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NEVER MIND THE BALLOTS

WAS THE FEE CUT REVERSAL MADE WITH ONE EYE ON ELECTION 2020, ASKS FINTAN MOORE

PLUS CLINICAL CONTENT

- CPD MODULE: DERMATOLOGY
- INFANT CARE
- MIGRAINE
- NUTRITION
- NASAL CONGESTION

THE POISON IN THE DOSE

A LOOK AT THE DAMAGE PHARMACEUTICAL RESIDUES ARE DOING TO OUR ENVIRONMENT

TRELEGY▼ELLIPTA

(fluticasone furoate/umeclidinium/vilanterol)

The only COPD Triple Therapy delivered in a single daily inhalation.[1]
Improvement in quality of life vs. ICS/LABA.[2,3]

LESS TO TAKE. **MORE TO TAKE IN.**

A combination of ICS/LAMA/LABA (FF/UMEC/VI) administered through a single daily inhalation from the Ellipta inhaler, which is easy to use[1-5]

TRELEGY▼ELLIPTA
fluticasone furoate/umeclidinium/vilanterol

▼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.

TRELEGY Ellipta FF/UMEC/VI 92/55/22 mcg OD is indicated for Maintenance treatment in adult patients with moderate to severe COPD who are not adequately treated by a combination of an inhaled corticosteroid (ICS) and a long-acting β_2-agonist (LABA) or a combination of a LABA and a long acting muscarinic antagonist.

COPD, chronic obstructive pulmonary disease; FF, fluticasone furoate; ICS, inhaled corticosteroids; LABA, long-acting β_2-agonist; LAMA, long-acting muscarinic antagonist; OD, once-daily; UMEC, umeclidinium, VI, vilanterol.

References: 1. TRELEGY Ellipta SmPC, available at www.medicines.ie, last accessed October 2019. **2.** Lipson DA *et al. Am J Respir Crit Care Med* 2017; 196:438–446. **3.** Lipson DA, *et al.* N Engl J Med. May 3 2018;378(18):1671-1680. **4.** Svedsater H *et al. BMC Pulm Med* 2013; 13:72–86. **5.** van der Palen J *et al. NPJ Prim Care Respir Med* 2016; 26:16079.

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

Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol [as trifenatate]) inhalation powder. Each single inhalation of fluticasone furoate (FF) 100 micrograms (mcg), umeclidinium bromide (UMEC) 62.5 micrograms and vilanterol as trifenatate (VI) 25 mcg provides a delivered dose of 92 mcg FF, 55 mcg UMEC and 22 mcg VI. **Indications:** Maintenance treatment in adult patients with moderate to severe COPD who are not adequately treated by a combination of an inhaled corticosteroid (ICS) and a long-acting β_2-agonist (LABA) or a combination of a LABA and a long acting muscarinic antagonist. **Dosage and administration:** One inhalation once daily at the same time each day. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients (lactose monohydrate & magnesium stearate). **Precautions:** Paradoxical bronchospasm, unstable or life-threatening cardiovascular disease or heart rhythm abnormalities, convulsive disorders or thyrotoxicosis, pulmonary tuberculosis or patients with chronic or untreated infections, narrow-angle glaucoma, urinary retention, hypokalaemia, patients predisposed to low levels of serum potassium, diabetes mellitus. In patients with moderate to severe hepatic impairment patients should be monitored for systemic corticosteroid-related adverse reactions. Eye symptoms such as blurred vision may be due to underlying serious conditions such as cataract, glaucoma or central serous chorioretinopathy (CSCR); consider referral to ophthalmologist. Increased incidence of pneumonia has been observed in patients with COPD receiving inhaled corticosteroids. *Risk factors for pneumonia include:* current smokers, old age, patients with a history of prior pneumonia, patients with a low body mass index and severe COPD. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take Trelegy. *Acute symptoms:* Not for acute symptoms, use short-acting inhaled bronchodilator. Warn patients to seek medical advice if short-acting inhaled bronchodilator use increases. Therapy should not be abruptly stopped without physician supervision due to risk of symptom recurrence. *Systemic effects:* Systemic effects of ICSs may occur, particularly at high doses for long periods, but much less likely than with oral corticosteroids. **Interactions with other medicinal products:** Caution should be exercised with concurrent use of β-blockers. Caution is advised when co-administering with strong CYP3A4 inhibitors (e.g. ketoconazole, ritonavir, cobicistat-containing products), hypokalaemic treatments or non-potassium-sparing diuretics. Co-administration with other long-acting muscarinic antagonists or long acting β_2-adrenergic agonists is not recommended. **Pregnancy and breast-feeding:** Experience limited. Balance risks against benefits. **Side effects:** *Common (≥1/100 to <1/10):* pneumonia, upper respiratory tract infection, bronchitis, pharyngitis, rhinitis, sinusitis, influenza, nasopharyngitis, candidiasis of mouth and throat, urinary tract infection, headache, cough, oropharyngeal pain, arthralgia, back pain. *Uncommon (≥1/1,000 to <1/100):* viral respiratory tract infection, supraventricular tachyarrhythmia, tachycardia, atrial fibrillation, dysphonia, dry mouth, fractures; *Not known (cannot be estimated from the available data):* vision blurred. **Marketing Authorisation (MA) Holder:** GlaxoSmithKline Trading Services Limited, Curabinny, Co. Cork, Ireland. **MA No. [EU/1/17/1236/002]. Legal category:** POM B. **Last date of revision:** June 2019. **Code:** PI-2093. 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.

A full list of adverse reactions can be found in the Summary of Product Characteristics.
In common with other corticosteroid-containing medicines, there is an increased risk of pneumonia in patients with COPD treated with TRELEGY Ellipta.[1] Trelegy Ellipta should be used with caution in patients with unstable life-threatening cardiovascular disease.[1]

Please see www.trelegy.ie to find out more

TRELEGY Ellipta was developed in collaboration with INNOVIVA

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UNAUTHORISED MEDICATIONS

Unauthorised medicines marketed as herbal sleep aid products

The Health Products Regulatory Authority (HPRA) is advising the public that U-Dream Full Night and U-Dream Lite, marketed as herbal sleep aid products, have been found to contain an undeclared substance that is similar to zopiclone, a prescription-only medicine. It is known that zopiclone can cause drowsiness, dizziness and abnormal sleep behaviours. The HPRA is advising anyone who purchased and is currently taking either product to consult with their doctor immediately. Anyone who may have recently stopped taking the product and who has health concerns should also seek medical advice, according to the Authority. Although these products are not authorised for sale in Ireland, the HPRA has become aware that packs of U-Dream Full Night and U-Dream Lite have been sold to consumers in Ireland from retail outlets, including health stores. It is also possible that some consumers may have purchased either of these products online. As part of an ongoing investigation, the HPRA is identifying these stores and any online outlets to ensure that packs are removed from sale.

The HPRA states that U-Dream Full Night and U-Dream Lite could cause adverse reactions, including if stopped abruptly. Therefore, it is recommended that anyone taking either product should consult with their doctor immediately. Anyone taking either of these products is also advised not to drive, operate machinery or perform other activities requiring mental alertness until they have safely stopped taking this product following consultation with their doctor. For those who have purchased either of the products, it is advised that they return it to the store from which it was purchased, or, in the case of an online purchase, contact the website.

The HPRA's investigation is ongoing and, as necessary, updates will be published. The testing of these products was carried out in Canada and the United States and the products have been recalled from those markets. If any of your patients have experienced an adverse reaction as a result of taking either of these products, a report can be made to the HPRA.

Contact details and online and downloadable report forms are available at ***www.hpra.ie***. Any other information on the availability of the product in Ireland should be reported to the HPRA on ***01 676 4971*** or ***reportacase@hpra.ie***.

ALZHEIMER'S DISEASE

Antipsychotic drugs associated with increased risk of head and brain injuries in Alzheimer's disease

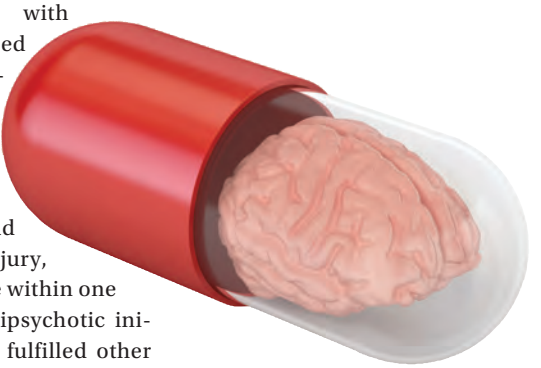
The use of antipsychotics is associated with increased risks of head and brain injuries among persons with Alzheimer's disease, according to a recent study. The risk increase was highest at the initiation of antipsychotic use. The results were published recently in the *Journal of the American Geriatrics Society* (*JAGS*).

"As adverse effects, antipsychotics may cause sedation, orthostatic hypotension and arrhythmias, which all may lead to falls. Among older persons, falls are the most common reason for traumatic brain injuries," researcher Dr Vesa Tapiainen from the University of Eastern Finland explained as a possible mechanism for the association.

Community-dwellers with Alzheimer's disease who used antipsychotics had a 29 per cent higher risk of head injuries and a 22 per cent higher risk of traumatic brain injuries when compared to community-dwellers with Alzheimer's disease who did not use antipsychotics.

Among persons with Alzheimer's disease, antipsychotics are commonly used to treat neuropsychiatric symptoms of Alzheimer's disease. According to clinical care guidelines, treating the cause of these symptoms, such as pain, is the first-line option and secondly, non-pharmacological treatments should be prioritised. The use of antipsychotics should be restricted to the most severe symptoms (such as severe aggression, agitation or psychosis). Following care guidelines and carefully considering benefits and risks of adverse effects and events could possibly lower the incidence of head injuries and traumatic brain injuries.

The study was conducted by the University of Eastern Finland using the nationwide register-based MEDALZ cohort, which includes Finnish community-dwellers with a newly-diagnosed Alzheimer's disease from 2005-2011 (70,719 persons). Persons were excluded if they had a prior head injury, antipsychotic use within one year prior to antipsychotic initiation or if they fulfilled other exclusion criteria of this study. The final study population was 21,795 persons who initiated antipsychotic use and 21,795 persons who did not use antipsychotics. Medicine use was extracted from the Finnish Prescription Register. Chronic diseases, use of other medications and socioeconomic position were taken into account.



