanks to Beckhard, are there clear goals, roles, interpersonal relationships and processes in place in-house in order to deliver for us? We can ask, is there a culture of high performance where results follow from accountability, commitment and trust based on a culture of healthy, respectful conflict?

Of course, what we wouldn't want in such an organisation is in-fighting at executive level, a culture of cronyism, an acceptance of mediocre performance in key roles, and an apparent unwillingness to hold people to account for poor performance. We wouldn't want a metaphorical 'circle-jerk', a reluctance to listen to and objectively evaluate dissenting opinions, or the group-think, such as in Anglo Irish Bank that contributed significantly to our previous economic crisis. We certainly wouldn't want a situation where pharmacists could be seen as a privileged, tuxedoed, chicken-dinner brigade, primarily concerned with their business interests over that of patient and customer care, on a win-win basis. We wouldn't want a body that offers much in terms of photoshoots and press for the media, and much less in terms of results for the community pharmacists who pay in order to have their interests professionally, responsibly and diligently represented.

We would want appropriate corporate governance and leadership. We would want a board that is holding the CEO and their executive team to account for their performance against set ambitious targets and metrics. We would want to see a demonstrated ability to build relationships, communicate effectively and influence policy at the most senior levels of Government. We would want to see an understanding of the perspectives of all the key shareholders clearly demonstrated, and those stakeholders engaging on foot of this. We would want the value of pharmacists as healthcare professionals and experts in the safe and effective use of medicines communicated clearly, consistently and concisely at every available opportunity.

'GOOD IS THE ENEMY OF GREAT'

Harry Hughes, Chair of the Hughes Group based out of Westport and employing 4,500 people worldwide and turning over €260 million, said their culture embraces a philosophy of "good" being "the enemy of great". Where does that leave 'average', I would ask? To anyone who suggests, 'well, things could have be much worse if I/we/they weren't there', I ask, would things have be significantly better if someone else was there instead?

To those of you who rest assured of your own brilliance, then maybe consider the foundation for that opinion (see 'circle-jerk', 'group-think' etc above). To those of you who spend much of their time dismantling and finding fault with yourself, and your own opinion, then maybe it's time to step up and back yourself.

A FIT-FOR-PURPOSE CONTRACT

I've included three of the paragraphs below from the Minister's correspondence for us to consider starting into 2020.

"The Minister recognises the significant role community pharmacists play in the delivery of patient care and the potential for this role to be developed further in the context of health service reform and modernisation. Community pharmacy is recognised as the most accessible element of our health service, with an unequalled reach in terms of patient contact and access.

"The comprehensive review of the pharmacy contract in 2020 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 multidisciplinary model of service delivery for patients, ensuring clarity of roles and achieving optimum value for money.

"However, any publicly-funded pharmacy service expansion should address unmet public healthcare needs, improve access to existing public health services or provide better value for money or patient outcomes. Accordingly, any measures to be considered must be evidence-based."

So meeting unmet patient needs, improving access to present services, better value for money and better patient outcomes. Evidence for these things, please? Anyone working in a community pharmacy has a sense of the value the service brings for patient care. Pilot trials in Ireland, evidence on initiatives through pharmacy from other jurisdictions and the significant impact of the vaccination service on immunisation rates appear not to have addressed the Minister's concerns to date. Is it therefore a case of 'There are none so blind as those who will not see', as quoted to me by a colleague recently, or are there other reasons? Could it be credibility, relationships, communication skills, influencing skills, insufficient evidence, or another variable in the mix, as best efforts to date have clearly not been good enough.

Good luck to all of us reading this for 2020 and beyond. We will need good luck, and much more than just good luck, if the future is to play out positively for ourselves, our patients, our customers and our communities. ●

CONTRIBUTOR INFORMATION

Ultan Molloy is a business and professional performance coach, pharmacist, facilitator and development specialist. He works with other pharmacists, business owners and third parties to develop business strategies. Ultan can be contacted on 086 1693343.

NiQuitin®

Contains nicotine

"I quit smoking for her"

***Fergus** O'Shea*

Help smokers quit with an **unbeatable combination*** from NiQuitin®

NiQuitin® Patch
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NiQuitin® Mini
ON THE GO CRAVING RELIEF

IRE/NIQ/2019-001

*Provides significant improvements in quit rates vs patch alone. Stead LF et al. 2012 Nicotine replacement therapy for smoking cessation, Cochrane Library.

NiQuitin CLEAR 24 hrs transdermal patches are indicated for the relief of nicotine withdrawal symptoms including cravings as an aid to smoking cessation. Indicated in adults and adolescents aged 12 years and over. NiQuitin patches should be applied once a day, at the same time each day and preferably soon after waking and worn continuously for 24 hours. Apply a patch to non-hairy clean dry skin surface, a new skin site should be used every day. Therapy should usually begin with NiQuitin 21 mg/24 hrs and reduced according to the following dosing schedule: **Step 1** NiQuitin Clear 21 mg/24 hrs transdermal patches first 6 weeks. **Step 2** NiQuitin Clear 14 mg/24 hrs transdermal patches next 2 weeks. **Step 3** NiQuitin Clear 7 mg/24 hrs transdermal patches last 2 weeks. Light smokers (e.g. those who smoke less than 10 cigarettes per day) are recommended to start at Step 2 (14 mg) for 6 weeks and decrease the dose to NiQuitin 7 mg/24 hrs for the final 2 weeks. **Contraindications:** Non-smokers, hypersensitivity, children under 12 years and occasional smokers. **Precaution:** Supervise use if hospitalised for MI, severe dysrhythmia or CVA, if haemodynamically unstable. Use with caution in patients with active oesophagitis, oral and pharyngeal inflammation, gastritis, peptic ulcers, GI disturbances, susceptible to angioedema, urticaria, renal/hepatic impairment, hyperthyroidism, diabetes, phaeochromocytoma, seizures & epilepsy. Discontinue if severe persistent skin rash. **Pregnancy and lactation:** Oral formats preferable to patches unless nauseous. Remove patches at bedtime. **Side effects:** *Transient rash, itching, burning, tingling, numbness, swelling, localised pain urticaria, hypersensitivity reactions. headache, dizziness, tremor, sleep disorders, nervousness, palpitations, tachycardia, dyspnoea, pharyngitis, cough, nausea, vomiting dyspepsia, upper abdominal pain, diarrhoea, constipation, dry mouth, sweating, dermatitis, photosensitivity, arthralgia, myalgia, asthenia, malaise, influenza-type illness, fatigue, seizures and anaphylaxis.* **Legal classification: GSL: PA 1186/18/4, PA 1186/18/5 & PA 1186/18/6. MAH:** Chefaro Ireland DAC, The Sharp Building, Hogan Place, Dublin 2, Ireland. http://www.medicines.ie/medicine/12136/SPC/NiQuitin+CLEAR+7+mg+24+hours+transdermal+patch/ http://www.medicines.ie/medicine/12137/SPC/NiQuitin+CLEAR+14+mg+24+hours+transdermal+patch/ http://www.medicines.ie/medicine/12138/SPC/NiQuitin+CLEAR+21+mg+24+hours+transdermal+patch/ **NiQuitin Mini 1.5mg/4mg Mint Lozenges** are used for the treatment of tobacco dependence by relief of nicotine withdrawal symptoms and cravings. Indicated in adults and adolescents aged 12 years and over. NiQuitin Mini 1.5 mg are suitable for those who smoke who smoke 20 cigarettes or less a day. NiQuitin Mini 4 mg are suitable for smokers who smoke more than 20 cigarettes a day. Place a lozenge in the mouth whenever there is an urge to smoke, allow to dissolve completely. Do not chew or swallow whole. **Abrupt cessation:** Use a lozenge whenever there is an urge to smoke, maximum of 15 lozenges a day. Continue for up to 6 weeks, then gradually reduce lozenge use. **Gradual cessation:** Use lozenges whenever there is an urge to smoke in order to reduce the number of cigarettes smoked for up to 6 weeks, followed by abrupt cessation. **Adolescents (12-17 years):** Only with advice from a healthcare professional. **Contraindications:** Hypersensitivity to nicotine or any of the excipients, children under the age of 12 years and non-smokers. **Precaution:** Supervised use in dependent smokers with a recent myocardial infarction, unstable or worsening angina pectoris including Prinzmetal's angina, severe cardiac arrhythmias, uncontrolled hypertensions or recent cerebrovascular accident. Use with caution in those with; stable cardiovascular diseases, diabetes mellitus, susceptibility to angioedema & urticaria renal/hepatic impairment, phaeochromocytoma & uncontrolled hyperthyroidism, GI disease & seizures. **Side effects:** *Nausea, mouth/throat and tongue irritation, irritability, anxiety, sleep disorders, dizziness, headaches, cough, sore throat, dyspnoea, vomiting, diarrhoea, GI discomfort, flatulence, hiccups, heartburn, dyspepsia, nervousness, depression, palpitation, rash, angioedema, pruritus, erythema, hyperhidrosis, fatigue, malaise chest pain, anaphylactic reactions, hypersensitivity, tremor, dysgeusia, paresthesia mouth, seizures & epilepsy, dysphagia, eructation, salivary hypersecretion, pharyngitis. http://www.medicines.ie/medicine/14493/SPC/NiQuitin+Mini+1.5mg+mint+lozenges/#PRODUCTINFO* http://www.medicines.ie/medicine/14492/SPC/NiQuitin+Mini+4mg+mint+lozenges/ **Legal classification: GSL: PA 1186/18/11 & PA 1186/18/12. MAH:** Chefaro Ireland DAC, The Sharp Building, Hogan Place, Dublin 2, Ireland.

Donna Cosgrove PhD MPSI

RISKS OF SMOKING TOBACCO

Tobacco use is the leading cause of preventable death in Ireland but the rewards of quitting are huge, writes ***Donna Cosgrove PhD MPSI***

Almost 6,000 people die annually from tobacco-related diseases.[1] It is the only legal drug product that kills many of its users when used exactly as intended by manufacturers. People who smoke cigarettes have a higher chance of developing:[2]

- **Breathing problems:** Nearly 80 per cent of deaths from COPD are attributable to smoking.
- **Cancer:** Lung, throat and mouth especially. Ninety percent of lung cancers, and at least 30 per cent of all cancer deaths, are attributable to smoking.[3]
- **Cardiovascular disease:** Myocardial infarction, coronary artery disease, hypertension, peripheral vascular disease.
- **Eye problems**, ie, cataracts.
- **Gastrointestinal issues**, ie, peptic ulcers and inflammatory bowel disease.[2]
- **Impaired fertility**, impotence, spontaneous abortions; also, ectopic pregnancies.
- **Mouth ulcers** and dental problems.
- **Osteoporosis**.[4]
- **Rheumatoid arthritis**.

Most of the harm from smoking is caused by the burning of tobacco, as opposed to nicotine itself. Cigarette smoke contains over 4,000 chemicals (Figure 1) — this includes approximately 69 chemicals that are well-established carcinogens, and over 400 other toxins.

NICOTINE ADDICTION

Nicotine is a highly-addictive compound. Smoking cigarettes, ie, administration through the lung, provides almost instant absorption, permitting nicotine to enter the brain in six seconds. The speed and efficiency of this route reinforces self-administration of nicotine.[2] The pharmacological basis of nicotine addiction is a due to positive reinforcement: Enhancement of mood, improved functioning, such as better concentration and reaction time; also, avoidance of withdrawal symptoms.

Smoking is associated with a pleasurable experience and a sense of satisfaction. This is caused by stimulation of the nicotinic cholinergic receptors in the brain, which releases neurotransmitters including dopamine. The release of multiple other neurotransmitters such as noradrenaline, acetylcholine, serotonin, γ-aminobutyric acid, gluta-

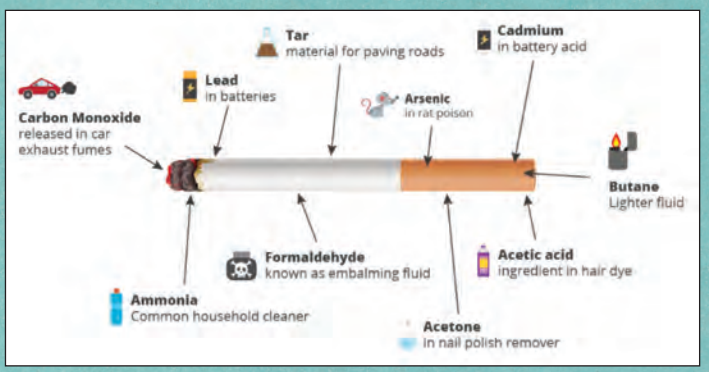

Figure 1: Cigarette smoke contains a number of carcinogens and toxins[1]

mate, and endorphins lead to the arousal, mood modulation, performance enhancement, analgesic, and weight-loss effects associated with smoking.[5] Tolerance and desensitisation develop with repeated use[4] due to an increase in the number of binding sites present on nicotinic receptors. This means that higher doses of nicotine are then required to achieve the same level of stimulation. When these desensitised receptors again become responsive in times of prolonged abstinence, craving and withdrawal symptoms such as anxiety and stress then manifest, ie, after waking up from an overnight sleep. Smoking again alleviates cravings and withdrawal symptoms, which provides positive reinforcement, further encouraging the smoking habit. The avoidance of withdrawal symptoms becomes a reason in itself to smoke. With regular smoking, certain cues may be associated with the habit: The mood modulation and arousal caused by nicotine may eventually be associated with the actions of, ie, rolling a cigarette, lighting it, and physical movement of smoking itself, separate to the direct pharmacological effect. The pairing of a significant stimulus or action like smoking or buying cigarettes with a certain signal like relief of anxiety will result in a conditioned response when the stimulus or action is performed.