COMBINING POWER AND CONFIDENCE

AGAINST LDL-C IN THE TREATMENT OF HYPERCHOLESTEROLAEMIA

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SUVEZEN®

Rosuvastatin + Ezetimibe

Rosuvastatin + Ezetimibe
10 mg/10 mg

Rosuvastatin + Ezetimibe
20 mg/10 mg

Rosuvastatin + Ezetimibe
40 mg/10 mg

New single-pill combination of rosuvastatin and ezetimibe available in 3 doses*

NOW AVAILABLE

Suvezen is indicated for substitution therapy in adult patients who are adequately controlled with rosuvastatin and ezetimibe given concurrently at the same dose level as in the fixed combination, but as separate products, as adjunct to diet for treatment of primary hypercholesterolaemia (heterozygous familial and non-familial) or homozygous familial hypercholesterolaemia[1]

Prescribing Information: Suvezen (rosuvastatin/ ezetimibe) film-coated tablets Please refer to the Summary of Product Characteristics (SPC) for full prescribing details. **Presentations:** Suvezen 10mg/10mg, 20mg/10mg and 40mg/10mg: Each film-coated tablet contains 10mg; 20mg or 40mg of rosuvastatin (as rosuvastatin calcium) respectively, and 10mg ezetimibe. **Indication:** Suvezen is indicated for substitution therapy in adult patients who are adequately controlled with rosuvastatin and ezetimibe given concurrently at the same dose level as in the fixed combination, but as separate products, as adjunct to diet for treatment of primary hypercholesterolaemia (heterozygous familial and non-familial) or homozygous familial hypercholesterolaemia. **Dosage and Administration:** The patient should be on and continue, an appropriate lipid-lowering diet, during treatment with Suvezen. Suvezen is not suitable for initial therapy. Treatment initiation or dose adjustment, if necessary, should only be done with the monocomponents and after setting the appropriate doses the switch to the fixed dose combination of the appropriate strength is possible. Patient should use the strength corresponding to their previous treatment. The recommended dose is one Suvezen tablet daily. To be administered at any time of the day, with or without food. The tablet should be swallowed whole with a drink of water. If co-administered with bile acid sequestrant (BAS), administration of Suvezen should occur either ≥2 hours before or ≥4 hours after administration of a BAS. **Special populations:** ***Paediatric (<18 years):*** Safety and efficacy has not been established. ***Elderly*** (>70 years): Starting dose of 5 mg rosuvastatin is recommended. The combination is not suitable for initial therapy. ***Hepatic impairment: Mild:*** No dosage adjustment is required. ***Moderate/Severe:*** Treatment with Suvezen is not recommended. ***Renal impairment: Mild:*** No dose adjustment is necessary. ***Moderate (creatinine clearance <60 ml/min):*** The recommended start dose is rosuvastatin 5mg. Race: The recommended start dose is rosuvastatin 5 mg for patients of Asian ancestry due to increased systemic exposure. The fixed dose combination is not suitable for initial therapy. Monocomponent preparations should be used to start the treatment or to modify the dose. Suvezen 40 mg/10 mg tablets are contraindicated in these patients. ***Genetic polymorphisms:*** In patients who are known to have specific types of genetic polymorphisms that can lead to increased rosuvastatin exposure, a lower daily dose of Suvezen is recommended. ***Dosage in patients with pre-disposing factors to myopathy:*** The recommended start dose is rosuvastatin 5mg in patients with predisposing factors to myopathy. Suvezen 40 mg/10 mg tablets are contraindicated in some of these patients. ***Concomitant therapy:*** The risk of myopathy (including rhabdomyolysis) is increased when Suvezen is administered concomitantly with certain medicinal products that may increase the plasma concentration of rosuvastatin (e.g. ciclosporin and certain protease inhibitors including combinations of ritonavir with atazanavir, lopinavir, and/or tipranavir). Whenever possible, alternative medications should be considered, and, if necessary, consider temporarily discontinuing Suvezen therapy. In situations where coadministration of these medicinal products with Suvezen is unavoidable, the benefit and the risk of concurrent treatment and rosuvastatin dosing adjustments should be carefully considered. **Contraindications:** Hypersensitivity to the active substances or excipients. Pregnancy, breast-feeding and in women of childbearing potential not using appropriate contraceptive measures. Active liver disease or any serum transaminase elevations which are unexplained, persistent or exceeding 3x the upper limit of normal (ULN). Severe renal impairment (creatinine clearance <30 ml/min); myopathy or receiving concomitant ciclosporin. 40mg/10mg dose contraindicated in patients with predisposing factors for myopathy/rhabdomyolysis; such factors include: Moderate renal impairment (creatinine clearance <60 ml/min), hypothyroidism, personal or family history of hereditary muscular disorders, previous history of muscular toxicity with another HMG-CoA reductase inhibitor or fibrate, alcohol abuse, situations where an increase in plasma levels of rosuvastatin may occur, Asian patients, concomitant use of fibrates. **Precautions and Warnings:** ***Skeletal muscle effects:*** have been reported in rosuvastatin-treated patients with all doses and in particular with doses >20 mg. As with other HMG-CoA reductase inhibitors, reporting rate for rhabdomyolysis is associated with use at doses >40mg. Post-marketing experience with ezetimibe, cases of myopathy and rhabdomyolysis have been reported. If myopathy is suspected based on muscle symptoms or is confirmed by a creatine phosphokinase (CPK) level, Suvezen and any of these other agents that the patient is taking concomitantly should be immediately discontinued. All patients starting therapy with Suvezen should be advised of the risk of myopathy and told to report promptly any unexplained muscle pain, tenderness or weakness, particularly if associated with malaise or fever. ***Creatine kinase (CK) measurement:*** CK should not be measured following strenuous exercise or in the presence of a plausible alternative cause of CK increase. If CK levels are significantly elevated at baseline (>5xULN) a confirmatory test should be carried out within 5-7 days. If the repeat test confirms a baseline CK >5xULN, treatment should not be started. ***Patients with pre-disposing factors for myopathy/rhabdomyolysis:*** Caution should be exercised in these patients. Risk: benefit of treatment should be considered and clinical monitoring is recommended. CK levels should be measured in these patients. Therapy should be discontinued if CK levels are markedly elevated (>5xULN) or if muscular symptoms are severe and cause daily discomfort. If symptoms resolve and CK levels return to normal, then consideration should be given to re-introducing treatment at the lowest dose. ***Immune-mediated necrotising myopathy (IMNM):*** Clinically characterised by proximal muscle weakness and elevated serum CK, has been reported very rarely during or after treatment with statins, including rosuvastatin, despite discontinuation of statin treatment. In clinical trials an increase in the incidence of myositis and myopathy has been seen in patients receiving other HMG-CoA reductase inhibitors together with fibric acid derivatives. Suvezen should not be used in any patient with an acute, serious condition suggestive of myopathy or predisposing to the development of renal failure secondary to rhabdomyolysis (e.g. sepsis, hypotension, major surgery, trauma, severe metabolic, endocrine and electrolyte disorders; or uncontrolled seizures). ***Liver effects:*** In controlled coadministration trials in patients receiving ezetimibe with statin, consecutive transaminase elevations ≥3×ULN have been observed. It is recommended that liver function tests be carried out prior to, and 3 months following, the initiation of treatment. Rosuvastatin should be discontinued or the dose reduced if the level of serum transaminases is ≥3xULN. The reporting rate for serious events is higher at the 40mg dose. In patients with secondary hypercholesterolaemia caused by hypothyroidism or nephrotic syndrome, the underlying disease should be treated prior to initiating therapy with rosuvastatin. ***Liver disease and alcohol:*** As with other HMG-CoA reductase inhibitors, rosuvastatin should be used with caution in patients who consume excessive quantities of alcohol and/or have a history of liver disease. ***Renal effects:*** Proteinuria has been observed in patients treated with higher doses of rosuvastatin and was transient or intermittent in most cases. Proteinuria has not been shown to be predictive of acute or progressive renal disease. An assessment of renal function should be considered during routine follow-up of patients treated with a dose of 40 mg. ***Diabetes mellitus:*** Some evidence suggests that statins raise blood glucose and in some patients, at high risk of future diabetes, may produce a level of hyperglycaemia where formal diabetes care is appropriate. This risk, however, is outweighed by the reduction in vascular risk with statins and therefore should not be a reason for stopping statin treatment. Patients at risk (fasting glucose 5.6 to 6.9 mmol/l, BMI >30 kg/m2, raised triglycerides, hypertension) should be monitored both clinically and biochemically according to national guidelines. ***Interstitial lung disease:*** Exceptional cases have been reported with some statins, especially with long term therapy. Presenting features can include dyspnoea, non-productive cough and deterioration in general health (fatigue, weight loss and fever). If it is suspected, statin therapy should be discontinued. ***Protease inhibitors:*** Increased systemic exposure to rosuvastatin has been observed in subjects receiving rosuvastatin concomitantly with various protease inhibitors in combination with ritonavir. Consideration should be given both to the benefit of lipid lowering by use of Suvezen in HIV patients receiving protease inhibitors and the potential for increased rosuvastatin plasma concentrations when initiating and up titrating rosuvastatin doses in patients treated with protease inhibitors. The concomitant use with certain protease inhibitors is not recommended unless the dose of rosuvastatin is adjusted. ***Fibrates:*** The safety and efficacy of ezetimibe administered with fibrates have not been established. If cholelithiasis is suspected in a patient receiving Suvezen and fenofibrate, gallbladder investigations are indicated and therapy should be discontinued. ***Anticoagulants:*** If Suvezen is added to warfarin, another coumarin anticoagulant, or fluindione, the International Normalised Ratio (INR) should be appropriately monitored. ***Fusidic acid:*** Suvezen must not be co-administered with systemic formulations of fusidic acid or within 7 days of stopping fusidic acid treatment. In patients where the use of systemic fusidic acid is considered essential, statin treatment should be discontinued throughout the duration of fusidic acid treatment. There have been reports of rhabdomyolysis (including some fatalities) in patients receiving fusidic acid and statins in combination. The patient should be advised to seek medical advice immediately if they experience any symptoms of muscle weakness, pain or tenderness. Statin therapy may be reintroduced seven days after the last dose of fusidic acid. In exceptional circumstances, where prolonged systemic fusidic acid is needed, e.g., for the treatment of severe infections, the need for co-administration of Suvezen and fusidic acid should only be considered on a case by case basis and under close medical supervision. ***Suvezen contains lactose monohydrate and sodium:*** Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine. This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'. ***Pregnancy, Breastfeeding and Fertility:*** No clinical data are available on the use of ezetimibe during pregnancy. Potential risk from inhibition of HMG-CoA reductase outweighs the advantage of treatment during pregnancy. If a patient becomes pregnant during use of Suvezen, treatment should be discontinued immediately. Animal studies have shown excretion of medicinal product through breast milk. However, there are no data in humans. No clinical trial data on the effects of fertility in humans. **Interactions:** Contraindicated combinations: Ciclosporin. Not-recommended combinations: Fibrates and other lipid-lowering products, protease inhibitors, transporter protein inhibitors and fusidic acid. Other possible interactions: Cytochrome P450 enzymes, antacids, colestyramine, anticoagulants, Vitamin K antagonists, erythromycin, Oral contraceptive/hormone replacement therapy. When coadministering rosuvastatin with other medicinal products known to increase exposure to rosuvastatin, doses should be adjusted (see SPC for full details). The maximum daily dose should be adjusted so that the expected rosuvastatin exposure would not likely exceed that of a 40 mg daily dose of rosuvastatin taken without interacting medicinal products. **Adverse Reactions:** Adverse drug reactions previously reported with one of the individual components (ezetimibe or rosuvastatin) may be potential undesirable effects with Suvezen. ***Common (≥1/100 to <1/10):*** diabetes mellitus, headache, dizziness, constipation, nausea, abdominal pain, diarrhoea, flatulence, myalgia, ALT and/or AST increased, asthenia and fatigue. ***Uncommon (≥1/1,000 to <1/100):*** decreased appetite, paraesthesia, hot flush, hypertension, cough, dyspepsia, gastroesophageal reflux disease, nausea, dry mouth, gastritis, pruritus, rash, urticaria, arthralgia, muscle spasms, neck pain, back pain, muscular weakness, pain in extremity, ALT and/or AST increased, blood CPK increased, gamma-glutamyltransferase increased, liver function test abnormal, chest pain, pain, asthenia, oedema peripheral. ***Rare (≥1/10,000 to <1/1,000):*** thrombocytopenia, hypersensitivity reactions including angioedema, pancreatitis, increased hepatic transaminases, myopathy (including myositis), rhabdomyolysis, lupus-like syndrome and muscle rupture. ***Very rare (<1/10,000):*** polyneuropathy, memory loss, jaundice, hepatitis, arthralgia, haematuria, gynaecomastia. ***Not known:*** thrombocytopenia, hypersensitivity (including rash, urticaria, anaphylaxis and angioedema), depression, peripheral neuropathy, sleep disturbances (including insomnia and nightmares), dizziness, paraesthesia, cough, dyspnoea, diarrhoea, pancreatitis, constipation, hepatitis, cholelithiasis, cholecystitis, Stevens Johnson syndrome, erythema multiforme, immune-mediated necrotising myopathy, tendon disorders (sometimes complicated by rupture), myalgia, myopathy/rhabdomyolysis, oedema, asthenia. **Legal Category:** POM. **Marketing Authorisation Numbers:** 10mg/10mg: PA0540/193/001; 20mg/10mg: PA0540/193/002; 40mg/10mg: PA0540/193/003. **Marketing Authorisation Holder:** Sanofi-Aventis Ireland Ltd. T/A SANOFI, Citywest Business Campus, Dublin 24, Ireland. **Further information is available from:** Sanofi, 18 Riverwalk, Citywest Business Campus, Dublin 24 or contact IEmedinfo@sanofi.com Tel.: (01) 4035600. **Date of Preparation:** December 2019.

Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie; email: medsafety@hpra.ie Adverse events should also be reported to Sanofi Ireland Ltd. Tel: 01 403 5600. Alternatively, send via email to IEPharmacovigilance@sanofi.com

*** Suvezen is available in 3 doses in Ireland. Suvezen 10mg/10mg, 20mg/10mg and 40mg/10mg: Each film-coated tablet contains 10mg; 20mg or 40mg of rosuvastatin (as rosuvastatin calcium) respectively, and 10mg ezetimibe.**

Reference: 1. Suvezen Summary of Product Characteristics

LDL-C: Low-density lipoprotein Cholesterol

SAIE.ZEN.19.09.0201p – January 2020

SANOFI

ANTIMICROBIAL RESISTANCE

Cancer drug effective against multi-resistant bacteria

Antibiotic-resistant bacteria are increasingly the source of deadly infections. A team of scientists from the Technical University of Munich (TUM) and the Helmholtz Centre for Infection Research (HZI) in Braunschweig, Germany, have now modified an approved cancer drug to develop an active agent against multidrug-resistant pathogens. The methicillin-resistant *Staphylococcus aureus* (MRSA) is the source of severe and persistent infections. Some strains are even resistant to multiple antibiotics. There is consequently an urgent need for new drugs effective against MRSA infections.

"The industrial development of new antibiotics is stalling and not keeping pace with the spread of antibiotic resistance. We urgently need innovative approaches to meet the need for new infection therapies that do not lead directly to renewed resistance," said Prof Eva Medina, Director of the HZI Infection Immunology Research Group.

New antibiotic development strategies

One promising strategy is to test the potential effect of approved drugs on bacteria. "Our focus was on a class of human proteins, called kinases, which have many inhibitors to begin with," explained study leader Prof Stephan Sieber, Professor of Organic Chemistry at TUM. In this vein, the researchers chemically modified the active ingredient sorafenib, a cancer drug that is effective against MRSA, to achieve a stronger antibiotic effect. This led to the development of PK150, a molecule 10 times more effective against MRSA than the original substance.

Multiple attacks prevent the development of resistance

The potent new agent targets various unconventional structures within the bacteria. Two targets were investigated in greater detail: For one, PK150 inhibits an essential protein involved in bacterial energy metabolism. For another, it acts on the cell wall.

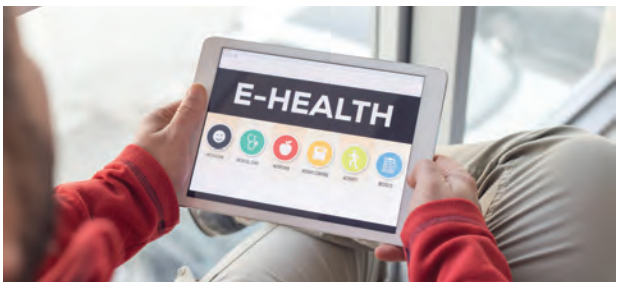
In contrast to previously-known antibiotics such as penicillin and methicillin, which interfere with cell wall formation, PK150 acts indirectly. It knocks the protein production in bacteria off-kilter. As a result, the bacteria release more proteins that control the cell wall thickness to the outside, causing the cells to burst. In mice, PK150 has proven to be effective against MRSA in a variety of tissues. While *staphylococci* rapidly develop resistance to other antibiotics, the researchers did not observe the development of any resistance to PK150.

Effectiveness against biofilms and persisters

Ms Eva Medina and Dr Katharina Rox, a pharmacologist from the Department of Chemical Biology at HZI, showed that PK150 has favourable pharmacological properties. It can be administered as a tablet, for example, and remains stable in the body for several hours. "As a result of the chemical changes to the molecule, PK150 no longer binds to human kinases, but acts very specifically against bacterial targets," said Prof Sieber. And PK 150 has another benefit: "MRSA infections are very often chronic, as the bacteria can become dormant. PK150 even kills these, as well as germs protected in biofilms," said Prof Dietmar Pieper, head of the HZI research group 'Microbial Interactions and Processes'.

In the context of the aBACTER project, Prof Sieber's team is now further optimising PK150 to enter the clinical development phase. The study was titled 'Repurposing human kinase inhibitors to create an antibiotic active against drug-resistant *Staphylococcus aureus*, persisters and biofilms'.

E-HEALTH



Concerns about structure of e-health in HSE

The division of HSE e-health responsibility between the offices of the Chief Information Officer (CIO) and the Director of Digital Transformation and Open Innovation risks the creation of "silo thinking" and "the environment for a 'turf war' to emerge", a former HSE CIO has stated.

Mr Richard Corbridge, who was the HSE's first CIO, left the position in 2017 after three years to pursue opportunities in the UK. He urged a review to ensure a "single leader of digital in post for the whole healthcare system".

Mr Corbridge, who speaks positively about his experience as CIO, also considers that the HSE's business case for a national electronic health record (EHR) "has not been delivered and therefore is now out of date". The business case was developed when Mr Corbridge was CIO.

The role of HSE Director of Digital Transformation and Open Innovation was created last year and is filled by former HSE CIO Mr Martin Curley. The interim HSE CIO is Mr Fran Thompson.

A HSE spokesperson said: "The Office of the Chief Information Officer (OoCIO) is committed to realising the e-health Ireland strategy by ensuring that information and technology support healthcare efficiently and effectively throughout the whole health service."

Asked in what ways the OoCIO and Mr Curley's office work together, the spokesperson said "they are broadly complementary but in very different areas".

As of November 2019, there were 320 staff (WTE) working in the OoCIO and its budget for last year was €49.2 million. This year, the budget has increased to €51.3 million.

Asked about staffing in Mr Curley's office, the spokesperson said: "[Mr] Curley is leading out on digital transformation agenda items, including the initiation of a Digital Masters Programme, and is currently supported by two staff members".

In 2016, the HSE finalised an EHR business case, which was submitted to the Department of Health.

"The Department has not approved the business [case] in its current form because of concerns raised regarding the scope, cost and proposed procurement approach," said a Department spokesperson.

"The HSE have been tasked with revising the business case to address these issues and we have jointly agreed a way forward for sites affected by delays associated with revising the business case."

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One Dose for ANC Recovery

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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Haematology

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

BLOOD SUPPLIES

'Influencers' could boost D'Olier Street blood donations

Use of "influencers" was recommended to the Irish Blood Transfusion Service (IBTS) to help boost donations at its clinic on D'Olier St, due to concerns it was not attracting enough donations. According to a report to the IBTS board by CEO Mr Andrew Kelly, the D'Olier St clinic does not deliver sufficient donations "despite the very significant footfall on that street and Westmoreland St". He emphasised "we need to get more donations from the biggest population centre in Ireland".

Last summer, postgraduate students from Trinity College Dublin conducted research into increasing donations at the clinic. In his report to the board in September, Mr Kelly stated these recommendations "centred primarily on social media and the use of influencers, more targeted campaigns and ways of streamlining the process rather than how we could get more donors into D'Olier St. They did not look at whether D'Olier St was the correct venue for Dublin or should we be elsewhere." The report was obtained under Freedom of Information law. An IBTS spokesperson said it had reviewed the recommendations in question.

"We have a stronger presence on social media and have a dedicated resource managing the appointments in D'Olier St."

Asked if the IBTS considered opening the clinic on Saturdays, the spokesperson said it had surveyed donors in the past and "the overall response was that it is a day for family activities and catching up on weekly jobs".

"We will continue to work at improving the donations collected in D'Olier St. The 2019 target for collections in D'Olier St was 14,700."

REGULATION

PSI investigating statutory complaint on Epilim supply

A statutory complaint has been made to the Pharmaceutical Society of Ireland (PSI) in relation to the supply of sodium valproate (Epilim) to a patient. Epilim is licensed in Ireland to treat epilepsy and bipolar disorder. If a woman becomes pregnant while taking the drug, her baby is at risk of serious birth defects and developmental disorders.

Two "matters" have been brought to the PSI's attention in regard to the supply of Epilim to patients since March 2019.

"One of these was raised as a concern and the PSI is seeking observations from the relevant pharmacy on the matter," a spokesperson said.

"The other was raised as a statutory complaint. The latter is still in deliberative process (which is confidential) and I am unable to provide any further details on it."

In March 2019, the PSI said it had received 13 "concerns" in relation to Epilim since April 2018. The information it received "indicated that supplies of valproate medicines have been made without the required alerts, educational material or counselling by pharmacists."

At the time, the spokesperson said it had followed-up on these concerns where specific information was provided. During 2019, a reminder to pharmacists about the appropriate supply and counselling of patients receiving valproate was included in a PSI newsletter.

"The PSI is the appropriate body to which any person may provide information or make a complaint in relation to their concern about how they have been treated in a pharmacy and about a pharmacist's care, behaviour or practice. And the PSI will take the appropriate regulatory action," according to its spokesperson.

In recent years, the Organisation for Anticonvulsant Syndrome (OACS) Ireland has highlighted numerous instances of patients receiving 'Epilim in a bag' without any warning materials.

PHARMACEUTICAL FUNDING

Pharma pays over €8 million to hospitals, clinical societies, etc

Healthcare organisations, including hospitals, were provided with over €8 million in funding by the pharmaceutical industry in 2018, according to figures.

The payments are listed on the pharmaceutical company pages within the transfer of value (ToV) register, which was established by the Irish Pharmaceutical Healthcare Association (IPHA).