MEDICATIONS FOR SMOKING CESSATION

Nicotine replacement therapy (NRT) helps reduce withdrawal symptoms by replacing the nicotine from cigarettes with nicotine from alternative, safer forms such as gum, a transdermal patch, nasal spray, inhaler or sublingual tablets/lozenges. Studies indicate that all these types of delivery systems help people increase their chances of successfully stopping. A systematic review of 150 trials comparing NRT to placebo found that NRT increased quitting rates by about 50-to-70 per cent.[6] No overall difference in effectiveness between the different forms of NRT was identified. However, combining a sustained delivery method, ie, the nicotine patch, with an additional rapid delivery preparation, such as gum, spray or lozenge, is more effective than use of one type of NRT by itself. When discontinuing the patch, abrupt withdrawal did not give rise to any difference in outcome compared to patch tapering. Furthermore, no significant difference in efficacy was observed between the 16-hour patch worn during waking hours only and 24-hour patch. In general, the side-effects from NRT use are mild and include hiccups, jaw pain, orodental problems (from the gum); and local irritation at the site of the patch. There is no association between NRT and an increased risk of adverse cardiovascular events in smokers with a history of cardiovascular disease.

Other smoking cessation medication available on prescription, such as bupropion (Zyban), provides a selective inhibitor of the neuronal re-uptake of catecholamines (noradrenaline and dopamine). When NRT use was compared with bupropion use, they were found to be equally effective. In contrast, a study found varenicline (Champix) to be superior to bupropion and NRT as a smoking cessation aid for both short and long term.[7] Varenicline acts as a partial agonist

Benefits of smoking cessation

Upon smoking cessation, the following benefits are noticeable:[1]

After 20 minutes
blood pressure and pulse rate decrease to normal range. Circulation in hands and feet improves.

After eight hours
blood oxygenation levels return to normal and the risk of myocardial infarction starts to decrease.

After 24 hours
poisonous carbon monoxide is eliminated from the body. The lungs start to clear out mucus and other debris.

After 48 hours
nicotine can no longer be detected in the body. Senses of taste and smell improve.

After 72 hours
breathing improves and becomes easier as the bronchial tubes relax, and energy levels increase.

After two weeks
circulation improves further, contributing to easier walking and other exercise.

After three-to-nine months
respiratory issues such as coughing, shortness of breath and wheezing substantially reduce.

After five years
the risk of myocardial infarction decreases to that of a non-smoker.

*Based on 2 x 1mg dose

Nicorette QuickMist1 mg/spray, oromucosal spray, solution. Composition: One spray delivers 1 mg nicotine in 0.07 ml solution. 1 ml solution contains 13.6 mg nicotine. Excipient with known effect: Ethanol (less than 100 mg of ethanol/spray). Propylene glycol, Butylated hydroxytoluene. Pharmaceutical form: Oromucosal spray, solution. A clear to weakly opalescent, colourless to yellow solution. **Indications:** For the treatment of tobacco dependence in adults by relief of nicotine withdrawal symptoms, including cravings, during a quit attempt. Permanent cessation of tobacco use is the eventual objective. Nicorette QuickMist should preferably be used in conjunction with a behavioral support program. Dosage: Subjects should stop smoking completely during the course of treatment with Nicorette QuickMist. *Adults and Elderly:* The following chart lists the recommended usage schedule for the oromucosal spray during full treatment (Step I) and during tapering (Step II and Step III). Up to 4 sprays per hour may be used. Do not exceed 2 sprays per dosing episode and do not exceed 64 sprays (4 sprays per hour, over 16 hours) in any 24-hour period. **Step I: Weeks 1-6:** Use 1 or 2 sprays when cigarettes normally would have been smoked or if cravings emerge. If after a single spray cravings are not controlled within a few minutes, a second spray should be used. If 2 sprays are required, future doses may be delivered as 2 consecutive sprays. Most smokers will require 1-2 sprays every 30 minutes to 1 hour. **Step II: Weeks 7-9:** Start reducing the number of sprays per day. By the end of week 9 subjects should be using HALF the average number of sprays per day that was used in Step I. **Step III: Weeks 10-12:** Continue reducing the number of sprays per day so that subjects are not using more than 4 sprays per day during week 12. When subjects have reduced to 2-4 sprays per day, oromucosal spray use should be discontinued. To help stay smoke free after Step III, subjects may continue to use the oromucosal spray in situations when they are strongly tempted to smoke. One spray may be used in situations where there is an urge to smoke, with a second spray if one spray does not help within a few minutes. No more than four sprays per day should be used during this period. Regular use of the oromucosal spray beyond 6 months is generally not recommended. Some ex-smokers may need treatment with the oromucosal spray longer to avoid returning to smoking. Any remaining oromucosal spray should be retained to be used in the event of sudden cravings. *Paediatric population:* Do not administer this medicine to persons under 18 years of age. There is no experience of treating adolescents under the age of 18 with this medicine. Method of administration: After priming, point the spray nozzle as close to the open mouth as possible. Press firmly the top of the dispenser and release one spray into the mouth, avoiding the lips. Subjects should not inhale while spraying to avoid getting spray into the respiratory tract. For best results, do not swallow for a few seconds after spraying. Subjects should not eat or drink when administering the oromucosal spray. Behavioural therapy advice and support will normally improve the success rate. **Contraindications:** Hypersensitivity to nicotine or to any of the excipients. Children under the age of 18 years. Those who have never smoked. **Special warnings and precautions for use:** This medicine should not be used by non-smokers. The benefits of quitting smoking outweigh any risks associated with correctly administered nicotine replacement therapy (NRT). A risk-benefit assessment should be made by an appropriate healthcare professional for patients with the following conditions: *Cardiovascular disease: Dependent smokers with a recent myocardial infarction, unstable or worsening angina including Prinzmetal's angina, severe cardiac arrhythmias, recent cerebrovascular accident and/or who suffer with uncontrolled hypertension* should be encouraged to stop smoking with non-pharmacological interventions (such as counselling). If this fails, the oromucosal spray may be considered but as data on safety in this patient group are limited, initiation should only be under close medical supervision. *Diabetes Mellitus.* Patients with diabetes mellitus should be advised to monitor their blood sugar levels more closely than usual when smoking is stopped and NRT is initiated as reduction in nicotine induced catecholamine release can affect carbohydrate metabolism. *Allergic reactions:* Susceptibility to angioedema and urticaria. *Renal and hepatic impairment:* Use with caution in patients with moderate to severe hepatic impairment and/or severe renal impairment as the clearance of nicotine or its metabolites may be decreased with the potential for increased adverse effects. *Phaeochromocytoma and uncontrolled hyperthyroidism:* Use with caution in patients with uncontrolled hyperthyroidism or phaeochromocytoma as nicotine causes release of catecholamines. *Gastrointestinal Disease:* Nicotine may exacerbate symptoms in patients suffering from oesophagitis, gastric or peptic ulcers and NRT preparations should be used with caution in these conditions. Paediatric population: *Danger in children:* Doses of nicotine tolerated by smokers can produce severe toxicity in children that may be fatal. Products containing nicotine should not be left where they may be handled or ingested by children. *Transferred dependence:* Transferred dependence can occur but is both less harmful and easier to break than smoking dependence. *Stopping smoking:* Polycyclic aromatic hydrocarbons in tobacco smoke induce the metabolism of drugs metabolised by CYP 1A2 (and possibly by CYP 1A1). When a smoker stops smoking, this may result in slower metabolism and a consequent rise in blood levels of such drugs. This is of potential clinical importance for products with a narrow therapeutic window, e.g. theophylline, tacrine, clozapine and ropinirole. The plasma concentration of other medicinal products metabolised in part by CYP1A2 e.g. imipramine, olanzapine, clomipramine and fluvoxamine may also increase on cessation of smoking, although data to support this are lacking and the possible clinical significance of this effect for these drugs is unknown. Limited data indicate that the metabolism of flecainide and pentazocine may also be induced by smoking. *Excipients:* The oromucosal spray contains small amounts of ethanol (alcohol), less than 100 mg per dose (1 or 2 sprays). This medicinal product contains less than 1 mmol sodium (23 mg) per spray, i.e. essentially 'sodium- free'. This medicine contains 12 mg propylene glycol in each spray which is equivalent to 150 mg/mL. Due to the presence of butylated hydroxytoluene, Nicorette QuickMist may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes. Care should be taken not to spray the eyes whilst administering the oromucosal spray. **Undesirable effects:** Effects of smoking cessation: Regardless of the means used, a variety of symptoms are known to be associated with quitting habitual tobacco use. These include emotional or cognitive effects such as dysphoria or depressed mood; insomnia; irritability, frustration or anger; anxiety; difficulty concentrating, and restlessness or impatience. There may also be physical effects such as decreased heart rate; increased appetite or weight gain, dizziness or presyncopal symptoms, cough, constipation, gingival bleeding or apthous ulceration, or nasopharyngitis. In addition, and of clinical significance, nicotine cravings may result in profound urges to smoke. This medicine may cause adverse reactions similar to those associated with nicotine given by other means and these are mainly dose-dependent. Allergic reactions such as angioedema, urticaria or anaphylaxis may occur in susceptible individuals. Local adverse effects of administration are similar to those seen with other orally delivered forms. During the first few days of treatment irritation in the mouth and throat may be experienced, and hiccups are particularly common. Tolerance is normal with continued use. Daily collection of data from trial subjects demonstrated that very commonly occurring adverse events were reported with onset in the first 2-3 weeks of use of the oromucosal spray, and declined thereafter. Adverse reactions with oromucosal nicotine formulations identified from clinical trials and during post-marketing experience are presented below. The frequency category has been estimated from clinical trials for the adverse reactions identified during post-marketing experience. Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1 000 to <1/100); rare (≥1/10 000 to <1/1 000); very rare (<1/10 000); not known (cannot be estimated from the available data). **Immune system disorders** Common Hypersensitivity Not known Allergic reactions including angioedema and anaphylaxis **Psychiatric disorders** Uncommon Abnormal dream **Nervous system disorders** Very common Headache Common Dysgeusia, paraesthesia **Eye disorders** Not known Blurred vision, lacrimation increased **Cardiac disorders** Uncommon Palpitations, tachycardia Not known Atrial fibrillation **Vascular disorders** Uncommon Flushing, hypertension **Respiratory, thoracic and mediastinal disorders** Very common Hiccups, throat irritation Uncommon Bronchospasm, rhinorrea, dysphonia, dyspnoea, nasal congestion, oropharyngeal pain, sneezing, throat tightness **Gastrointestinal disorders** Very common Nausea Common Abdominal pain, dry mouth, diarrhoea, dyspepsia, flatulence, salivary hypersecretion, stomatitis, vomiting Uncommon Eructation, gingival bleeding, glossitis, oral mucosal blistering and exfoliation, paraesthesia oral Rare Dysphagia, hypoaesthesia oral, retching Not known Dry throat, gastrointestinal discomfort, lip pain **Skin and subcutaneous tissue disorders** Uncommon Hyperhidrosis, pruritus, rash, urticaria Not known Erythema **General disorders and administration site conditions** Common Burning sensation, fatigue Uncommon Asthenia, chest discomfort and pain, malaise. **MAH:** Johnson & Johnson (Ireland) Limited, Airton Road, Tallaght, Dublin 24, Ireland. **PA Number:** PA 330/37/13. **Date of revision of text:** PA 330/37/13: May 2019. Product not subject to medical prescription. Full prescribing information available upon request. IRE/NI/19-4006

at the α4β2 neuronal nicotinic acetylcholine receptors. There is also evidence for the efficacy of nortriptyline and clonidine as second-line therapies for smoking cessation.

ELECTRONIC CIGARETTES

The use of electronic cigarettes (e-cigarettes) as a smoking aid has become increasingly controversial. Although non-combustible tobacco products have offered a way for adult smokers to move away from more harmful forms of nicotine delivery, it is important that these opportunities do not come at the expense of leading a generation of young people towards nicotine addiction. Young people who have tried e-cigarettes are more likely to try combustible tobacco products later.

There have been several recent newspaper reports based on a study by researchers in Germany published at the end of 2019 in the *European Heart Journal*.[8] One report[9] describes the damage of e-cigarettes to brain, heart, lungs and blood vessels; another is about the Irish Heart Foundation calling for a ban on all e-cigarette advertising.[10] The results of the study in question strongly indicate that the perceived 'safety' of e-cigarette products (compared to tobacco) is not warranted. Contributing to the drive for this research is the increase in e-cigarette use among high school students in the US from 1.5 per cent to 20.8 per cent between 2011 and 2018. In addition, there are ongoing investigations on severe pulmonary disease and deaths among people using e-cigarettes in the US. The authors state that there is lack of clarity as to the overall population health consequences of e-cigarette use: A majority of available studies provide evidence that e-cigarette vaping is the 'lesser of two evils' when compared to tobacco cigarette smoking, but considering that e-cigarette vaping is associated with a decrease in the average age of first-time (e)-cigarette users, the 'healthier' e-cigarette profile might easily be negated by the higher portion of adolescent users.