The organisations include public hospitals, clinical societies, membership colleges and faculties, and hospital foundations.

Higher-end payments to hospitals across the 44 company pages on the ToV register included €74,090 from Gilead and €63,229 from Janssen to the Mater Misericordiae University Hospital (MMUH), Dublin; €93,314 from Sanofi to the Tallaght University Hospital (TUH) cardiology department and €64,000 to TUH from Takeda; and €58,741 from Daiichi Sankyo and €85,686 from Novartis to Beaumont Hospital, Dublin.

A TUH spokesperson said: "With regard to the sums that you referenced, TUH received €93,314 from Sanofi into the TUH bank account. This project was supported by the hospital and the cardiology department, led by Prof Vincent Maher. The funding was to support the establishment of the Familial Hypercholesterolaemia (FH) National Network. All of the funds were used to support medical hours and nursing hours to carry out the research.

"The €64,000 from Takeda was received by a research account with an address at TUH. TUH is named as the healthcare organisation with an address at TUH. The hospital only has governance over funds which are transferred into the hospital's bank account so cannot comment."

A spokesperson for MMUH said the cited payments "are disclosure of payments made to individuals for research and development, donations and grants (including medical education and unrestricted educational grants), consultancy fees, registration fees or travel costs to attend medical conferences. These payments may have been made to an individual, or a service, within the Mater Misericordiae University Hospital."

Nappy Rash?

Time to recommend Caldesene.

Caldesene prevents and treats nappy rash.

TENDER CARE AT *Every Change*

Caldesene®

For topical use only. Cleanse and dry the affected area before applying. A copy of the summary of product characteristics is available upon request. The active ingredient in Caldesene Medicated Powder is Calcium Undecylenate 10% w/w, 20g, 55g, 100g pack size. For supply through general sale. PA 126/152/1 PA Holder: Clonmel Healthcare Ltd., Waterford Road, Clonmel, Co. Tipperary. Date Prepared: October 2019. 2019/ADV/CAL/112H

CLONMEL HEALTHCARE
STADA GROUP

ANALGESIA

Treatment of pain a challenge in Alzheimer's disease

Finding the best course of treatment to alleviate pain in people with Alzheimer's disease (AD) is a complex and multifaceted issue. One recent contribution to increasing the understanding of the bigger picture around AD, pain and painkillers is a PhD thesis by Researcher Mr Aleksi Hamina, MSc (Pharm) at the University of Eastern Finland. Using data from nationwide healthcare registers, he studied the use of opioids and other painkillers in more than 70,000 people diagnosed with AD in Finland.

"Treating pain in older adults is a massively important issue, which will become even more important in the near future. Analgesics are very widely used, but the evidence on their harms and benefits is not as strong as we would hope for. This goes even more for people with cognitive disorders, such as AD, and there really isn't enough research on how and which analgesics are being used," he added.

Pain is commonly reported by older people, regardless of whether they have Alzheimer's or not. However, AD makes things more complicated, as there are frequent problems in communication and people may express their pain through behavioural and psychiatric symptoms. Indeed, antipsychotics, anti-anxiety drugs and sleep-inducing drugs are often prescribed to people with AD, sometimes in response to their symptoms of pain.

"We found that when people with AD were prescribed an opioid analgesic, use of antipsychotics and benzodiazepine drugs began to decrease. This could indicate better management of their pain, although it is impossible to know for certain from the data we used," Prof Hamina pointed out.

People with Alzheimer's disease are prescribed an opioid almost as frequently as people without AD. There are, however, differences in how opioids are used. Pills are often replaced by opioid skin patches, whose effect can last up to several days. Long-term use is also common in people with AD: Once an opioid is started, more than 30 per cent continue using them for six months or more.

"Long-term use of opioids can be problematic, as adverse effects may occur. In any case, regular assessment of pain and opioid use is important in all patients, those with and without cognitive disorders alike," Prof Hamina said.

It was also found that while opioids may alleviate pain and other possible pain-induced symptoms in people with AD, they also increase the risk of pneumonia by around 30 per cent. Strong opioids such as oxycodone and fentanyl increase the risk most, but an increased risk was also found among those using buprenorphine, tramadol or codeine.

"Opioids weaken the cough reflex and increase sedation, possibly explaining the increased risk of pneumonia," said Prof Hamina. "On one hand, pain should be treated, but on the other hand, all drugs have adverse effects. Non-pharmacological methods should be preferred and also facilitated on a system level. If opioids are used, low initial doses and careful monitoring should follow. Research should focus on investigating the safest and most effective ways of treating pain in individuals with cognitive disorders."

CHILD HEALTH

Physical literacy consensus statement commissioned by Sport Ireland

Sport Ireland has commissioned a consensus statement on "physical literacy" in partnership with Sport Northern Ireland as part of efforts to increase children's physical activity. Ulster University won the contract to undertake the project which is worth €60,000 (excluding VAT), a meeting of Sport Ireland's board heard last year.

Physical literacy can be described as the motivation, confidence, physical competence, knowledge and understanding to value and take responsibility for engagement in physical activities for life.

According to a spokesperson for Sport Ireland, the origins of the project are based in the Government's National Sports Policy 2018-2027, which sets out the public policy framework for the development of sport over the next 10 years.

"The policy recognises that, while the vast majority of younger children are involved in sport to some extent, many are not sufficiently engaged to optimally benefit their health," commented the spokesperson.

"Developing more physically literate cohorts of younger children will require that we provide positive and rewarding experiences for them in sport, physical education and physical activity in the belief that they will be more inclined to either stay 'in the game' or return to sport and physical activity at future stages of their lives."

Sport Ireland said developing strong consensus around physical literacy throughout the sport, physical education and physical activity systems is regarded as a key potential enabler "in our efforts to achieve the desired policy objectives around participation including addressing the significant gradients that represent a key limiting factor in this regard".

In conjunction with Sport Northern Ireland, it has appointed Ulster University to develop an agreed position (a consensus statement) around physical literacy from those involved in developing and delivering sport, physical education and physical activity opportunities for children.

"The expectation is that the consensus statement will be adopted and embraced in a systematic way by all those involved in developing and delivering sport, PE and physical activity for children."

The project is underway and expected to be completed by the end of October 2020.

BLOOD DONATIONS

MSM deferral period was not endorsed by IBTS medical committee

The Irish Blood Transfusion Service (IBTS) introduced a one-year deferral period for blood donations from men who have sex with men (MSM) despite its medical advisory committee (MAC) recommending the establishment of an expert advisory group to deliberate on the deferral duration.

While the MAC found that the lifetime ban on donations from MSM was "disproportionate", it could not reach a consensus on what constituted a safe deferral period for MSM donors, according to correspondence sent to the IBTS board in February 2019 by medical consultants who participated in the decision-making process.

The consultants wrote to the IBTS board about an external review of board effectiveness. This review contained some criticisms of the MAC by board members, including a "sense of frustration with the MSM decision-making process".

The MAC, which met to discuss the MSM donation issue in June 2016, included a number of "highly experienced" consultants, while external experts also presented data, according to the consultants' letter.

Where a committee of such seniority and experience had difficulty reaching consensus on the deferral period, this could not be termed a "failure", they stated.

The letter noted that the IBTS board did not accept the MAC's recommendation on establishing an expert group, "instead deciding to adopt a one-year deferral period for MSM donors, as recommended by the then medical director.

"In an attempt to increase the safety margins of the one-year deferral, a decision was also taken by the board to defer all donors who had an STI in the preceding five years. The data underpinning this was unclear and the decision represented a uniquely restrictive deferral by international standards; this was subsequently rescinded."

The IBTS introduced the one-year deferral for MSM in January 2017. According to its website, international experience had shown that this deferral was "as effective as a lifetime deferral from the point of view of protecting the blood supply against the risk of HIV transmission".

NHS Blood and Transplant introduced a three-month deferral period in late 2017, having adopted 12-month deferral in 2011.

An IBTS spokesperson said its board did not believe an expert advisory panel would provide "any additional value to the decision-making process" above what was already available, following the holding of an international colloquium on the matter and a subsequent report.

A poisoned chalice for the environment

Not enough is being done to prevent pharmaceutical residues contaminating our ecosystem, says the OECD

A recent Organisation for Economic Co-operation and Development (OECD) report warns that too little is being done to prevent pharmaceutical residues seeping into soil, water supplies, fresh-water ecosystems and the food chain, or to assess potential risks.

Pharmaceutical Residues in Freshwater: Hazards and Policy Responses says the vast majority of the roughly 2,000 active ingredients currently used in human and veterinary pharmaceuticals have never been evaluated for environmental risks. Several dozen new active ingredients are typically approved for use each year.

A study cited in the report estimates that 10 per cent of pharmaceuticals have the potential to cause environmental harm. Those of greatest concern include hormones, painkillers and antidepressants. Concern over rising antibiotic content in wastewater fuelling the spread of drug-resistant microbes have been raised at G20 level.

SEWAGE AND LANDFILLS

Pharmaceutical residues can enter the environment during the manufacture, use and disposal of medicines. When humans and animals ingest medicines, between 30 per cent and 90 per cent of the ingredients are excreted as active substances into the sewage system or the environment. Some medicines are thrown away unused, going into landfill, or from bathroom disposal into sewer systems. In the United States, an estimated one-third of the four billion medicines prescribed each year ends up as waste.

Conventional wastewater treatment plants are not designed to remove pharmaceuticals, and water resources are not systematically monitored for residues. High levels of pharmaceutical residues have been found downstream of drug manufacturing plants. Veterinary pharmaceuticals used in farming and aquaculture can enter water bodies directly or via surface run-off without any treatment.

Because pharmaceuticals are designed to interact with living organisms at low doses, even low concentrations can affect freshwater ecosystems. There is growing evidence of negative impacts, with laboratory and field tests showing traces of oral contraceptives causing the feminisation of fish and amphibians, and residues of psychiatric drugs altering fish behaviour.

Unless adequate measures are taken to manage the risks, the situation is set to worsen as the use of pharmaceuticals rises with ageing populations, advances in healthcare, rising meat and fish production, and as emerging countries increasingly administer antibiotics to livestock.

MONITORING

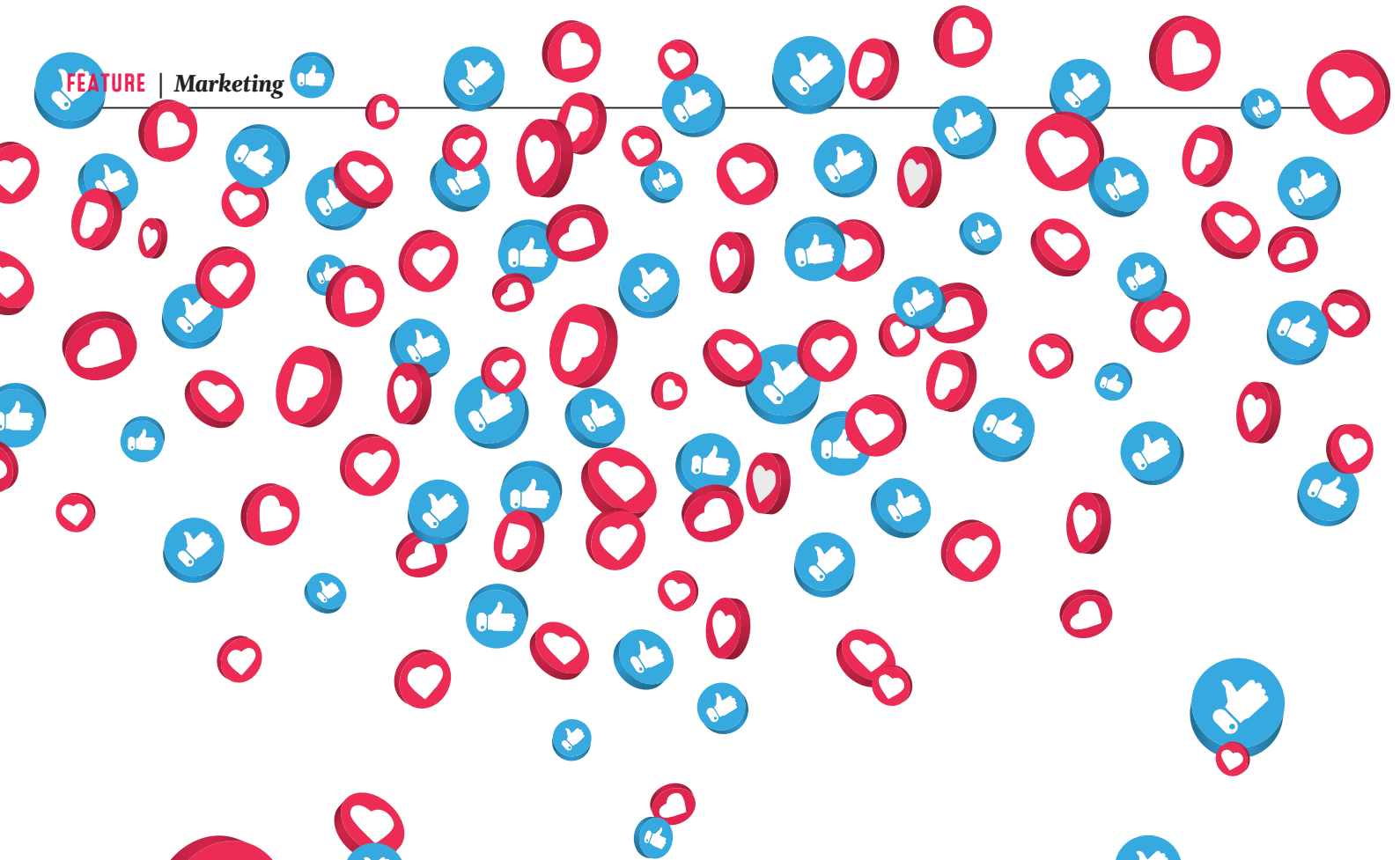
The report says countries should:

- Increase monitoring and reporting of pharmaceutical residues in the environment.
- Consider environmental risks in the authorisation of pharmaceuticals.
- Provide incentives to design pharmaceuticals that do not accumulate in or harm the environment.
- Reduce pharmaceuticals entering the environment, ie, by using public procurement to demand high standards of manufacturers or with 'take-back' systems to return unused or expired medicines for safe disposal.
- Raise awareness among the public, doctors and vets to reduce excessive consumption.
- Upgrade wastewater treatment plants with technology to remove pharmaceuticals.

"This report calls for a better understanding of the effects of pharmaceutical residues in the environment, greater international collaboration and accountability distribution, and policy actions to prevent and remedy emerging concerns," wrote the OECD in the report. "Laboratory and field tests show traces of oral contraceptives causing the feminisation of fish and amphibians, and residues of psychiatric drugs altering fish behaviour.

"Antimicrobial resistance, linked to the overuse of antibiotics, has rapidly escalated into a global health crisis. Unless adequate measures are taken to manage the risks, pharmaceutical residues will increasingly be released into the environment as ageing populations, advances in healthcare, and intensification of meat and fish production spur the demand for pharmaceuticals worldwide.

"The report outlines a collective, life-cycle approach to managing pharmaceuticals in the environment. A policy mix of source-directed, use-orientated and end-of-pipe measures, involving several policy sectors, can help to improve health and protect the environment." ●



Social responsibility

Putting healthcare first to grow your community pharmacy business with social media

As community pharmacists, we have studied subjects such as pharmacology, pharmacognosy and pharmaceutics for years before completing rigorous examinations to ensure our competence as medical experts. It's only after we qualify and begin working that we realise we also have to become experts in less familiar areas such as management, business development and marketing. As we graduate into managerial or ownership roles, these skills become even more important and we realise that these competencies can be as challenging to develop as their clinical counterparts.

One of the newest and most dynamic areas that pharmacists have to contend with is digital marketing and more specifically, social media. Pretty much every pharmacist has realised their community pharmacy needs to have a social media presence but many pharmacists are not sure what to do with it or what purpose it should serve other than promoting special offers. Often times, the responsibility for posting to social media is pushed off to a counter assistant who has zero marketing knowledge or expertise.

As a result, the majority of pharmacies' social media profiles have become littered

Uncontrolled blood sugar can't wait

INVOKANA is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus (T2DM) as an adjunct to diet and exercise.[1]

Improvements in cardiovascular and renal outcomes by Invokana are additional benefits but not licensed indications.

Lower HbA_{1c} levels

In patients with HbA1c higher than 9%, INVOKANA reduces HbA_{1c} by **1.57%** and **1.80%** with its 100 mg and 300 mg doses, respectively, compared with placebo.[2]

Long-term cardiovascular benefits

14% reduction in the risk of cardiovascular death, nonfatal myocardial infarction and nonfatal stroke (3-point MACE) HR 0.86 (95% CI 0.75-0.97), compared with placebo and SoC.[3]

33% reduction in risk of hospitalisation for heart failure HR 0.67 (95% CI 0.52-0.87), compared with placebo and SoC.[3]

Improved renal outcomes

47% relative risk reduction in time to first adjudicated nephropathy event (doubling of serum creatinine, need for renal replacement therapy, and renal death) HR 0.53 (95% CI 0.33-0.84), compared with placebo and SoC.[4]

27% reduction in the progression of albuminuria in patients with normo- or micro-albuminuria HR 0.73 (95% CI 0.67-0.79), compared with placebo and SoC.[3]

The recommended starting dose of INVOKANA is 100mg once-daily.

SoC; standard of care

Invokana® canagliflozin tablets

Seize the moment to make years of difference

INVOKANA*® (canagliflozin) 100 mg & 300 mg film-coated tablets. PRESCRIBING INFORMATION. Republic of Ireland Please refer to Summary of Product Characteristics (SmPC) before prescribing. INDICATIONS:** The treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise as monotherapy when metformin is considered inappropriate due to intolerance or contraindications, or in addition to other medicinal products for the treatment of diabetes. **DOSAGE & ADMINISTRATION: Adults:** recommended starting dose: 100 mg once daily. In patients tolerating this dose and with eGFR ≥ 60 mL/min/1.73 m^2 needing tighter glycaemic control, dose can be increased to 300 mg once daily. For oral use, swallow whole. Caution increasing dose in patients ≥ 75 years old, with known cardiovascular disease or for whom initial canagliflozin-induced diuresis is a risk. Correct volume depletion prior to initiation. When add-on, consider lower dose of insulin or insulin secretagogue to reduce risk of hypoglycaemia. **Children:** no data available. **Elderly:** consider renal function and risk of volume depletion. **Renal impairment:** not to be initiated with eGFR < 60 mL/min/1.73 m^2. If eGFR falls below this value during treatment, adjust or maintain dose at 100 mg once daily. Discontinue if eGFR persistently < 45 mL/min/1.73 m^2. Not for use in end stage renal disease or patients on dialysis. **Hepatic impairment:** mild or moderate; no dose adjustment. Severe; not studied, not recommended. **CONTRAINDICATIONS:** Hypersensitivity to active substance or any excipient. **SPECIAL WARNINGS & PRECAUTIONS:** Not for use in type 1 diabetes. **Renal impairment:** eGFR < 60 mL/min/1.73 m^2: higher incidence of adverse reactions associated with volume depletion particularly with 300 mg dose; more events of elevated potassium; greater increases in serum creatinine and blood urea nitrogen (BUN); limit dose to 100 mg once daily and discontinue when eGFR < 45 mL/min/1.73 m^2. Not studied in severe renal impairment. Monitor renal function prior to initiation and at least annually. **Volume depletion:** caution in patients for whom a canagliflozin-induced drop in blood pressure is a risk (e.g. known cardiovascular disease, eGFR < 60 mL/min/1.73 m^2, anti-hypertensive therapy with history of hypotension, on diuretics or elderly). Not recommended with loop diuretics or in volume depleted patients. Monitor volume status and serum electrolytes. **Diabetic ketoacidosis (DKA):** rare DKA cases reported, including life-threatening and fatal. Presentation may be atypical (blood glucose <14mmol/l). Consider DKA in event of non-specific symptoms. If DKA is suspected or diagnosed, discontinue ***Invokana treatment immediately. Interrupt treatment in patients who are undergoing major surgical procedures or have acute serious medical illnesses. Monitoring of (preferably blood) ketone levels is recommended in these patients. Consider risk factors for development of DKA before initiating ***Invokana*** treatment. **Elevated haematocrit:** careful monitoring if already elevated. **Genital mycotic infections:** risk in male and female patients, particularly in those with a history of GMI. **Lower limb amputation:** Consider risk factors before initiating. Monitor patients with a higher risk of amputation events. Counsel on routine preventative foot care and adequate hydration. Consider discontinuing ***Invokana*** when events preceding amputation occur (e.g. lower-extremity skin ulcer, infection, osteomyelitis or gangrene). **Urine laboratory assessment:** glucose in urine due to mechanism of action. **Lactose intolerance:** do not use in patients with galactose intolerance, total lactase deficiency or glucose-galactose malabsorption. **Necrotising fasciitis of the perineum (Fournier's gangrene):** post-marketing cases reported with SGLT2 inhibitors. Rare but serious, patients should seek medical attention if experiencing symptoms including pain, tenderness, erythema, genital/perineal swelling, fever, malaise. If Fournier's gangrene suspected, ***Invokana*** should be discontinued, and prompt treatment instituted. **INTERACTIONS: Diuretics:** may increase risk of dehydration and hypotension. **Insulin and insulin secretagogues:** risk of hypoglycaemia; consider lower dose of insulin or insulin secretagogue. **Effects of other medicines on *Invokana*:** Enzyme inducers (e.g. St. John's wort, rifampicin, barbiturates, phenytoin, carbamazepine, ritonavir, efavirenz) may decrease exposure of canagliflozin; monitor glycaemic control. Consider dose increase to 300 mg if administered with UGT enzyme inducer. Cholestyramine may reduce canagliflozin exposure; take canagliflozin at least 1 hour before or 4-6 hours after a bile acid sequestrant. **Effects of *Invokana* on other medicines:** Monitor patients on digoxin, other cardiac glycosides, dabigatran. Inhibition of Breast Cancer Resistance Protein cannot be excluded; possible increased exposure of drugs transported by BCRP (e.g. rosuvastatin and some anti-cancer agents). **PREGNANCY:** No human data. Not recommended. **LACTATION:** Unknown if excreted in human milk. Should not be used during breast-feeding. **SIDE EFFECTS: Very common (≥1/10):** hypoglycaemia in combination with insulin or sulphonylurea, vulvovaginal candidiasis. **Common (≥1/100 to <1/10):** constipation, thirst, nausea, polyuria or pollakiuria, urinary tract infection (including pyelonephritis and urosepsis), balanitis or balanoposthitis, dyslipidemia, haematocrit increased. **Uncommon (<1/100) but potentially serious:** anaphylactic reaction, diabetic ketoacidosis, syncope, hypotension, orthostatic hypotension, urticaria, angioedema, necrotising fasciitis of the perineum (Fournier's gangrene) (frequency not known), bone fracture, renal failure (mainly in the context of volume depletion), lower limb amputations (mainly of the toe and midfoot, incidence rate of 0.63 per 100 subject-years, vs 0.34 for placebo). **Refer to SmPC for details and other side effects. LEGAL CATEGORY:** POM. **PACK SIZES & MARKETING AUTHORISATION NUMBER(S): *Invokana* 100 mg film-coated tablets:** 30 tablets; EU/1/13/884/002. ***Invokana* 300 mg film-coated tablets:** 30 tablets; EU/1/13/884/006. **MARKETING AUTHORISATION HOLDER:** Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse, Belgium. ® INVOKANA is a registered trade mark of Janssen-Cilag International NV and is used under licence. © 2017 Napp Pharmaceuticals Limited. **FURTHER INFORMATION IS AVAILABLE FROM:** Mundipharma Pharmaceuticals Limited, Millbank House, Arkle Road, Sandyford, Dublin 18. For medical information enquiries, please contact medicalinformation@mundipharma.ie **IRE/INV-19401 Date of Preparation** November 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 drugsafetyJNJ@mundipharma-rd.eu or by phone on 01 2063800 (1800 991830 outside office hours).