In the study,[8] experiments were performed in mice, administering unflavoured e-cigarette liquids with and without nicotine to determine the impact on vascular (endothelial) function. The researchers characterised the mechanisms behind oxidative stress and inflammation, and validated findings in human endothelial cells and in healthy smokers.

Results show that in otherwise healthy smokers (n = 20), e-cigarette vapour exposure reduced arterial dilation, increased blood pressure, and increased arterial stiffness. This indicates induction of endothelial dysfunction by e-cigarette vaping. This dysfunction was also identified in mice and in human endothelial cells.

Results show that the act of e-cigarette vaporisation adds additional toxicity to its components. This mechanism has been identified by the authors to be due to NADPH oxidase 2 (NOX-2) mediation, which induces oxidative stress. Toxic compounds including formaldehyde, acetaldehyde, butyraldehyde, and acrolein were identified in e-cigarette liquid, but to much larger extent in vapour condensate.

To examine the toxicity of these vapour-enhanced products, cultured human endothelial cells were incubated with mixtures of these aldehydes. This resulted in concentration-dependent cell death and increased expression of the inflammatory marker COX-2.

Overall, e-cigarette vapour exerts a broad negative influence on the vasculature due, in part, to vaporisation-enhanced aldehyde generation that activates NOX-2, leading to oxidative stress, inflammation, and endothelial dysfunction.

Much data in this publication seems to indicate that e-cigarette vapour shares many of the same adverse vascular consequences of traditional tobacco smoke. Both the smoking of combustible cigarettes and e-cigarettes increase oxidative stress and appear to degrade blood-brain barrier integrity and to induce vascular inflammation in endothelium. Likewise, both tobacco smoke and e-cigarette vapour induce cerebrovascular inflammation and post-stroke ischaemia/reperfusion damage in mice.

After 10 years, lung cancer risk decreases to about half that of a smoker.

It has been estimated that 75-to-85 per cent of people who smoke would like to quit smoking. Pharmacists in the community, often the first point of contact with the health services, can help by providing these individuals with advice on smoking cessation.[11] As part of the conversation, the pharmacist can assess the readiness of the individual to quit and enquire about previous attempts. Pharmacists should discuss the potential withdrawal symptoms following smoking cessation (sleep disturbance, nausea, headache, dizziness, cough, mouth ulcers). These symptoms, along with the urge to smoke, can lead to relapse. Most withdrawal symptoms, however, stop after two-to-four weeks, so it is especially important for the individual to have support during this time. The Irish website ***www.quit.ie*** offers further help and information for people who want to stop.

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NEW

To Relieve **ANY** Cough[1]

For children from 1 year

[1]Associated with a cold.

IRE/NHCPT/BRO/19-015

Eamonn Brady (MPSI), owner of Whelehans Pharmacies, Mullingar

Spotlight on asthma

Eamonn Brady MPSI
provides a clinical overview of the presentation, diagnosis and treatment options for asthma

Asthma is a long-term condition that can cause a cough, wheezing and breathlessness. The severity of the symptoms varies from person to person.

In Ireland, respiratory diseases are the third-commonest long-term illness group after cardiovascular and musculoskeletal diseases, with asthma being the second-most common single condition reported after COPD.[1]

CAUSES

With asthma, the airways become over-sensitive and react to stimuli that would normally not

cause a problem, such as cold air or dust. Muscles around the wall of the airway tighten-up, making it narrow and difficult for air to flow in and out. The lining of the airways swells, and sticky mucus is produced. This makes it difficult for air to move in and out. Tightening of muscle around the airways can happen quickly and is the most common cause of mild asthma. The tightening of muscle can be relieved with a reliever inhaler. However, the swelling and build-up of mucus happen more slowly and need a different treatment. This takes longer to clear up and is a serious problem in moderate-to-severe asthma.

FACTS ABOUT ASTHMA

The exact cause of asthma is not known. According to the *Asthma Insights and Realities in Ireland* (AIRI) report in 2002, 470,000 people have asthma in Ireland, meaning approximately one-in-eight of the population suffer from it. Ireland has the fourth-highest prevalence of asthma in the world after Australia, New Zealand and the UK. The Irish Pharmaceutical Health Care Association (IPHA) reported there were 600,000 GP consultations for asthma in 1997 and it is likely this figure has risen since.[1]

There is a strong genetic link. If a parent has asthma, the risk of their child getting it doubles. If both parents have it, it doubles again. And if one in a family has asthma, the risk of the other children getting it increases, but it is not known by how much. In adults, it is more common in women than men. Asthma can start at any age, but most commonly starts in childhood. Adult-onset asthma may develop after a respiratory tract infection. In many cases, asthma disappears during teenage years. Many asthma sufferers also suffer from other allergic conditions such as hayfever, eczema and hives. Asthmatics who also have hayfever find that their symptoms get worse during hayfever symptoms. In fact, research by Allergy UK found that 69 per cent of asthmatics who also had hayfever found their symptoms worsened during hayfever season. Asthma has got more common in recent years. The incidence of asthma among 13- and 14-year-olds has increased by 40 per cent from 1995 to 2003.[14] The exact reason for this is not known. Many aspects of modern living, such as changes in housing, diet and a more sterile home environment may have contributed to the rise in asthma over recent decades. This theory is called the 'hygiene hypothesis'.

HYGIENE HYPOTHESIS

The 'hygiene hypothesis' is a theory that lack of exposure in early childhood to infectious agents means that the child's immune system has not been activated sufficiently during childhood. This lack of exposure is down to our super-clean world of modern living, including antibacterial washes, vaccinations and general sterility where children are not exposed to germs in a similar manner to previous generations of children. The theory hypotheses that because the immune system is 'not activated' during childhood, this leads to the immune system becoming over-sensitive to common substances such as pollen, dust-mites and animal fur, leading to the higher incidence of auto-immune conditions like asthma, hayfever and eczema in recent years. One of the first scientific explanations of this theory was by a lecturer in epidemiology from the London School of Hygiene and Tropical Medicine, David P Strachan, who published a paper on the theory in the *British Medical Journal* in 1989.[15] He noticed that children from larger families were less likely to suffer from autoimmune conditions like asthma. Families have got smaller in the Western world over the last 40 years, meaning less exposure to germs and infections; it is over the same period that health authorities have seen an explosion in autoimmune conditions such as asthma. Further studies have been conducted since, supporting the theory. For example, studies show that autoimmune diseases are less common in developing countries, however when immigrants from developing countries come to live in developed countries where living environments are more sterile, these immigrants suffer from increased levels of autoimmune conditions like asthma and the rate of autoimmune conditions increases the longer immigrants live in developed countries.[16] It is a difficult issue to tackle for healthcare professionals advising parents who want the best for their children; common sense tells us all that cleanliness is important. As a pharmacist, it is difficult to advise on the best balance for parents in relation to this theory. No journal or book will give a pharmacist exact advice. In my opinion, a balanced view is to ensure children are administered important vaccines but 'allow kids be kids', let children play outside with friends and try not to worry about them coming in contact with dirt and germs, but always be cautious with children with life

ASTHMA IN CHILDREN

Asthma in children is more common in boys than girls. Children who develop asthma at a very young age are more likely to 'grow out' of the condition as they get older. If asthma is moderate-to-severe during childhood, it is more likely to continue into adulthood. During the teenage years, the symptoms of asthma disappear in about three-quarters of all children with the condition.

Known risk factors for the development of asthma in children include:

A family history of asthma, or other related allergic conditions (known as atopic conditions) such as eczema, hayfever or allergic conjunctivitis.

Developing another atopic condition.

Being exposed to tobacco smoke, particularly if the child's mother smoked during pregnancy.

Being born prematurely.

Being born with a low birth weight.

A child with asthma should be taught to recognise the initial symptoms of an asthma attack, how they should respond, and when they should seek medical attention. Some children are less likely to develop asthma than others. Studies have found those children who are given fewer antibiotics and those who live on or near farms have less asthma than children with different backgrounds. Medical researchers explain this with the 'hygiene hypothesis'.

SYMPTOMS OF ASTHMA

Difficulty in breathing/ shortness of breath

A tight feeling in the chest

Wheezing (a whistling noise in the chest)

Coughing, particularly at night

Hoarseness

threatening food allergies.

These symptoms may occur in episodes, perhaps brought on by colds or chest infections, exercise, change of temperature, dust or other irritants in the air, or by an allergy, ie, pollen or animals. Episodes at night are common, often affecting sleep.

Common triggers

Anything that irritates the airways and brings on the symptoms of asthma is called a trigger. Common triggers include house dust mites, animal fur, pollen, tobacco smoke, exercise, cold air and chest infections. Other triggers which are less common include non-steroidal anti-inflammatory drugs such as ibuprofen and diclofenac, emotional factors such as stress, sulphites in some foods and drinks (found in certain wines and used as a preservative in some foods such as fruit juices and jam), mould or damp in houses, and food allergies, ie, nut allergy.

What happens during an asthma attack?

During an asthma attack, something triggers inflammation, a natural biological process. Inflammation is one of the ways that the body's immune system fights infection. If the body detects a lung infection, it starts the process of inflammation. White blood cells engulf the infection area to kill the infection and prevent it spreading. The white blood cells cause the airways to swell and produce mucus. In an asthmatic, the airways are over-sensitive to the effects of inflammation. As a result, too much mucus is produced and the airways swell more than usual. Also, as a response to the inflammation, the muscles surrounding the airways begin to contract, making the airways narrower and narrower. The combination of excess mucus, swelling and contraction of the airways makes breathing difficult and produces the wheezing and coughing that is associated with asthma.

Non-pharmacological management

Asthmatics should be advised strongly not to smoke and to lose weight.[2] Allergen avoidance measures may be helpful, but the benefit of avoiding allergens such as dust mites and animal fur has not been proven in studies.[3, 4] Currently, there is insufficient or no evidence of the clinical benefit of complementary therapy for asthma, such as Chinese medicine, acupuncture, breathing exercises and homeopathy.[5]

TREATMENT

There is no cure for asthma. Symptoms can come and go throughout the person's life. Treatment can help control the condition. Treatment is based on relief of symptoms and preventing future symptoms and attacks from developing. Successful prevention can be achieved through a combination of medicines, lifestyle changes and identification and avoiding asthma triggers.

Reliever inhalers

A short-acting beta 2-agonist opens the airways. These work quickly to relieve asthma. They work by relaxing the muscles surrounding the narrowed airways. Examples of beta 2-agonists include salbutamol and terbutaline. They are usually blue in colour. They are generally safe medicines with few side-effects, unless they are over-used. It is important for every asthmatic to have a beta-2 agonist inhaler. If an asthmatic needs to use their beta agonist inhaler too regularly (three or more times per week), they should have their therapy reviewed. The main side-effects include a mild shaking of the hands, headache and muscle cramps. These usually only occur with high doses of relievers and usually only last for a few minutes. Excessive use of short-acting relievers has been associated with asthma deaths.[5, 6] This is not the fault of the reliever medication, but down to the fact that the patient failed to get treatment for their worsening asthma symptoms. In exercise-induced asthma, suffers are advised to use a short acting beta 2-agonist 10-to-15 minutes before they exercise, and again after two hours of prolonged exercise, or when they finish.