References: 1. Invokana SmPC www.medicines.ie November 2019. **2.** Wilding JP *et al* J Diabetes Complications 2015; 29;438-44. **3.** Neal B. *et al.* N Engl J Med 2017; 377:644-657. **4.** Perkovic V. *et al* Lancet Diabetes Endocrinol. 2018 Sep;6(9):691-704

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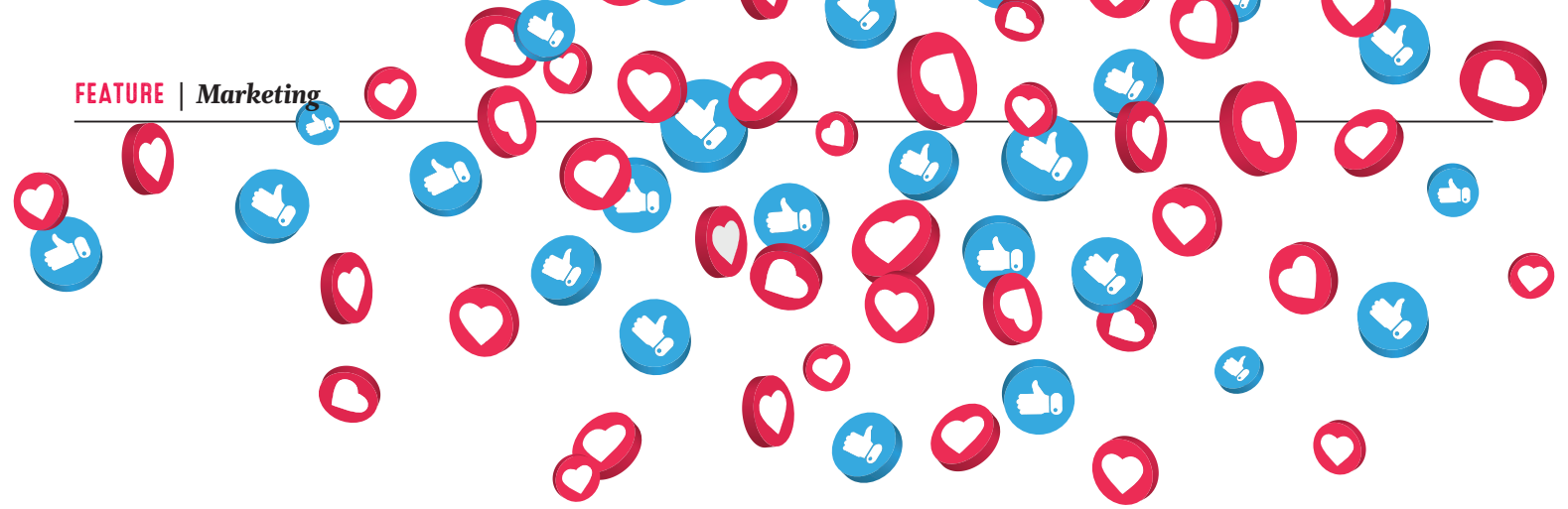

with 'Like & Share' competitions, discounts, deals and special offers. Whether you are aware of it or not, this 'Discount & Deals' approach is negatively impacting not only your business, but also the public's perception of pharmacists.

Putting healthcare first on social media

Did you know that consumer studies show over 80 per cent of people's purchasing decisions are influenced by what they see on social media?

It's clear that there is a real opportunity for any business, including community pharmacies, to utilise social media to increase sales and grow their business. Unfortunately, whether through the lack of time, knowledge or expertise, most pharmacies are missing out on what can be the most significant opportunity to grow your business by adopting an outdated strategy.

At The Social Pharmacist, we advocate that community pharmacies should implement a 'Healthcare-First' strategy on social media. By doing so, you can promote your business in a way that enhances the value of your brand, increases your sales but also distinguishes your pharmacy as the local healthcare experts.

With this 'Healthcare First' approach, you will develop a reputation that allows your pharmacy to become the go-to place in your community for healthcare advice, medications and other clinical services. You will attract new customers that have a greater lifetime value to your pharmacy business than those who were just seeking a once-off discount on promoted products. Your pharmacy will become the default option for those who are starting prescription medication because they know and trust your brand as healthcare experts. You will attract customers who value your expertise rather than those who choose based on price.

Consistent content creation is the key to social media success

Having worked in community pharmacy for seven years, I understand the pressures and time constraints on pharmacy staff and understand how non-critical tasks such as social media and marketing can be overlooked. However, creating a couple of posts on social media whenever you have some spare time will make little, if any, impact on your business.

> *"Did you know that consumer studies show over 80% of people's purchasing decisions are influenced by what they see on social media?*

Without publishing regular content, you will never be able to gain the trust of your local audience and social media will continue to have little influence on your business performance. If you want to use social media to actually grow your pharmacy business, you will need to implement this 'Healthcare-First' strategy in a thorough, consistent manner.

When you implement this strategy consistently, people will begin to know, like and trust your brand as healthcare experts. Your pharmacy will become recognised as a place where they can easily access reliable healthcare advice and expertise. When dealing with people's health and wellness, trust is a key factor in purchasing decisions. As you will know from your existing relationships with customers, while it can take time to develop that relationship, once you gain their trust, they are unlikely to leave your business. While your local competitors are still posting about discounts and deals, you will be leveraging social media to become the only obvious choice that people trust with their healthcare.

Enhancing the public perception of the pharmacist profession

Undoubtedly, more pharmacies could use social media marketing to grow their pharmacy business. However, if this 'Healthcare First' strategy was adopted at a large scale, a by-product of this shift in strategy would be an enhanced public perception of the pharmacist profession.

Social media has revolutionised the way people consume information and it has played a phenomenal role in shaping the opinions and perceptions of the public on a wide range of issues. As we can see from the importance placed on social media in recent referendums and elections both at home and abroad, it is a valuable tool to influence public perceptions.

As a result, I believe that adopting a 'Healthcare-First' strategy will not only increase your pharmacy's revenue, but it will also contribute to enhancing the public's perception of the pharmacy profession in general. If pharmacies across the country shifted from retail-based messaging to one of health promotion, which demonstrates our expertise, this can only reinforce our calls and the public's demand for a broadening of our clinical roles and thereby Government funding.

AUTHOR

Colm Baker started working as a community pharmacist in 2013 and has gone on to become an award-winning digital marketer. He currently assists pharmacies to grow their business with his new pharmacy-specific digital marketing brand 'The Social Pharmacist'.

NEW*

LOOKING FOR A BETTER NIGHT'S SLEEP?

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***New to Nytol range in Ireland.** **Nytol One-A-Night 50 mg Tablets** contains diphenhydramine hydrochloride. A symptomatic aid to the relief of temporary sleep disturbance in adults. **Adults:** One tablet to be taken 20 minutes before going to bed, or as directed by a physician. Do not exceed the maximum dose of one tablet in 24 hours. Elderly patients or patients with liver or kidney problems should consult their doctor before taking this medicine. **Children under 18 years:** Not recommended. The product should not be taken for more than 7 days without consulting a doctor. **Contraindications:** hypersensitivity to the active substance or to any of the excipients, stenosing peptic ulcer, pyloroduodenal obstruction, phaeochromocytoma, known acquired or congenital QT interval prolongation, known risk factors for QT interval prolongation. **Special warnings and precautions:** pregnancy/lactation, renal and hepatic impairment, myasthenia gravis, epilepsy or seizure disorders, narrow-angle glaucoma, prostatic hypertrophy, urinary retention, asthma, bronchitis, COPD. Patients should be advised to promptly report any cardiac symptoms. Do not take for more than 7 consecutive nights without consulting a doctor. Use in the elderly should be avoided. Avoid concomitant use of alcohol or other antihistamine-containing preparations. Do not drive or operate machines. **Interactions:** CNS depressants, MAO inhibitors, anticholinergic drugs (e.g. atropine, tricyclic antidepressants), metoprolol and venlafaxine, CYP2D6 inhibitors, Class Ia and Class III anti-arrhythmics. **Side effects:** thrombocytopenia, hypersensitivity reactions, confusion, paradoxical excitation, sedation, drowsiness, disturbance in attention, unsteadiness, dizziness, convulsions, headache, paraesthesia, dyskinesias, blurred vision, tachycardia, palpitations, thickening of bronchial secretions, dry mouth, gastrointestinal disturbance, muscle twitching, urinary difficulty, urinary retention, fatigue. **Legal classification:** P: PA1186/016/001. **MAH:** Chefaro Ireland DAC. The Sharp Building. Hogan Place. Dublin 2. Ireland. **RRP** (ex. VAT)**:** 20s €7.99. **SPC:** https://www.medicines.ie/medicines/nytol-one-a-night-50-mg-tablets-34889/smpc

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Providing a nationwide

PALLIATIVE MEDICINES INFORMATION SERVICE

***Ms Eimear O'Dwyer**, Chief Pharmacist, Our Lady's Hospice and Care Services,* *outlines the importance of providing an information service dedicated to patients' palliative care needs*

Based at Our Lady's Hospice and Care Services (OLH&CS) in Dublin, the Palliative Medicines Information Service (Palliative Meds Info) is a free information and advice service on medicines in palliative care for all health professionals across the Republic of Ireland, regardless of their level of expertise.

Celebrating its 140th anniversary this year, Our Lady's Hospice and Care Services, Ireland's largest specialist palliative care provider, adopts a holistic approach to end-of-life care, meeting the wide range of needs of both patients and their families.