Preventer inhalers

Preventer inhalers are slower-acting inhalers that reduce inflammation in the airways and prevent asthma attacks occurring. The preventer inhaler must be used daily for some time before full benefit is achieved. The preventer inhaler usually contains an inhaled corticosteroid. Examples of preventer medicines include beclomethasone, budesonide, and fluticasone. Preventer in-

gsk

Avamys

fluticasone furoate

Allergic rhinitis relief

Relieving the symptoms of allergic rhinitis in patients over 6 years[1]

The incidence of epistaxis during long term treatment was higher than 10% but was generally mild to moderate in intensity[1]

www.avamys.ie

Prescribing Information (Please refer to the full Summary of Product Characteristics before prescribing)

Avamys Nasal Spray Suspension (fluticasone furoate 27.5 micrograms/metered spray) Uses: Treatment of symptoms of allergic rhinitis in adults and children aged 6 years and over. **Dosage and Administration:** For intranasal use only. *Adults and adolescents (12 years and older):* Two sprays per nostril once daily (total daily dose, 110 micrograms). Once symptoms controlled, use maintenance dose of one spray per nostril once daily (total daily dose, 55 micrograms). Reduce to lowest dose at which effective control of symptoms is maintained. *Children aged 6 to 11 years:* One spray per nostril once daily (total daily dose, 55 micrograms). If patient is not adequately responding, increase daily dose to 110 micrograms (two sprays per nostril, once daily) and reduce back down to 55 micrograms daily dose once control is achieved. **Contraindication:** Hypersensitivity to active substance or excipients. **Special warnings and precautions:** Systemic effects of nasal corticosteroids may occur, particularly when prescribed at high doses for prolonged periods. These effects are much less likely to occur than with oral corticosteroids and may vary in individual patients and between different corticosteroid preparations. Potential systemic effects may include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, cataract, glaucoma and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). Treatment with higher than recommended doses of nasal corticosteroids may result in clinically significant adrenal suppression. Consider additional systemic corticosteroid cover during periods of stress or elective surgery. Caution when prescribing concurrently with other corticosteroids. A reduction in growth velocity has been observed in children treated with fluticasone furoate 110 micrograms daily for one year. Therefore, children should be maintained on the lowest possible efficacious dose which delivers adequate symptom control. It is recommended that growth of children receiving prolonged treatment with nasal corticosteroids is regularly monitored. Consider referring to a paediatric specialist. May cause irritation of the nasal mucosa. If a patient presents with visual disturbance they should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma, central serous chorioretinopathy. **Drug interactions:** Caution is recommended when co-administering fluticasone furoate with potent CYP3A inhibitors including cobicistat-containing products as an increase in the risk of systemic side effects is expected. Co-administration should be avoided unless the benefit outweighs the increased risk. Co-administration with ritonavir is not recommended because of the risk of increased systemic exposure of fluticasone furoate. **Pregnancy and Lactation:** No adequate data available. Recommended nasal doses result in minimal systemic exposure. It is unknown if fluticasone furoate nasal spray is excreted in breast milk. Only use if the expected benefits to the mother outweigh the possible risks to the foetus or child. **Side effects:** *Very common (≥1/10):* epistaxis. Epistaxis was generally mild to moderate, with incidences in adults and adolescents higher in longer-term use (more than 6 weeks). *Common (≥1/100 and <1/10):* headache, nasal ulceration. *Uncommon (≥1/1000 and <1/100):* rhinalgia, nasal discomfort (including nasal burning, nasal irritation, and nasal soreness), nasal dryness. *Rare (≥1/10,000 and <1/1000):* hypersensitivity reactions including anaphylaxis, angioedema, rash, and urticaria. *Very rare (<1/10,000):* Nasal septum perforation. *Not known:* transient ocular changes, vision blurred, growth retardation. **Marketing Authorisation (MA) Holder:** GlaxoSmithKline (Ireland) Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland. **MA Number:** EU/1/07/434/003. **Legal category:** POM B. **Last date of revision:** December 2018. **Job Ref:** IE/FF/0002/16(5). Further information available on request from GlaxoSmithKline, 12 Riverwalk, Citywest Business Camp, Dublin 24. Tel: 01-4955000.

Adverse events should be reported to the Health Products Regulatory Authority (HPRA) using an Adverse Reaction Report Form obtained either from the HPRA or electronically via the website at www.hpra.ie. Adverse reactions can also be reported to the HPRA by calling (01) 6764971. Adverse events should also be reported to GlaxoSmithKline on 1800 244 255.

24 HOUR EFFECT[1]

Not actual size

Reference:

1. Avamys Summary of Product Characteristics, available on www.medicines.ie, accessed April 2019.

PM-IE-FLF-ADVT-190004
Date of preparation: April 2019

halers are often brown, red or orange. The dose of inhaler will be increased gradually until symptoms ease. For example, a patient may start on a beclomethasone 100mcg inhaler and may be put on a beclomethasone 250mcg inhaler if there is not enough improvement in symptoms. Preventer treatment is normally recommended if the patient:

- Has asthma symptoms more than twice a week.
- Wakes up once a week due to asthma symptoms.
- Must use a reliever inhaler more than twice a week.

Regular inhaled corticosteroids have been shown to reduce symptoms, exacerbations, hospital readmissions and asthma deaths.[5,7,8-11] The majority of patients require a dose of less than 400mcg per day to achieve maximum or near-maximum benefit. Side-effects are minimal at this dose. Smoking can reduce the effects of preventer inhalers. Preventers are very safe at usual doses, although they can cause some side-effects at high doses, especially over long-term use. The main side-effect of preventer inhalers is a fungal infection (oral candidiasis) of the mouth or throat.

This can be prevented by rinsing the mouth with water after inhaling a dose. The patient may also develop a hoarse voice. Using a spacer can help prevent these side-effects.

Long-acting reliever inhaler

If short-acting bets 2-agonist inhalers and preventer inhalers are not providing enough symptom relief, a long-acting reliever (long-acting beta 2-agonist) may be tried. Inhalers combining an inhaled steroid and a long-acting bronchodilator (combination inhaler) are more commonly prescribed than long-acting beta 2-agonists on their own. Long-acting beta 2-agonists work in the same way as short-acting relievers, but they take longer to work and can last up to 12 hours. A salmeterol inhaler is an example of a long-acting reliever inhaler used in Ireland. Long-acting relievers may cause similar side-effects to short-acting relievers, including a mild shaking of the hands, headache and muscle cramps. Long-acting reliever inhalers should only be used in combination with a preventer inhaler. Studies have shown that using a long-acting reliever on its own (without a combination corticosteroid) can increase asthma attacks and can even increase the risk of death from asthma, though increased risk of death is small.[17] In November 2005, the Food and Drug Administration in the United States issued an alert indicating the potential increase risk of worsening symptoms and sometimes death associated with the use of long-acting beta 2-agonists on their own.[18]

Combination inhalers

Examples of combination inhalers containing long-acting beta 2-agonists and steroids include Seretide and Symbicort. Combination inhalers containing beta 2-agonists and corticosteroids can be very effective in attaining asthma control. They have been shown to have better outcomes compared to leukotriene receptor antagonists such as montelukast.[19] Both treatment options lead to improved asthma control; however, compared to leukotriene receptor antagonists, the addition of a long-acting beta 2-agonist to inhaled corticosteroids is associated with significantly improved lung function, symptom-free days, need for short-term beta 2-agonists, night awakenings, and quality of life.[19] However, the magnitude of some of these differences is small.[19]

Other preventer medications

If treatment of asthma is still not successful, additional preventer medicines can be tried. Two possible alternatives include:

- **Leukotriene receptor antagonists (montelukast):** Act by blocking part of the chemical reaction involved in inflammation of the airways.
- **Theophyllines:** Helps widen the airways by relaxing the muscles around them.

If asthma is still not under control, regular oral corticosteroids may be prescribed. This treatment is usually monitored by a respiratory specialist. Long-term use of oral corticosteroids has possible serious side-effects, so they are only used once other treatment options have been tried. Theophylline is known to cause potential side-effects, including headaches, nausea, insomnia, vomiting, irritability and stomach upsets. These can usually be avoided by adjusting the dose. Leukotriene receptor agonists do not usually cause side-effects, although there have been reports of stomach upsets, feeling thirsty and headache.

Occasional use of oral corticosteroids

Most patients only need to take a course of oral corticosteroids for one or two weeks. Once the asthma symptoms are under control, the dose can be reduced slowly over a few days. Oral corticosteroids can cause side-effects if they are taken for more than three months or if they are taken frequently (three or four courses of corticosteroids a year). Side-effects can include:

- Weight gain.
- Thinning of the skin.
- Osteoporosis.

DIAGNOSIS OF ASTHMA

The following questions can help ascertain if asthma is the problem

Is there a family history of asthma?

Are symptoms frequent and do they affect quality of life?

Has there been an attack or recurrent attacks of wheezing?

Is there a regular night-time cough?

Does exercise trigger wheezing or coughing?

Is there wheezing, chest tightness, or cough after exposure to airborne allergens or pollutants?

Does the patient suffer from constant chest infections?

Do chest infections take a long time to clear up?

Are symptoms improved by when using a reliever inhaler?

* * *

The following tests are often done to confirm the diagnosis of asthma

1

Spirometry is a simple breathing test that gives measurements of lung function. A spirometer is the device that is used to make the measurements. It is common to measure lung function with a spirometer before and after a dose of reliever to see if lung function has improved.

2

Peak expiratory flow rate (PEFR) is a breathing test. It uses a simple hand-held device called a peak flow meter, which a patient blows into to measure lung function. The PEFR test is only suitable for children over five years of age.

3

An exercise test to check if exercise worsens asthma symptoms.

flutiform® *k-haler*® **(fluticasone propionate/formoterol fumarate) 50 µg/5 µg and 125 µg /5 µg pressurised inhalation suspension. Prescribing Information Republic of Ireland. Please read the Summary of Product Characteristics (SPC) before prescribing. Presentation** Pressurised inhalation suspension, in a breath-actuated pressurised aerosol inhaler. **Indications** Regular treatment of asthma where the use of a combination product (inhaled corticosteroid [ICS] and long-acting β_2-agonist [LABA]) is appropriate: (i) for patients not adequately controlled with ICS and 'as required' inhaled short-acting β_2-agonist (SABA) (ii) for patients already adequately controlled on both an ICS and a LABA. For adults and adolescents aged 12 years and above. **Dosage and administration** for inhalation use. Patients should be shown how to use the inhaler correctly by a healthcare professional. Patients should be given the strength of ***flutiform k-haler*** containing the appropriate fluticasone propionate dose for their disease severity (50 µg/5 µg per actuation is not appropriate in patients with severe asthma). The appropriate strength should be taken as two inhalations, twice daily (normally morning and evening) and used every day, even when asymptomatic. ***flutiform k-haler*** is not recommended in children under 12 years. Prescribers should be aware that in asthmatics, fluticasone propionate is as effective as some other inhaled steroids when administered at approximately half the total daily microgram dose. Patients should be assessed regularly and once asthma is controlled, treatment should be reviewed and stepped down to the lowest effective dose, or an ICS alone. ICSs alone are first line treatment for most patients. ***flutiform k-haler*** is not intended for initial treatment of mild asthma. For patients with severe asthma the ICS therapy should be established before prescribing a fixed-dose combination product. Patients on ***flutiform k-haler*** must not use an additional LABA. An inhaled SABA should be taken for immediate relief of asthma symptoms arising between doses. Patients should be advised to contact their prescriber when ***flutiform k-haler*** dose counter is getting near zero. **Contra-indications** Hypersensitivity to the active substances or to any of the excipients. **Precautions and warnings** ***flutiform k-haler*** should not be used as the first asthma treatment, to treat acute asthma symptoms or for prophylaxis of exercise-induced asthma. It should not be initiated during an exacerbation, during significantly worsening or acutely deteriorating asthma, and should not be stopped abruptly. If a patient experiences serious asthma-related adverse events or exacerbations, they should continue treatment and seek medical advice. Patients should be reviewed as soon as possible if there is any indication of deteriorating asthma control. In case of sudden and progressive deterioration, seek urgent medical assessment. Caution in patients with: pulmonary tuberculosis; quiescent tuberculosis; fungal, viral or other infections of the airway; thyrotoxicosis; phaeochromocytoma; diabetes mellitus (consider additional blood sugar controls); uncorrected hypokalaemia; predisposition to low levels of serum potassium; impaired adrenal function (monitor HPA axis function regularly); hypertrophic obstructive cardiomyopathy; idiopathic subvalvular aortic stenosis; severe hypertension; aneurysm or other severe cardiovascular disorders; unstable or acute severe asthma and other conditions when the likelihood for hypokalaemia adverse effects is increased. There is risk of potentially serious hypokalaemia with high doses of β_2-agonists or concomitant treatment with β_2-agonists and drugs that can induce or potentiate a hypokalaemic effect. Monitoring of serum potassium levels is recommended during these circumstances. Formoterol may induce prolongation of the QTc interval. Caution must be observed when treating patients with existing prolongation of QTc interval. ***flutiform k-haler*** should be discontinued immediately if there is evidence of paradoxical bronchospasm. Visual disturbance may be reported with corticosteroid use. Systemic effects with an ICS may occur, particularly at high doses for prolonged periods or when combined with potent CYP3A4 inhibitors, but are less likely than with oral corticosteroids. Possible systemic effects include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density and cataract glaucoma. Children may also experience anxiety, sleep disorders and behavioural changes. Increased exposure can be expected in patients with severe hepatic impairment. Prolonged treatment with high doses of corticosteroids may result in adrenal suppression and acute adrenal crisis, particularly in children and adolescents or potentially as a result of trauma, surgery, infection or rapid dose reduction. ***flutiform k-haler*** contains a negligible amount of ethanol that does not pose risk to patients. Interactions Co-treatment with CYP3A inhibitors (e.g. ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nelfinavir, saquinavir, ketoconazole, telithromycin, cobicistat) should be avoided unless the benefit outweighs the increased risk of systemic side-effects. Caution is advised with concomitant use of non-potassium sparing diuretics (e.g. loop or thiazide), xanthine derivatives, glucocorticosteroids, L-Dopa, L-thyroxine, oxytocin, alcohol or other adrenergic drugs, including anaesthesia with halogenated hydrocarbons and digitalis glycosides, β-adrenergic drugs, known to prolong the QTc interval, such as tricyclic antidepressants or MAOIs (and for two weeks following their discontinuation), antipsychotics (including phenothiazines), quinidine, disopyramide, procainamide, antihistamines, furazolidone and procarbazine. ***flutiform k-haler*** should not normally be used with β-blockers including those that are used as eye drops to treat glaucoma. Under certain circumstances, e.g. as prophylaxis after myocardial infarction, cardioselective β-blockers could be considered with caution. **Pregnancy and lactation** ***flutiform k-haler*** is not recommended during pregnancy unless the benefits to the mother outweigh risks to the foetus. A risk to the breastfeeding infant cannot be excluded. **Side-effects** *Uncommon (<1/100) but potentially serious:* hyperglycaemia, agitation, depression, aggression, behavioural changes (predominantly in children), vision blurred, vertigo, palpitations, ventricular extrasystoles, angina pectoris, tachycardia, hypertension, dyspnoea, peripheral oedema. Please consult the SPC a full list of side-effects and those reported for the individual molecules. **Legal category** POM **Package quantities** One inhaler (120 actuations) **Marketing Authorisation numbers** PA 1688/013/004-005 **Marketing Authorisation holder** Mundipharma Pharmaceuticals Limited, Millbank House, Arkle Road, Sandyford, Dublin 18, Ireland. Tel: +353 (0)1 2063800. For medical information enquiries, please contact medicalinformation@mundipharma.ie. ® FLUTIFORM is a registered trademark of Jagotec AG, and is used under licence. ® K-HALER is a registered trade mark of Mundipharma AG. © 2018 Napp Pharmaceuticals Limited. UK/FLUT-K-18036a(1). Date of Preparation July 2019.

Adverse events should be reported to: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. Adverse events should also be reported to Mundipharma Pharmaceuticals Limited on drugsafetyireland@mundipharma.ie or by phone on 01 2063800 (1800 991830 outside office hours)

References: 1. https://www.medicines.ie/medicines/flutiform-k-haler-50-microgram 5-microgram-125-microgram-5-microgram-peractuation-pressurised-inhalation suspension-34603/ last accessed September 2019. **2.** Bell D *et al.* J Aerosol Med Pulm Drug Deliv 2017; 30:425–34.

Intelligently designed. Simple to use.[1,2]

The **first** and **only** ICS/LABA delivered in a breath-actuated aerosol inhaler.

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- Hypertension.
- Diabetes.
- Cataracts and glaucoma.
- Easy bruising.
- Muscle weakness.

To minimise the risk of taking oral corticosteroids:

- Eat a healthy, balanced diet with plenty of calcium.
- Maintain a healthy body weight.
- Stop smoking.
- Only drink alcohol in moderation.
- Do regular exercise.

When can therapy be reduced?

Once control is achieved and sustained, gradual stepping-down of therapy is recommended.[5] Good control is reflected by the absence of night-time symptoms, no symptoms on exercise and the use of relievers less than three times a week. Patients should be maintained on the lowest effective dose of inhaled steroids, with reductions of 25-50% being considered every three months.

Spacer devices

Spacers are large plastic or metal containers with a mouthpiece at one end and a hole for the inhaler at the other. The medicine is puffed into the spacer by the inhaler and it is then breathed in through the spacer mouthpiece. Spacer devices in combination with metered dose inhalers (MDI) have a number of advantages: a) no need to co-ordinate inhaler activation with inspiration, b) improvement in lung deposition and c) reduction in oropharyngeal deposition (resulting in fewer local side effects and lower systemic absorption).[2] Some inhalers emit an aerosol jet when pressed. These work better if given through a spacer, which increases the amount of medication that reaches the lungs and reduce side effects.[6] Some patients, especially children and elderly patients, find using inhalers difficult, and spacers can help. However, spacers are often advised even for patients who use inhalers well as they improve the distribution of medication in the lungs. Spacers are also good for reducing the risk of thrush in the mouth or throat with corticosteroid inhalers. When a spacer device is being used, only one puff of the inhaler must occur at a time.

ASTHMA DEATHS

Underestimating the severity of the fatal attack by the doctor, patient or relatives is considered to be the biggest cause of death in asthmatics.[5,12,13] There were 92 asthma-related deaths in Ireland in 1999.[1] The risk of dying from asthma increases with age and asthma-related deaths are extremely rare in children. Patients at most at risk of death are those who have severe asthma, are obese, have a history of non-compliance with therapy and have one or more adverse psychological factors, such as: Alcohol or drug use, employment or income problems, social isolation, or current or recent tranquilliser use.

ASTHMA AND PREGNANCY

Medication used for asthma will not cause any problems for the developing baby in the womb. Due to the changes that take place in the body during pregnancy, asthma symptoms may change during pregnancy. For some women, asthma improves; for others asthma worsens and for others, asthma stays the same. The most severe asthma symptoms experienced by pregnant women tend to occur between the 24th and 36th week of pregnancy. Symptoms then decrease significantly during the last month of pregnancy.

Only 10 per cent of women experience asthma symptoms during labour and delivery, and these symptoms can normally be controlled using reliever medicine.

Asthmatics who are pregnant should manage their asthma in the same way as before pregnancy. The medicines used for asthma have been proven to be safe to take during pregnancy and when breastfeeding. The one exception is leukotriene receptor antagonists (Montelukast). There is no evidence that it can harm babies during pregnancy and breastfeeding. However, there is not enough evidence about its safety compared with other asthma medications.

However, if leukotriene receptor antagonists are needed to control asthma during pregnancy, the GP or asthma clinic may recommend that they are continued. This is because the risks to the patient and child from uncontrolled asthma are far higher than any potential risk from this medicine. Theophylline is often avoided during pregnancy and breastfeeding because of reports of neonatal irritability and apnoea. ●

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ONLY ANORO▼ ELLIPTA

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HAS POSITIVE HEAD-TO-HEAD DATA VS. ANOTHER ONCE-DAILY LAMA/LABA*[1]

In symptomatic patients with moderate COPD

*Anoro Ellipta compared to tiotriopium/olodaterol ▼showed statistical superiority on pre-specified secondary endpoint of trough FEV_1 at 8 weeks in the Intent to Treat population. ITT population n=236 (180mL vs. 128mL in trough FEV_1; Difference 52ml (p<0.001, 95% CI:28,77).

The primary endpoint of non-inferiority on trough FEV_1 at Week 8 in the PP population was met. Non-inferiority was met for the primary endpoint at Week 8 in the PP population (n=227) (175mL Anoro Ellipta and 122mL tiotropium/olodaterol, 95% CI: 26, 80; p<0.001)[1]

An 8-week, randomised, open-label, two-period crossover in symptomatic patients with moderate COPD (post bronchodilator FEV_1 ≤70% and ≥ 50% of predicted value, mMRC≥2) and not receiving ICS at inclusion.[1]

COPD, chronic obstructive pulmonary disease; FEV_1, forced expiratory volume in 1 second; LABA, long-acting β_2-agonist; LAMA, long-acting muscarinic antagonist; mMRC, modified Medical Research Council scale; ITT, intent to treat. COPD, FEV PP, ITT

Learn more by visiting: www.anoro.ie/headtohead

Anoro Ellipta is contraindicated for patients who are hypersensitive to the active substances or to any of the excipients. Anoro Ellipta is not indicated for the treatment of acute episodes of bronchospasm. Cardiovascular events, such as cardiac arrhythmias, may be seen after the administration of muscarinic receptor antagonists and sympathomimeticagents, including umeclidinium/vilanterol. Therefore, Anoro Ellipta should be used with caution in patients with severe cardiovasular disease. Due to antimuscarinic activity (i.e. LAMA class activity), umeclidinium/vilanterol should be used with caution in patients with urinary retention or with narrow-angle glaucoma.[2]

ANORO▼ ELLIPTA
umeclidinium/vilanterol

Anoro Ellipta 55/22mcg is indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD)[2]

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

Anoro▼ Ellipta (umeclidinium bromide/vilanterol [as trifenatate]) Prescribing information (Please consult the full Summary of Product Characteristics (SmPC) before prescribing)

Anoro Ellipta 55/22mcg (umeclidinium bromide/vilanterol [as trifenatate]) inhalation powder. Each single inhalation of umeclidinium bromide (UMEC) 62.5 micrograms (mcg) and vilanterol (VI) 25mcg provides a delivered dose of UMEC 55mcg and VI 22mcg. Each delivered dose contains approx. 25mg lactose. **Indications:** *COPD*: Maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD. **Dose and administration:** Inhalation only. *COPD*: One inhalation once daily at the same time of the day. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients (lactose monohydrate and magnesium stearate). **Precautions:** Anoro Ellipta should not be used in patients with asthma. Treatment with Anoro Ellipta should be discontinued in the event of paradoxical bronchospasm and alternative therapy initiated if necessary. Cardiovascular effects may be seen after the administration of muscarinic receptor antagonists and sympathomimetics therefore Anoro Ellipta should be used with caution in patients with severe cardiovascular disease. Anoro Ellipta should be used with caution in patients with urinary retention, narrow angle glaucoma, convulsive disorders, thyrotoxicosis, hypokalaemia, hyperglycaemia and severe hepatic impairment. No dose adjustment is required in renal or mild to moderate hepatic impairment. Patients with rare hereditary problems of galactose intolerance, the Lapp total lactase deficiency or glucose-galactose malabsorption should not use Anoro Ellipta. **Acute symptoms:** Anoro Ellipta is not indicated for acute episodes of bronchospasm. Warn patients to seek medical advice if short-acting inhaled bronchodilator use increases, a re-evaluation of the patient and of the COPD treatment regimen should be undertaken. **Interactions with other medicinal products:** Interaction studies have only been performed in adults. Avoid β-blockers. Caution is advised when co-administering with strong CYP3A4 inhibitors (e.g. ketoconazole, clarithromycin, itraconazole, ritonavir, telithromycin). Anoro Ellipta should not be used in conjunction with other long-acting β_2-adrenergic agonists or medicinal products containing long-acting muscarinic antagonists. Caution is advised with concomitant use with methylxanthine derivatives, steroids or non-potassium-sparing diuretics as it may potentiate possible hypokalaemic effect of β_2-adrenergic agonists. **Fertility, pregnancy, and breast-feeding:** No available data. Balance risks against benefits. **Side effects:** Common: Urinary tract infection, sinusitis, nasopharyngitis, pharyngitis, upper respiratory tract infection, headache, cough, oropharyngeal pain, constipation and dry mouth. Uncommon: Hypersenstivity reactions including rash, tremor, dysgeusia, dysphonia, atrial fibrillation, supraventricular tachycardia, rhythm idioventricular, tachycardia, supraventricular extrasystoles and palpitations. Rare: Anaphylaxis, angioedema, urticaria, vision blurred, glaucoma, intraocular pressure increased, paradoxical bronchospasm, urinary retention, dysuria and bladder outlet obstruction. **Marketing Authorisation (MA) Holder:** GlaxoSmithKline (Ireland) Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland. **MA Nr:** 55/22mcg 1x30 doses [EU/1/14/898/002]. **Legal category:** POM B. **Last date of revision:** February 2019. **Job Ref:** IE/UCV/0063/15 (8). Further information available on request from GlaxoSmithKline, 12 Riverwalk, Citywest Business Campus, Dublin 24, Tel: 01-4955000.

Adverse events should be reported to the Health Products Regulatory Authority (HPRA) using an Adverse Reaction Report Form obtained either from the HPRA or electronically via the website at **www.hpra.ie**. Adverse reactions can also be reported to the HPRA by calling (01) 6764971. Adverse events should also be reported to **GlaxoSmithKline on 1800 244 255**.

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ANORO ELLIPTA was developed in collaboration with INNOVIVA

IE/UCV/0006/17a(2)
Date of Preparation: January 2019

AUTHOR: Dr Nick Flynn, MyCorkGP.ie Group and Union Quay Medical Centre

EARLY DIAGNOSIS OF COPD

The early diagnosis of COPD has a significant potential to benefit patients and reduce costs to the health service

Perhaps unsurprisingly, the best place to start a discussion on the benefits of early diagnosis and treatment in chronic obstructive pulmonary disease (COPD) is with the definition of COPD from the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines. The GOLD guidelines talk about COPD being a common, preventable, treatable lung condition characterised by airflow limitation that is not fully reversible and is usually caused by significant exposure to noxious gases (ie, cigarette smoke). GOLD reminds us that COPD is also normally progressive.

Let's look at that. How common is COPD in Ireland?

The incidence of COPD in Ireland is 10 per cent of the adult population. Every COPD talk I've ever attended has used the iceberg analogy. That is to say that the visible iceberg above the water represents the 110,000 Irish patients we

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have diagnosed with COPD and the larger iceberg under the water reminds us that there are 200,000 patients living with COPD who have not yet been diagnosed.

In fact, I believe there are two icebergs in COPD, the second one representing those 110,000 patients we have diagnosed with COPD. If you visualise the COPD patients in your practice, you will probably be visualising the symptomatic and exacerbating patients. Yet only 15 per cent of your COPD patients fit into this bracket. So, the second iceberg in COPD is within those patients already diagnosed with COPD. Above the water are the exacerbating patients but remember that underneath the water are over half the patients with COPD in your practice who will have at most one exacerbation in a year and who we may be less aware of.