The Palliative Meds Info service, now in its tenth year, is unique in that it is the only medicines information service in both Ireland and the UK that is dedicated to patients' palliative care needs. The service was established in response to the volume and frequency of ad-hoc calls for information on medicines received by the OLH&CS pharmacy team and enabled them to better facilitate these requests.

Using a broad range of standard and specialist literature resources, combined with practical experience, ensures comprehensive, well-researched, up-to-date responses to the clinical questions received. The service responds to telephone and email enquiries from healthcare professionals caring for patients with life-limiting illnesses and has developed a range of resources available on its website.

Managed by the Chief Pharmacist and a senior pharmacist, the service aims to encourage best practice with medicines in palliative care and to assist health professionals in the community, in hospitals and in hospices nationwide in providing the best care by giving them up-to-date, evidence-based information.

Frequently, the necessary use of drugs beyond their licence presents a challenge, in that readily-available, relevant medicines information may not be easily available. As the Palliative Meds Information Service is provided by specialist pharmacists working day-to-day with patients as part of a multidisciplinary team at the hospice, it provides hospice-based expertise to both specialist and non-specialist practitioners (including GPs and community pharmacists).

The service is not a substitute for effective multidisciplinary teams (ie, community palliative care teams and GPs consulting with their local hospice pharmacist or community pharmacist resource), but can augment the care provided to patients and support healthcare professionals, regardless of the setting.

VALUABLE RESOURCE

In addition to supporting specialists in palliative medicines nationally, Palliative Meds Info aims to also provide a valuable resource to healthcare professionals who infrequently care for palliative care patients and in this way, helps to address regional inequalities in the availability of expertise.

Supporting healthcare professionals in making informed treatment decisions when managing pain and addressing symptom problems contributes to the improved quality-of-life for both the patient and their family.

Since the service was launched in 2009, enquiries have been received from professionals working with patients' care needs in different settings, including hospitals, hospices, community palliative care teams, palliative care specialists, GPs, and community pharmacists throughout the country. The service has built up an extensive database of more than 5,000 enquiry responses. Trends in enquiries help identify topics for which guides are required and these are published as guidance documents on the Palliative Meds Info website.

QUERIES

A wide range of different and patient-specific queries are received and each response is tailored to the patient and their clinical setting. The urgency of each query is discussed with the enquirer so that the service can meet the needs of each patient. If the enquiry is particularly complex, the service will provide initial verbal, informal advice and provide a more detailed written response after reviewing the evidence in greater detail.

An evaluation of enquiries received between March 2010-March 2019 showed that the largest proportion of enquiries, 45.5 per cent, were received from pharmacists in hospital, hospice and community pharmacy practice, who often refer queries from medical and nursing colleagues locally. The second-largest group were nurses, either in hospital, hospice, nursing home or community practice, from whom 35.2 per cent of all enquiries were received. Doctors, including GPs, NCHDs and consultants, of which the largest group was medical consultants, formed 16.4 per cent of those submitting enquiries to the service over the years. Approximately two-thirds of all enquiries came from specialist palliative care professionals, as there is a much greater awareness of the service amongst the palliative care community.

The website provides out-of-hours access to Palliative Meds Info resources, hosting information on symptom management, opioid conversions, non-opioid analgesic options, topical preparations, mouth care, medicines administered by continuous subcutaneous infusions, and practical information on access to medicines used in palliative care in the community. In addition, the service publishes regular newsletter bulletins that are available by email.

Palliative Meds Info operates five days a week with a dedicated phone line and email address for receiving queries. Enquiries can be made by telephone between 9am and 4pm, Monday–Friday, except public holidays. An answering service records a phone message outside of these times.

Tel: +353 (0)1 4912578.
Email: palliativemedsinfo@olh.ie.

Palliative Meds Info is committed to upholding the core values of Our Lady's Hospice and Care Services and to the delivery of integrated palliative care services in the community and other healthcare settings.

To find out more information on the service, visit www.olh.ie/our-services/palliative-care/palliative-meds-info/. To sign up to receive the newsletter bulletins, email palliativemedsinfo@olh.ie.

NEW

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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

Send your comments to **pat@greenx.ie** or by post to
The Editor, Irish Pharmacist, GreenCross Publishing Ltd,
Top Floor, 111 Rathmines Road Lower, Dublin 6, D06K5F6.

Promises, promises

By the time you read this, you may be interrupted by a knock on the door from a local TD pitching for your vote. Like suitors in the throes of passion, we are hearing the usual range of wildly ambitious promises from the politicians sweating for their seats and promising the sun, moon and stars.

There are a number of current issues that are a disgrace to our little island — the homelessness crisis is a scandal and should be treated as an emergency. Likewise, property/rent prices are scandalously high. I'm sure the fact that many members of Dáil Eireann are landlords has nothing whatsoever to do with that.

By 2028, people who want to retire and don't have a private pension will have to wait until age 68 to qualify for a modest income. Sixty-eight! Our ageing population has created a pension time-bomb for Government. Their solution? Keep putting the retirement age up. Instead of looking after older people who have contributed to society their whole lives, the asshats who made this decision are throwing them on the scrapheap. Another disgrace.

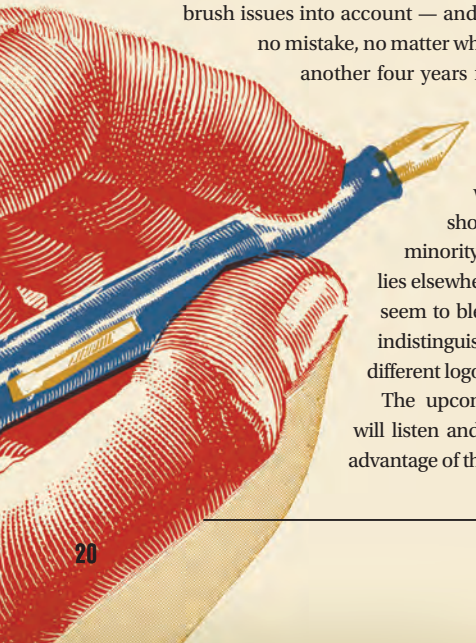
And then of course, there's the health system. As it goes tumbling from one crisis to another, instead of overhauling it and actually looking at inefficiency in health expenditure and top-heavy administration and bureaucracy, the powers-that-be are using the sticking-plaster solution of dumping as much of the burden onto primary care as they can get away with. One must have some sympathy with GPs in this regard. But as a consequence, there is no option but to expand the role of pharmacists to help shore-up a creaking primary care system. Good work has been done to make policy-makers aware of the potential for community pharmacy, but let's not kid ourselves — if there had been no primary care crisis, the policy-makers may not have been so receptive. On the plus side, that means that pharmacy will at some point have the Department of Health over a barrel. And they wanted to impose further fee cuts — you couldn't make it up.

It's not a case of 'where to begin', but rather where to end when it comes to the challenges we face as a nation because of the combination of incompetence and arrogance of politicians past and present — trolleys, waiting lists, the outrageous and unregulated cost of childcare, legalised extortion in the insurance market, a dysfunctional and haphazard public transport system. Each of these is worthy of a column or editorial on its own. The latest figures show there are 6,696 adults and 3,752 children currently homeless in Ireland. The founding fathers of our little nation are turning in their graves and really, we should be getting the yellow vests out on the basis of this and all of the above.

I freely admit my cynicism, but it is borne out of experience. Taking the above broad-brush issues into account — and as you know, there are many more — make no mistake, no matter what we are promised, we are destined to spend another four years fire-fighting. Once the votes have been cast, our political representatives will again fade into the background.

Obviously, there are some Irish politicians who actually give a damn, but bitter experience should have demonstrated to us that this selfless minority are voices in the wilderness. The real power lies elsewhere and increasingly, our main political parties seem to blend into each other to the point of becoming indistinguishable, apart from some window-dressing and different logos.

The upcoming election is one of the few times TDs will listen and take us seriously, temporarily at least. Take advantage of that — when the doorbell rings, give 'em hell.



THAR AN GCUNTAR AS GAEILGE

Bliain nua, Duine nua

Agus muid ag cur fáilte roimh 2020 agus deich mbliana nua, bíonn níos mó béim curtha ar an sean fhocal "bhliain nua, duine nua".

Ach má athraíonn tú, an bhfuil an domhan timpeall ort ag athrú freisin? Ar chóir duit athrú?

Ag deireadh 2019, d'athnaighcógaiseoirí athrú mór toisc go raibh beagnach 50 milliún le gearradh ón tionscal. Ciallaíonn sé sin go gcaillfeadh gach cógaslann thart ar 30,000 euro in aghaidh na bliana ar bharr FEMPI.

Ach, níl sé seo le tarlú anois go dtí go bhfuil toghcháin, má tharlaíonn sé in aon chuir.

Mar chomhlacht gairmiúil, ní mór dúinn a bheith cinnte faoi cé agus cén fáth a vótálfaimid sa chéad áit.

Cad iad na tosca eile a mbeadh tionchar acu orainn sa chéad toghchán eile?

Bhuel, má fhéachann tú ar an gcóras sláinte ina iomláine ní gá dúinn scrúdú a dhéanamh air. Tá sé briste.

Tá an iomarca airgead caite ag an HSE ach tráth ar bith cloisimid faoi mhaoiniú agus faoin HSE sa phianbhreith chéanna cé chomh beag airgid atá acu.

I mo thuairimse, ciallaíonn sé seo go dtugtar airgead do na réimsí mícheart mar thoradh ar pholasaithe nó cinntí bochta eile.

Ag caitheamh an iomarca mar gheall ar easpa foirne.

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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A STAY OF EXECUTION

Was the fee cut reversal made with one eye on the General Election, wonders ***Fintan Moore***

At the tail end of 2019, we collectively dodged a bullet in the shape of a proposed batch of FEMPI cuts. If they had been implemented, the loss in fees to the average pharmacy would have been over €25,000, so it's certain that these cuts would have put the kibosh on some struggling pharmacies. It took a concerted lobbying effort by the IPU and individual pharmacists to get the message through to government TDs that these proposals were unfair and unreasonable, especially at a time when FEMPI was being reversed for other groups. It would be nice to think that the various supportive TDs were all converted to our point of view, but it is equally likely that they just wanted to avoid adding one more pissed-off lobby group to an ever-growing list.

The timing of the issue probably worked in our favour because Fine Gael had just lost four by-elections, which I reckon had the party rattled. They were obviously going to be calculating that if that kind of underperformance continues, then the impending General Election could be a massacre. At the time, the date of the Election had not been announced, but they were aware that it was possible at any time. So it suited them not too badly to kick the pharmacy can down the road pending contract negotiations, etc.

Now that we do have an election in progress, with the real possibility that Fianna Fáil may be forgiven enough by the electorate to end up in power, then we will almost certainly have a new Minister for Health. Whatever happens, Simon Harris will want to shuffle to a safer portfolio anyway. Whether it makes much difference as to who is in power is a moot point, in my view. I think the deferral of the recent proposed cuts was a temporary stay of execution, rather than a full pardon. If we end up with a stable new Government with a working majority and no prospect of an election for a few years, then we could be faced with similar cuts again, and this time the politicians we lobby might be doing the sympathetic shrug of the shoulders as they trot out the well-rehearsed 'love to help you, but… ' line. Time will tell.