Next, GOLD says COPD is preventable. For the majority of our Irish patients, smoking will be the only cause of their COPD. That we are reminded that COPD is preventable is a call to arms for general practitioners (GPs) with regards to smoking cessation. Smoking cessation has been shown to be the most significant intervention to slow the rate of decline of lung function and the earlier a smoker stops smoking, the more lung function is preserved. Pharmacotherapy and nicotine replacement are known to reliably increase long-term smoking abstinence rates. The effectiveness and safety of e-cigarettes as a smoking cessation aid is uncertain at present.

So why are there 200,000 patients living with COPD in Ireland who are undiagnosed? There are patient factors, GP or practice factors, and system factors.

Patient factors: COPD progresses relentlessly, but slowly, and as such, many patients do not realise that they have a problem. COPD patients may associate their symptoms (ie, dyspnoea) with the ageing process, with being less active, with being deconditioned and less 'fit'. They may normalise their cough as a 'smoker's cough' and do not consider it to be a sign of illness. COPD patients can be stoic regarding their condition, known as the 'silence of COPD'.

GP and practice factors: In the course of a busy winter flu season, patients presenting with recurrent chest infections may not be regarded as at-risk of having COPD. Also, as COPD patients tend to underemphasise their symptoms, we may tend towards being less aggressive when it comes to investigating their symptoms. Patients with COPD commonly have comorbidities and these conditions may be perceived to be more pressing and perhaps easier to diagnose and manage. There is concern among some doctors regarding the accuracy of spirometry performed in general practice. However, studies show that accurate spirometry can be performed in general practice, where the practice nurses have appropriate training and interest.

System factors: Irish general practice is contracted to a 40-year-old general medical services (GMS) contract, which is predicated on the treatment of acute illness. Reflecting on the changes which have taken place in your television since 1978, and considering that similar changes have taken place in medicine with regards to the diagnosis and treatment of patients during this time, gives an idea of how disadvantaged Irish patients and Irish GPs have been when it comes to diagnosing and managing chronic illnesses. Moreover, COPD requires spirometry to confirm the diagnosis and there is no HSE funding to general practice to support diagnostic spirometry. Until 2019, there has been no funding towards a 'COPD cycle of care', which might ensure that Irish COPD patients received evidence-based care.

However, the recent introduction of funding to Irish GPs to support case finding and a COPD cycle of care in chronic disease management should help identify more of those 200,000 Irish people living with undiagnosed COPD. It should also improve the quality of care COPD patients receive.

GOLD also reminds us that COPD is treatable. Pharmacological therapy can reduce COPD symptoms, reduce the frequency and severity of exacerbations, and improve health status and exercise tolerance. GOLD states that each pharmacologic treatment regimen should be individualised and guided by the severity of symptoms, risk of exacerbations, side-effects, comorbidities, drug availability and cost, and the patient's response, preference and ability to use various drug delivery devices.

Finally, GOLD states that COPD is a progressive condition. Degenerative changes in lung function with age in non-smoking healthy adults result in the loss of 25 per cent of lung function (as defined by a decrease in FEV1) by the age of 75. Smoking is known to accelerate this loss of lung function considerably, as demonstrated by the Fletcher-Peto graph. Additionally, every purulent COPD exacerbation further decreases a patient's quality of life, longevity and reduces lung function.

So why should we worry about our 200,000 Irish patients who are living with COPD and have yet to be diagnosed? Why is early diagnosis of COPD going to help?

Diagnosis of COPD usually does not occur until significant lung function has already been lost. By the time patients recognise that they have symptoms, their airflow limitation, as defined by a reduction in FEV1, has usually fallen to about 50 per cent of predicted. They will be having two or more exacerbations per year and there is a significant amount of systemic inflammation leading to comorbidities.

Direct costs of respiratory disease account for 6 per cent of the total healthcare budget in the EU, with COPD accounting for 56 per cent (€38.6 billion) of this cost. COPD exacerbations account for the greatest proportion of the total economic burden associated with COPD. So, the financial costs of COPD are high. As well as the direct costs of hospitalisation and other healthcare costs, there are other indirect costs of disability, lost productivity, carer support and family costs. As Ireland has the highest rate of COPD hospitalisations among the Organisation for Economic Co-operation and Development (OECD) countries (395 COPD admissions per 100,000 population), we can be sure that COPD is contributing significantly to both healthcare costs and our significant trolley crisis.

It is evident that if we can diagnose COPD earlier in the course of the illness, we can improve patient outcomes by focusing on smoking cessation, increasing uptake of influenza and pneumonia vaccinations, ensuring adequate nutrition,

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increasing physical activity among our patients, and ensuring patients are on evidence-based inhaled pharmacotherapy, which is appropriate for each individual patient and which is shown to decrease exacerbation rates.

Smoking cessation has the greatest capacity to influence the natural history of COPD. If effective resources and time are dedicated to smoking cessation, long-term quit success rates of up to 25 per cent can be achieved. Smoking cessation interventions are more successful in those who are actually given a firm diagnosis.

Influenza vaccination can reduce serious illness (such as lower respiratory tract infections requiring hospitalisation) and death in COPD patients. Pneumococcal vaccinations have been shown to reduce community-acquired pneumonia in patients under 65 with severe airflow limitation (FEV1<40 per cent).

Early diagnosis allows for earlier lifestyle changes, such as exercise and pulmonary rehabilitation. As already discussed, exertional dyspnoea often leads patients to reduce their exercise and activities of daily living to reduce the intensity of their distress. This reduction in activities of daily living leads to deconditioning which, in turn, can lead to increased dyspnoea.

Early pharmacological intervention can improve the health and exercise capacity of COPD patients and reduce COPD exacerbations, even in patients with mild-to-moderate COPD. The 2017 GOLD guidelines have made the treatment decision-making pathways in COPD more doctor-friendly, as they uncoupled spirometry findings from treatment algorithms. As spirometry is not specifically funded in the new chronic disease management pathways in the Irish GP GMS, this development is particularly GP-friendly. Patients require spirometry to confirm the diagnosis.

However, once confirmed, the decision relating to choice of inhaled pharmacotherapy is based on four questions:

1. Does the patient have asthma and COPD?

If yes, a long-acting β-agonist/inhaled corticosteroid (LABA/ICS) combination is the first choice in COPD patients with a history of asthma.

2. How many exacerbations has the patient had in the last year?

3. Has the patient got symptoms?

Zero or one exacerbations and no symptoms, the patient should start with a short-acting β-agonist, increasing to single-agent long-acting bronchodilator (ie, a long-acting muscarinic antagonist (LAMA) or LABA).

Zero or one exacerbations and symptomatic, the patient should start with a single-agent long-acting bronchodilator (ie, a LAMA or LABA), increasing to a dual-acting bronchodilator (ie, LAMA/LABA combination).

Two or more exacerbations or one hospitalisation and no symptoms, the patient should start with a LAMA, increasing to a LAMA/LABA and then a LAMA/LABA/ICS triple therapy combination if the patient continues to have exacerbations.

Two or more exacerbations or one hospitalisation and symptomatic, the patient should start with a LAMA, increasing to a LAMA/LABA and then LAMA/LABA/ICS if the patient continues to have exacerbations.

4. What is the patient's eosinophil count?

Blood eosinophil counts have been shown to predict steroid responsiveness in reducing exacerbations in COPD and the 2019 GOLD guidelines have introduced blood eosinophil counts to the treatment algorithms.

If the blood eosinophil counts ≥300 cells/μL, a LABA/ICS combination has the greatest likelihood of reducing exacerbations. Even in patients without a previous history of frequent exacerbations (ie, they have had one exacerbation in the last year), an ICS has been shown to decrease the risk of future exacerbations.

In patients with frequent exacerbations and blood eosinophil counts ≥100 cells/μL, an ICS should be considered earlier in the course of treatment. This refers to patients who are diagnosed with COPD, are symptomatic and have had two or more exacerbations in the last year. During follow-up with these patients, you should consider the early introduction of an ICS in addition to a single- or dual-acting bronchodilator.

So how can we promote earlier diagnosis of our patients with COPD?

There are a number of strategies which can be used to facilitate the earlier diagnosis of COPD.

For the first time in Irish general practice, we have funding to support screening at-risk patients, case finding and chronic disease management. It is unfortunate that there is not dedicated funding to also facilitate spirometry, which is essential for the diagnosis of COPD.

However, I believe the funding for chronic disease management, including COPD, will help identify more of those 200,000 Irish people living with undiagnosed COPD. It should also improve the quality-of-care COPD patients receive.

We should consider COPD in any patient who is a current smoker or ex-smoker over the age of 35 who has any respiratory symptoms, particularly cough, sputum, dyspnoea, wheeze or recurrent chest infections. Opportunistic spirometry to detect COPD in these patients has been shown to be cost-effective and forms part of the National Institute for Health and Care Excellence (NICE) guidelines in the UK. If spirometry is not available in your practice or not financially viable, consider referral of these patients to a respiratory clinic for diagnostic spirometry.

In summary, early diagnosis of COPD has the potential to benefit patients and save costs for the HSE. An early diagnosis will encourage smoking cessation, facilitate exercise interventions, facilitate earlier influenza and pneumonia vaccination and enable earlier inhaler treatment to prevent exacerbations and hospitalisations. Considering that we have the worst rate of COPD exacerbations leading to hospitalisation in the OECD, surely our COPD patients deserve more. ●

This article has been written in association with A.Menarini Pharmaceuticals. A.Menarini Pharmaceuticals had no input into the content of this piece.

References available on request

Genuair® – has it 'clicked' yet?

The ONLY prefilled inhaler with visual and audible feedback for confirmed dose delivery[1-4]

Genuair - a simple to use inhaler for patients with COPD[4]

LAMA

Eklira® Genuair®▼

aclidinium bromide inhalation powder

LAMA + LABA

Brimica® Genuair®▼

aclidinium bromide + formoterol

Abbreviated Prescribing Information

Eklira® Genuair®▼ 322 micrograms inhalation powder. Please consult the Summary of Product Characteristics (SPC) for the full prescribing information. **Presentation:** Inhalation powder in a white inhaler with an integral dose indicator and a green dosage button. Each delivered dose contains 375 µg aclidinium bromide equivalent to 322 µg of aclidinium. Also, contains lactose. **Use:** Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). **Dosage:** For inhalation use. Recommended dose is one inhalation of 322 micrograms aclidinium twice daily. Patients should be instructed on how to administer the product correctly as the Genuair inhaler may work differently from inhalers used previously. It is important to instruct the patients to read the Instructions for Use in the pack. No dose adjustments are required for elderly patients, or those with renal or hepatic impairment. No relevant use in children and adolescents. **Contraindications:** Hypersensitivity to aclidinium bromide or to any of the excipients. **Warnings and Precautions:** Stop use if paradoxical bronchospasm occurs and consider other treatments. Do not use for the relief of acute episodes of bronchospasm. Use with caution in patients with myocardial infarction in the previous 6 months, unstable angina, newly diagnosed arrhythmia within the previous 3 months, or hospitalisation within the previous 12 months for heart failure functional classes III and IV. Dry mouth, observed with anticholinergic treatment, may be associated with dental caries in the long term. Use with caution in patients with symptomatic prostatic hyperplasia or bladder-neck obstruction or with narrow-angle glaucoma. Do not use in patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption. **Interactions:** Do not administer with other anticholinergic-containing medicinal products. No other interactions expected. Please consult the SPC for more details. **Fertility, pregnancy and lactation:** No data on use in pregnancy. Risk to newborns/infants cannot be excluded. Consider risk-benefit before using during lactation. Unlikely to affect fertility at the recommended dose. **Side-effects:** Common (1-10%): Sinusitis, nasopharyngitis, headache, cough, diarrhoea, nausea. Uncommon (0.1- 1%): Dizziness, blurred vision, tachycardia, palpitations, dysphonia, dry mouth, stomatitis, rash, pruritus, urinary retention. Rare (0.01-0.1%): hypersensitivity. Not known: angioedema, anaphylactic reaction. **Pack sizes:** Carton containing 1 inhaler with 60 unit doses. **Legal category:** POM **Marketing Authorisation Number:** EU/1/12/778/002 **Marketing Authorisation holder:** AstraZeneca AB, SE-151 85 Södertälje, Sweden. **Marketed by:** A. Menarini Pharmaceuticals Ireland Ltd., Castlecourt, Monkstown Farm, Monkstown, Glenageary, Co. Dublin A96 T924. Further information is available on request to A. Menarini Pharmaceuticals Ireland Ltd. or may be found in the SPC. **Last updated:** May 2018

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions to: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie. Adverse events should also be reported to A. Menarini Pharmaceuticals Ireland Ltd. Phone no: 01 284 6744.

Date of item: October 2019. IR-BRI-17-2019

Abbreviated Prescribing Information

Brimica® Genuair®▼ 340 micrograms/12 micrograms inhalation powder. Please consult the Summary of Product Characteristics (SPC) for the full prescribing information. **Presentation:** Inhalation powder in a white inhaler with an integral dose indicator and an orange dosage button. Each delivered dose contains 396 µg aclidinium bromide (equivalent to 340 µg of aclidinium) and 11.8 micrograms of formoterol fumarate dihydrate. Also, contains lactose. **Use:** Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). **Dosage:** For inhalation use. Recommended dose is one inhalation of 340 µg/12 µg twice daily. Patients should be instructed on how to administer the product correctly as the Genuair inhaler may work differently from inhalers used previously. It is important to instruct the patients to read the Instructions for Use in the pack. No dose adjustments are required for elderly patients, or those with renal or hepatic impairment. No relevant use in children and adolescents. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients. **Warnings and Precautions:** Do not use in asthma. Stop use if paradoxical bronchospasm occurs and consider other treatments. Do not use for the relief of acute episodes of bronchospasm. Use with caution in patients with myocardial infarction in the previous 6 months, unstable angina, newly diagnosed arrhythmia within the previous 3 months, or hospitalisation within the previous 12 months for heart failure functional classes III and IV. Discontinue if increases in pulse rate, blood pressure or changes in ECG occur. Use with caution in patients with a history of or known prolongation of the QTc interval or treated with products affecting the QTc interval. Use with caution in patients with severe cardiovascular disorders, convulsive disorders, thyrotoxicosis and phaeochromocytoma. Hypokalaemia may occur, is usually transient and supplementation not needed. In patients with severe COPD, hypokalaemia may be potentiated by hypoxia and concomitant treatment. Use with caution in patients with symptomatic prostatic hyperplasia, urinary retention or with narrow-angle glaucoma. Dry mouth, observed with anticholinergic treatment, may be associated with dental caries in the long term. Do not use in patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption. **Interactions:** Do not administer with other anticholinergic and/or long-acting β2-adrenergic agonist containing medicinal products. Caution in use with methylxanthine derivatives, steroids, non-potassium-sparing diuretics, β-adrenergic blockers or medicinal products known to prolong the QTc interval. Please consult the SPC for more details. **Fertility, pregnancy and lactation:** No data on use in pregnancy. Consider risk-benefit before using during lactation. Unlikely to affect fertility at the recommended dose. **Side-effects:** Common (1-10%): Nasopharyngitis, urinary tract infection, sinusitis tooth abscess, insomnia, anxiety, headache, dizziness, tremor, cough, diarrhoea, nausea, dry mouth, myalgia, muscle spasms, peripheral oedema, increased blood creatine phosphokinase. Uncommon (0.1- 1%): Hypokalaemia, hyperglycaemia, agitation, dysgeusia, blurred vision, tachycardia, electrocardiogram QTc prolonged, palpitations, angina pectoris, dysphonia, throat irritation, stomatitis, rash, pruritus, urinary retention, increased blood pressure. Rare (0.01-0.1%): Hypersensitivity, bronchospasm, including paradoxical. Not known: anaphylactic reaction, angioedema. **Pack sizes:** Carton containing 1 inhaler with 60 unit doses. **Legal category:** POM **Marketing Authorisation Number:** EU/1/14/963/001 **Marketing Authorisation holder:** AstraZeneca AB, SE-151 85 Södertälje, Sweden. **Marketed by:** A. Menarini Pharmaceuticals Ireland Ltd., Castlecourt, Monkstown Farm, Monkstown, Glenageary, Co. Dublin A96 T924. Further information is available on request to A. Menarini Pharmaceuticals Ireland Ltd. or may be found in the SPC. **Last updated:** October 2019

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. Adverse events should also be reported to A. Menarini Pharmaceuticals Ireland Ltd. Phone no: 01 284 6744.

A. MENARINI PHARMACEUTICALS IRELAND LTD *Healthcare for Life*

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Donna Cosgrove PhD MPSI

LIFTING THE LID ON EYE CARE

Donna Cosgrove PhD MPSI *looks at the range of eye conditions that typically present in the pharmacy*

As people get older, they are at greater risk for common eye diseases and conditions, including age-related macular degeneration (AMD), cataracts, glaucoma and dry eyes. While cataracts are treated with surgical intervention and glaucoma with prescription medication, there are products available over-the-counter to treat dry eyes and potentially help with AMD.

DRY EYES

When a person does not produce enough quality tears to lubricate and nourish the eye, dry eye occurs. Tears are required to maintain the health of the eye, especially the anterior surface, and to provide clear vision.[1] The act of blinking spreads tears across the cornea, which provides lubrication, reduces the risk of eye infections and washes away foreign matter in the eye. This keeps the surface of the eyes smooth and clear. Excess tears flow into drainage ducts in the inner corners of the eyelids, which drain into the back of the nose. Dry eye is a common and often chronic problem, particularly in older adults and can occur when tear production and drainage are not in balance.

When dry eye occurs, this is due either to not enough tears being produced, or else the tears are not good quality.

- **Inadequate amount of tears:** Tear production tends to reduce as we age and can be caused by various medical conditions, or as a side effect of certain medicines (see list of *'Medications that may cause dry eyes'*). Environmental conditions can also decrease tear volume by increasing the rate of tear evaporation. When the normal amount of tear production decreases or tears evaporate too quickly from the eyes, symptoms of dry eye can develop.
- **Poor quality of tears:** Tears are made up of oil, water and mucus (Figure 1). Each of these layers protects and nourishes the eye. The smooth oil layer helps prevent evaporation of the water layer, while the mucin layer allows uniform distribution of the tears over the eye surface. If the tears evaporate too quickly or do not spread evenly over the cornea due to deficiencies with any of the three layers, dry eye symptoms can develop. The most common form of dry eyes is due to inadequate amount of the water layer of tears. This condition, called *keratoconjunctivitis sicca* (KCS), is also referred to as dry 'eye syndrome'.

Mild or moderate cases of dry eye can be treated with tear substitutes, designed to mimic the tears produced in the eye. The underlying mechanism of symptomatic improvement with tear supplementation is still poorly understood. It has been proposed that improvements are due to the increased tear volume, improved tear stabilisation, reduced tear osmolarity, a dilution of inflammatory biomarkers, or a combination of these.[3] Hydrogel polymers, such as those containing hypromellose (also called hydroxypropyl methylcellulose) or carbomer are effective for treating mild cases of dry eye. Hypromellose is frequently recommended as first-line, but to achieve adequate relief of symptoms, use may be required up to hourly. In these cases, more viscous products may be required, ie, carbomer 980, which binds moisture to the ocular surface, increasing the time for which moisture is retained. Carboxymethylcellulose drops are often considered if the hydrogel polymer products do not provide enough relief. In more severe cases or if symptoms are chronic, it may be necessary to use a lubricant with viscosity-increasing properties, such as sodium hyaluronate. Hydroxypropyl guar products increase in viscosity on contact with the ocular surface, forming a bio-adhesive gel. This mimics the mucous layer of the tear film, increasing aqueous retention. These products may be beneficial in mucous and aqueous deficiency. Preservative-free eye drops are available for people who wear soft contact lenses, and for those whose eyes are irritated by eye drops containing a preservative. Eye ointment is also available — research suggests a superior long-lasting effect compared with aqueous based ocular lubricants.

Lifestyle changes can improve the symptoms of dry eyes, such as use of humidifiers, stopping smoking, taking regular breaks from the computer to encourage blinking, and increasing dietary omega-3 fatty acid intake.

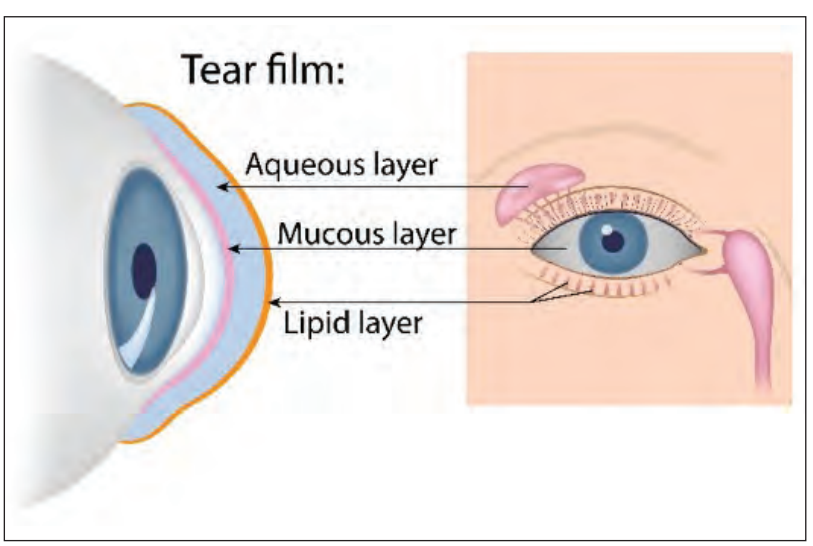

Figure 1: Tear film composition[1]

Medications that may cause dry eyes[2]

- Adjuncts to anaesthesia
- Antipyretic agents
- Analgesics
- Antirheumatic agents
- Antiandrogens
- Antispasmodics
- Antiarrhythmics
- Antivirals
- Anticholinergics
- Anxiolytics
- Antidepressants
- Bronchodilators
- Antiemetics
- Chelating agents
- Antihistamines
- Decongestants
- Antihypertensives
- Diuretics
- Antileprosy agents
- Neurotoxins
- Antimalarial agents
- Opioids
- Antimuscarinics
- Psychedelic agents
- Antineoplastics
- Retinoids
- Antiparkinsonians
- Sedatives and hypnotics
- Antipsychotics

Age-related macular degeneration

AMD is the term given to ageing changes without any other obvious cause that occur in the central area of the retina (macula). AMD is painless but leads to the gradual impairment of vision.[4] It can sometimes cause a rapid reduction in vision. It predominantly affects the central vision, which is used for reading and recognising faces. AMD is more common with older age, family history of AMD, smoking, hypertension, BMI of 30kg/m2 or higher, diet low in omega 3 and 6, vitamins, carotenoid and minerals, a diet high in fat, and lack of exercise.

There are two forms of AMD:[5]

- **Dry AMD:** This causes central vision to become dimmer, and as the disease progresses, distorted. This is the most common form of AMD (90 per cent). The cells of the macula at the back of the eye become thinner and less efficient as we age. These cells

lose lutein, a pigment essential to good eyesight. AMD is an acceleration of the natural ageing process at the back of the eye. Dry AMD cannot be treated, but taking lutein supplements, following a healthy diet and lifestyle with plenty of exercise and using good UV protective sunglasses can stabilise the progression of the condition.

- **Wet (neovascular) AMD:** Abnormal blood vessels (in the choriocapillaris) behind the retina start to leak, which causes a drop in oxygen supply to the cells in the macula. The body responds by generating more abnormal (fragile) blood vessels and scar tissue. This process causes permanent vision loss to the central visual field. Unlike dry AMD, wet AMD causes rapid vision loss and requires treatment. Wet AMD in particular is thought to have strong genetic link, so if a family member has had wet AMD, it is a good idea to take a lutein supplement, follow a healthy diet and get plenty of exercise. Wet AMD does not develop suddenly; dry AMD usually occurs first, although the individual may not have been aware of it.

Wet AMD is treated by a specialist ophthalmologist using either photodynamic therapy, laser photocoagulation, or injections which prevent the formation of scar tissue and promote better healing at the macula. Anti-VEGF injections (ie, aflibercept, bevacizumab, ranibizumab) are given directly into the eyes. This prevents worsening of vision in 90 per cent of cases and improves vision in 30 per cent.[6] These drugs bind to circulating vascular endothelial growth factors (VEGF) and inhibit their activity. This decreases the proliferation of the fragile blood vessels in the choriocapillaris.

Vitamins A, C and E are thought to maintain healthy cells and tissues in the eye. More recently, interest has grown in another antioxidant, lutein, and a similar substance, zeaxanthin. Both are yellow plant pigments (ie, the yellow and orange in peppers, sweetcorn and saffron). Green leafy vegetables such as kale, spinach and broccoli also have high levels of lutein.[7] Macular pigment is made up of three carotenoids: Lutein, zeaxanthin and meso-zeaxanthin. Meso-zeaxanthin is not typically found in diet, but has been identified in some fish species. It is thought to be formed at the macula by conversion from lutein, but the mechanism for this has not been confirmed.[8] Antioxidants present in the retina (vitamin C, vitamin E, carotenoids, selenium and zinc) may prevent cellular damage by reacting with free radicals produced in the process of absorbing light.[9] Dietary supplements are available, with varying combinations of these antioxidants and carotenoids. Multiple research studies have been performed to examine the effect of supplementation on macular degeneration. The Age-Related Eye Disease Study (AREDS) investigated the use of vitamin C 500mg, vitamin E 400 IU, beta carotene 15mg and zinc 80mg in the progression of macular degeneration. Results were positive in some groups, with patients experiencing a modest delay of 20-to-25 per cent in progression to advanced AMD at seven-year follow-up.[4]

> *Vitamins A, C and E are thought to maintain healthy cells and tissues in the eye...*

A separate study published in 2016[8] that included 49 patients evaluated the effect of once-daily oral macular pigment supplementation in eyes with retinal pathology after six months. Supplementation consisted of 10mg lutein, 2mg zeaxanthin, and 10mg meso-zeaxanthin (Macushield). Results showed an increase in the mean macular pigment density, and significant improvement in glare disability and low-contrast sensitivity (the ability to distinguish an object from its background). The authors suggest that these findings warrant further investigation in larger studies with a longer follow-up period. The effects and benefits of each individual component in the supplements on AMD progression is unclear, as a combined supplement was used.[4] The Meso-zeaxanthin Ocular Supplementation Trial (MOST) AMD study[10] was conducted to examine the effect of sustained supplementation with carotenoids on visual function and disease progression. Forty-seven individuals completed the study to the 36-month follow-up point. Findings indicate that the inclusion of meso-zeaxanthin in a supplement formulation confer benefits in terms of macular pigment increase, and in terms of enhanced contrast sensitivity in subjects with early AMD. Although macular pigment increased after supplementation of all the carotenoids examined (lutein, zeaxanthin and meso-zeaxanthin), the inclusion of meso-zeaxanthin may lead to the best results. Researchers also observed benefits with sustained supplementation with the macular carotenoids over a three-year period in patients with early AMD. Although many studies indicate positive results, for now, neither the NHS or HSE recommend prescription of these products, and a Cochrane review recommends that further trials are needed to promote the use of antioxidants and their role in the progression of AMD.9

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Fit for a McQueen

Channel your inner Steve McQueen with the Mustang Bullitt, writes ***Morgan Flanagan Creagh***

In 1968, Lieutenant Frank Bullitt, played by Steve McQueen, famously hurtled through the mean streets of San Francisco, hot on the heels of a dastardly, black Dodge Charger in the blockbuster film *Bullitt*. After the movie, the Mustang GT Fastback reached superstardom and Ford is now celebrating its 50th anniversary with a special, souped-up Mustang GT Bullitt.

The supremely cool Mustang is painted in the same Dark Highland Green as the movie car and they have completely de-badged the exterior, except for one logo at the back that simply says 'Bullitt'. It was mentioned to me that it looked like a prop car from the *Fast & Furious* franchise, and I'd have to agree; for a stock car, it has an undeniably custom look. It has also been bestowed with a behemoth 5.0-litre, V8 engine that makes more noise than Croke Park on match day.

Mustangs have a reputation for being 'widow-makers', especially the quick ones, and I learned rather rapidly, in some frosty conditions, that this car requires a soft touch and your utmost respect. The tail-happy nature of this car is a big part of its charm and the limited slip differential will reel it in if you are being a little silly; however, on icy or frosty roads, it can quickly become a 'squeaky bum' experience. The 5.0 litre is an unbridled piece of old-world magnificence as it relentlessly accelerates through every millimetre of the rev-range. I didn't get anywhere close to testing its full capabilities, but if you had a track and were brave enough, I'm sure this car would perform magnificently, if you could hang on tight enough.

The interior of the Mustang is a little cheap in places but all-in-all, I found it to be grand; the RECARO seats were wonderful and it is very spacious. The smorgasbord of track-derived settings, such as the g-meter, acceleration timer, performance shift indicator and track mode, were a hoot, not to mention the famous 'line lock', which locks the front

wheels and allows you to smoke the rear tyres in preparation for a drag race. The car also has exhaust mode, which you can use to quieten or exaggerate your V8 bellow and control the V8 'blip' the car makes when you shift down the gears. This, paired with the impressive Bang and Qlufsen sound system, with boot-mounted subwoofer, makes the Bullitt its own travelling orchestra.

Thanks to wonders of modern engineering, the Bullitt stops quite well despite its weight and power, thanks to its Brembo brake set-up. It also boasts safety features like Pre-Collision Assist with Pedestrian Detection (Automatic Emergency Braking & Forward Collision Warning), Adaptive Cruise Control and Lane Departure Warning. The model I tested also had the MagneRide Suspension Damping System at an additional cost of €3,030.

In 2018, I tested its smaller sibling, the 2.3-litre Ecoboost (turbo) and I noticed that Irish people loved the Mustang, a point that was exaggerated in the louder and more brutish Bullitt. The general public couldn't get enough of this car, happy faces, waves and smiles that you wouldn't see from the driver's seat of an ice-cream van. In a previous review, I likened the Ford Fiesta ST3 to a Jack Russell terrier, "small and feisty, with the guts to back it up". Well, the Bullitt is more like riding around on a disgruntled Rottweiler; it looks very cool and it is very powerful; however you are always acutely aware that it might eat you. Personally, despite the lack of impressive engine note, I preferred the €55,500, 317hp, 2.3 litre Ecoboost, both for its handling, which I found to be sharper and overall practicality, as I feel the cost of running the 450hp, 5.0-litre V8 and paying the €2,350 road tax to cover its 277g/km emissions may become a little tedious.

The Bullitt starts at €73,092, however the model I tested cost €78,842. You get a lot of power for that money and I love fast Fords, but I must admit, if it was my money I'd go for the more practical and less expensive Ecoboost, which I adore, and deal with people taunting me for being a realist instead of a purist.

L to R: Mr Alan Smith and Mr Paul Tighe

Ms Annmarie O'Neill and Prof Fionnuala Ni Ainle

IMSN 2019 Conference morning speakers

Mr Eamon Quinn, Ms Katherine Morrow, and Ms Niamh O'Hanlon

Mr Dan Burns

Prof Fionnuala Ni Ainle

Ms Ciara Kirke

Prof Mary Day

Mr Sotiris Antoniou

IMSN 2019 Conference afternoon speakers

Attendees and speakers at the IMSN Annual Conference 2019

Mr Paddy Byrne, Ms Gerardine Gahan, and Ms Elizabeth Hoctor

Ms Murial Pate, Ms Dolores Dempsey-Ryan, Ms Aoife Lenihan, and Ms Nora O'Mahony

Ms Aoife Lenihan

Prof Fionnuala Ni Ainle and Ms Tracy Robson

Mr Kieran Ryan

Ms Katherine Morrow, Ms Tracy Robson, Ms Niamh O'Hanlon, and Ms Pat O'Brien

PRODUCT LAUNCH

Over 100,000 fewer inhalers may be disposed of each year as Boehringer Ingelheim launches Respimat reusable — the first reusable, soft mist inhaler

Boehringer Ingelheim has announced the launch of the Respimat reusable inhaler in Ireland, which could lead to over 112,500 fewer inhalers being disposed of each year. The first soft mist, reusable inhaler is now available for use with up to six refill cartridges, no longer disposed of and replaced each time the medication runs out. Respimat has always been propellant-free but by using the reusable inhaler with six refill cartridges (rather than six of the previous disposable inhalers with one cartridge each), the product carbon footprint is reduced by 71 per cent. Respimat reusable delivers the chronic obstructive pulmonary disease (COPD) medications tiotropium/olodaterol (Spiolto), olodaterol (Striverdi) and tiotropium (Spiriva), as well as the asthma medication tiotropium (Spiriva).

Asthma and COPD affect over 490,000 people in Ireland and chronic lower respiratory disease, which includes COPD and asthma, is the fourth-most common cause of death. Nurses and pharmacists are likely to see people with COPD and asthma more regularly than a GP or specialist, so they play a pivotal role in educating patients on their medicines and inhaler technique, whether this is part of routine practice or a specialist commissioned pharmacy-based inhaler technique check service.

Ireland had the third-highest emission of greenhouse gases per capita in the EU in 2017. The HSE's *Sustainability Strategy for Health* outlines its commitment to reducing carbon emissions and delivering low-carbon, quality sustainable healthcare. A recent study highlighted that the carbon footprint of the original, disposable Respimat is approximately 20 times smaller than that of pressurised metered-dose inhalers (pMDIs) and the transition to Respimat reusable has the potential to reduce this by an additional 71 per cent.

Prof Richard Costello, Professor of Medicine at the Royal College of Surgeons in Ireland, commented: "This move to a reusable Respimat inhaler is positive for the environment, with patients able to reduce the number of inhalers used from 12 to two per year. As prescribers in respiratory medicine, we are aware of the environmental impact of medicines, including their carbon emissions and plastic waste.

"I welcome developments towards more environmentally-friendly options with a significantly reduced product carbon footprint to help support HSE targets in the *Sustainability Strategy for Health*."

Dr Tim Crossman, Head of Medical Affairs, Boehringer Ingelheim UK and Ireland, added: "Boehringer Ingelheim is committed to sustainable healthcare, and we recognise the need to reduce plastic waste and carbon emissions. We are increasingly conscious of the environmental impact of the medicines we develop and hope that the introduction of this reusable inhaler is seen as a positive step in reducing the carbon footprint of inhalers."

This inhaler is a reusable version of Boehringer Ingelheim's well-established Respimat (disposable) soft mist inhaler and was introduced following patient and healthcare professional feedback. Nurses, pharmacists and patients will be familiar with the day-to-day use of Respimat reusable, which remains the same for patients; indications for prescribing, recommended dose, and the safety and efficacy profile of the inhalers remain unchanged.

Prescribing and dispensing of Respimat inhalers will change so that a patient's initial prescription pack contains one inhaler plus one cartridge, followed by packs containing just one refill cartridge.

At six months, the patient will once again receive one inhaler plus one cartridge. The dose counter has been improved — it is larger and more clearly shows when the medication is running low and needs to be replaced. The clear base of the Respimat reusable inhaler automatically detaches when the cartridge is empty as a clear indication to the patient of when the cartridge needs to be replaced.

Boehringer Ingelheim has created dedicated educational websites for healthcare professionals and patients to find out more about the change in order to support the transition to Respimat reusable. For more information, please visit **www.medical.respimat.com/ie**.

APPOINTMENT

Pharmaforce announces appointment of Ms Alison Conroy to Recruitment Specialist as the Pharmed Group expansion continues

Contract Sales Outsourcing and Recruitment experts Pharmaforce has further accelerated its growth plans with the appointment of Ms Alison Conroy to Recruitment Specialist.

Ms Conroy joins the Pharmaforce team with an extensive business background and over eight years' experience working across a number of industries including healthcare, IT, online and gaming, and most recently manufacturing and engineering. Ms Conroy has extensive experience in delivering on complex business resourcing needs, including high-volume recruitment campaigns. Prior to joining Pharmaforce, she was a recruiter with Intel, where she was responsible for managing the business resourcing needs of high-volume recruitment and selection across all their divisions. She was also instrumental in developing their graduate programme and related recruitment activities.

Pharmaforce provides a range of contract sales outsourcing and recruitment services to pharmaceutical and healthcare companies. It is also the HR and recruitment arm of the Pharmed Group — an award-winning healthcare and pharmaceutical services provider that offers sales, marketing, distribution and support services to all sectors of the healthcare market across Ireland and the UK. Operating across three core business units: Medical and Scientific, Pharmaceutical and OTC, and contract outsourcing and recruitment, the Group has experienced significant growth recently and now employs over 170 people.

Commercial Director of Pharmaforce Ms Bethann Doherty said: "We are delighted to have Alison join us at a time when we have seen substantial growth across all areas of the Pharmaforce business, as well as the unprecedented growth across the Pharmed Group as a whole. I have no doubt that she will make a dynamic contribution to the team. Alison's experience of recruitment within the manufacturing and engineering sectors will enhance this growing area of our business."

Ms Conroy graduated from Waterford Institute of Technology in 2010 with a Bachelor of Science in Retail Management and from NUI Galway in 2011 with a Master of Science in Industrial Relations and HR Management.

Ms Alison Conroy

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

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Product Information: Please consult the summary of product characteristics for full product information. **Panadol Extra 500mg/65mg Soluble Effervescent Tablets,** paracetamol 500mg, caffeine 65mg. **Indications:** Relief of mild to moderate pain including rheumatism, neuralgia, musculoskeletal disorders, headache, symptoms of colds and flu, fever, toothache and menstrual pain. **Dosage: Adults and children 16 years and over:** 2 tablets up to 4 times a day. Do not exceed 8 tablets in 24 hours. **Children aged 12-15 years:** 1 tablet up to 4 times a day. Do not exceed 4 tablets in 24 hours. Do not give to children under 12 years. Minimum dosing interval: 4 hours. **Contraindications:** Hypersensitivity to paracetamol, caffeine or any ingredients. **Precautions:** Avoid concurrent use with other paracetamol-containing products. Diagnosed liver of kidney impairment. Patients with depleted glutathione levels or chronic alcoholism or sepsis. Avoid excessive caffeine intake. Caution in those with hereditary sugar intolerance or on a low sodium diet. Should not be used in pregnancy or lactation without medical advice. Do not exceed the stated dose. Prolonged use except under medical supervision may be harmful. **Side effects:** See SPC for full details. *All very rare:* Thrombocytopenia, hypersensitivity reactions including anaphylaxis and skin rash, angioedema, Stevens-Johnson syndrome, bronchospasm, hepatic dysfunction. *Frequency unknown:* Nervousness, dizziness. When combined with dietary caffeine intake, higher doses of caffeine may increase potential for caffeine related adverse events such as insomnia, restlessness, anxiety, irritability, headaches, GI disturbances and palpitations. **Overdose:** Immediate medical advice should be sought in the event of an overdose, even if symptoms of overdose are not present. **Legal Category:** Supply through pharmacy only. **MA Number:** PA 678/39/10. **MA Holder:** GlaxoSmithKline Consumer Healthcare (Ireland) Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24. Additional information is available upon request. **Text prepared:** November 2019. CHGBI/CHPAN/0107/19