APPETITE FOR SUCCESS

It can interesting to hear what people regard as a sign that the country is doing well economically. A recent caller to the Newstalk breakfast show, who was by his own admission a Fine Gael member, wanted to challenge the narrative that large numbers of people were in financial difficulty. He claimed, probably using accurate data, that if you look at various metrics and indices to compare Ireland with other countries, then we are performing well. He stated that we have higher levels of home ownership and better health indices than most other countries, but the statistic that stood out for me was that we have the highest level of spending on food in restaurants and takeaways. He was presenting this as evidence that we are generally earning enough money to have high levels of discretionary income enabling us to eat out or 'order in' more. However, this level of 'success' is actually evidence of a much larger failure.

> *The sad reality also is that many of the families relying on Deliveroo or Dominos for their dinner are in deprived areas*

The clear narrative behind the idea that eating out is a positive sign of financial well-being makes sense up to a point — it's nice that people can go out for a meal every so often. What should be setting alarm bells ringing is the level of takeaway food that people are eating, and the implications that has for health generally and obesity in particular. Rather than being a sign of progress, this is a sign that a whole swathe of the population has lost the ability to select, prepare and cook basic meals for themselves. The reasons for this vary but the end result is clear to see when you look at the statistics for obesity and diabetes.

The sad reality also is that many of the families relying on Deliveroo or Dominos for their dinner are in deprived areas. They are spending money on junk food because they don't know how to do better. There is a myth propagated in the media that 'healthy food is too expensive', which never gets challenged, despite being so blatantly false. I'm not much of a cook but with minimal effort, I can feed my family for two days with a decent stew from fresh ingredients made for about €20. On the occasional nights we get a 'chippy', it costs about €30 for one meal. Healthy eating is not decided by money, but there needs to be a significant investment in teaching people how to cook in schools and in communities, or else the negative health consequences will have negative economic ones also.

SIGN OF THE FUTURE

As our pharmacy days have got more time-pressured, I find it is harder to keep the levels of patient service that I used to. In general, I will do whatever I can to fill any prescription that comes in to me, but recently, I had to think again. A lady who was new to my pharmacy handed in a hospital prescription from a consultant with two items. As I took the prescription, I knew I had neither, so I told her I would check availability. She said that she normally goes to the 'pharmacy beside the doctor' and maybe he would have them, but I asked her to give me a moment to check, and I went to the dispensary to look at the wholesaler website.

The first item was one of the various unavailable steroid creams, so I would have had to ring the consultant for an alternative. The second item had no GMS code, but the patient had a medical card, so I know from past dealings with this consultant that I would have been told 'tell her she can get it through the Hardship Scheme'. As I was thinking about my options, the penny dropped with me that no matter what I said to this patient, she would doubtless think that her usual pharmacist would do it better, so I gave her back the prescription and told her to bring it to him. Some fish you just have to throw back.

CONTRIBUTOR INFORMATION

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Prescription for disaster

***Dr Des Corrigan** reviews the appalling death toll revealed in data from the Drug-Related Deaths Index*

The Health Research Board released data from the National Drug-Related Deaths Index (NDRDI) for 2017 in mid-December. There were 786 such deaths recorded, up from 772 in 2016. To put this appalling toll into context, there were 158 deaths due to road traffic accidents in the same year. In response, the Government invests millions of euro and promises more gardaí to reduce the toll from accidents still further, but we hear precious little about the need to reduce drug-related deaths. Admittedly, there are initiatives such as naloxone provision that have the potential to save lives but given that the vast majority of the fatalities involve drugs other than opioids, this can only have limited impact.

The big take-home message for pharmacists is that yet again, prescribed medications were implicated in the majority of 'poisoning' deaths. There were 376 such deaths determined by coroners as being due to the direct toxic effects of one or more drugs. In popular parlance, these are described as 'overdose deaths'. In addition, there were 410 non-poisoning deaths where an individual had a history of drug dependence or problematic drug use, or where drugs were detected but the person died from trauma such as hanging, drowning, or a road accident, or from medical causes such as a cardiac event, liver disease or cancer. The most common drug used by those who died by hanging was cannabis, followed by cocaine. There was also an increase in poisoning deaths linked to cocaine, which mirrors media and anecdotal reports of increased cocaine use, including that of 'crack' in the general population.

Ecstasy (MDMA)-related deaths increased by 75 per cent to 14, half of which were due to MDMA on its own. This is unusual because most 'poisonings' involve polydrug use. The only other drug that similarly features on its own as being responsible for deaths is alcohol, which was deemed culpable for 61, or 16 per cent, of all poisoning deaths. Apart from alcohol, the main drug type im-

plicated in overdose deaths was the opioid group, mainly methadone (95, or 25 per cent of all poisonings), followed by heroin (77 fatalities) and to a much lesser extent, fentanyl, where the seven recorded deaths has remained unchanged over a three-year period. It is somewhat reassuring that synthetic opioids such as the fentanyls, oxycodone and hydrocodone, which have been responsible for an avalanche of overdose deaths in North America, do not feature prominently in the Irish figures. I hope that will continue to be the case.

The headline figure for the involvement of prescribable drugs relates to alprazolam, where deaths linked to either prescription or counterfeit forms rose by 34 per cent from 2016, to 63 in 2017. Of course, other benzodiazepines and the zed drugs continue to feature prominently, with 90 deaths linked to diazepam, 42 to zopiclone, 34 to flurazepam, and five in which the designer-benzo etizolam was detected. Deaths related to antidepressants such as amitriptyline and citalopram, at nine each, were significantly lower compared to the 20-plus reported the previous year. The continued involvement of so many medicines must be of concern to those prescribing them and those dispensing them. The scary aspect is the number of drugs detected in each poisoning death, which has risen year-on-year. In 2008, only 3 per cent of all deaths involved four or more drugs but by 2017, this had increased to 18 per cent of all such deaths, or 67 in total. Polydrug use is very much the norm, accounting for 58 per cent of poisonings. Half of the deaths where alcohol was implicated involved other drugs, while in 89 per cent of methadone fatalities, benzos were also detected. All of the deaths linked to benzos, including alprazolam, involved other drugs, mainly opioids. Yet again, I would make the point that there is an opportunity for pharmacists to intervene with advice about not mixing psychoactive medicine, opioids and alcohol that will save lives.

One positive aspect was a welcome drop in pregabalin-related deaths, from 66 to 45 in 2017. The researchers at the HRB have looked at gabapentinoid deaths in considerable detail in an article in *Drugnet Ireland*, the newsletter of the Irish Focal Point that reports to the EU's Drugs Agency (EMCDDA). Lead researcher Ena Lynn investigated whether an increase in pregabalin dispensing influenced poisoning deaths. She gathered data from the PCRS covering the GMS, LTI and DPS. In 2013, there were 612,641 prescriptions for pregabalin products and 14 pregabalin-positive deaths. By 2016, the number of scripts had risen to 755,159 and deaths had increased to 66. Strangely, the corresponding increase in prescribing of gabapentin, from 75,000 in 2003 to over 500,000 in 2017, does not appear to have resulted in any notable increase in fatalities involving that particular molecule.

> *Apart from alcohol, the main drug type implicated in overdose deaths was the opioid group, mainly methadone (95, or 25 per cent of all poisonings), followed by heroin (77 fatalities) and to a much lesser extent fentanyl, where the seven recorded deaths has remained unchanged over a three-year period...*

Ms Lynn notes the scheduling of both gabapentinoids within the UK's Misuse of Drugs Act from April 2019 and goes on to write that "results from our study support the consideration of similar reclassification of pregabalin in Ireland". Ms Lynn is also the lead author of a paper from the HRB and the RCSI that has been accepted for publication in the journal *Drug and Alcohol Dependence*.

This looked at factors associated with pregabalin-positive deaths in this country. The study found evidence of inappropriate prescribing to those known to misuse opioids and those known to be problematic drug users.

The authors call for more guidance and training for prescribers and drug treatment providers to better inform them and the public about the potential harm arising from 'off-label' prescribing and of inappropriate use. Close monitoring of prescribing practices and of the diversion and misuse of pregabalin is, they claim, urgently needed. However, the fact that the gabapentinoids are not controlled drugs in the Republic makes monitoring of any black market virtually impossible for the gardaí.

It is noteworthy that the Medical Council included pregabalin in its recent warning to medical practitioners about the inappropriate and over-prescribing of benzos and zed drugs. This is a welcome intervention. Equally welcome, in my opinion, would be an initiative by the Department of Health to schedule pregabalin. No doubt the industry, some members of the profession and of the medical profession will see any attempt to restrict the over-prescribing of this drug as another 'end of civilisation as we know it' moment. Equally, the DoH may be influenced by the chilling effect of the Supreme Court judgement in the Bederev case. But given the number of deaths linked to pregabalin since 2013 (187), it must be possible to protect the legitimate needs of patients while reducing inappropriate over-prescribing and preventing unauthorised possession, especially where there is an intent to supply a black market. How many more deaths will be needed before the obvious action is taken? ●

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.

Looking back with 2020 vision

***Terry Maguire** outlines his vision for pharmacy in 2020, drafted in 1995, and reflects on what has come to pass*

George Orwell and Stanley Kubrick were never exposed to this risk of humiliation. When 1984 arrived, the author was long dead and when 2001 dawned, Kubrick the film-maker was firmly in the heavens. No-one was scrutinising and comparing their fictional visions with the reality. I authored *Vision 2020* in the late 1990s and now 2020 is here some, assuming they are still alive, may ask if the vision has become reality? Did *Vision 2020* have an impact on the development of community pharmacy practice in Northern Ireland?

In 1998, the Pharmaceutical Society of Northern Ireland (PSNI) finally agreed *Vision 2020* as its vision for

the future of community pharmacy. It had been a slog, as there were important and influential dissenting voices. At that time, and perhaps today still, I find difficulty seeing the real concerns, the true agendas behind the fake excuses; they were there then and they still are.

In 1995, I started work on *Vision 2020* because it was my view that real risks existed if pharmacy failed to adopt a clinical future. Supply services needed to change to clinical services or we risked no future. *Pharmaceutical Care*, defined by Charles Hepler and Linda Strand in the early 1990s, was the inspiration for, and the main thrust of, *Vision 2020* as it offered the necessary change and sustainability for community pharmacy. But Hepler and Strand's definition was, for me at least, too restrictive; it did not consider how pharmacists might make an impact on public health and improve self-care. Indeed, I had a number of frank discussions with Charles Hepler who, while always polite, found my argument on the limitations of *Pharmaceutical Care* somewhat irritating and stated during one discussion that I clearly misunderstood the fundamental essence of the idea. *Pharmaceutical Care* is not care by pharmacists; rather, it is care by pharmaceuticals (medicines, drugs) and I was fully aware of this but we needed something wider than this to transform the service our 500 pharmacies provided to their patients and communities.

I added public health and self-care speculating on community pharmacy's potential contribution to changing behaviours that impacted on health and wellbeing; smoking, alcohol, nutrition and exercise. *Vision 2020* boiled down to three domains: 'Pharmaceutical care', 'self-care' and 'public health'. Of course, these domains were not distinct and mutually exclusive — there is significant overlap. For example, the smoker collecting her inhaler to treat her COPD needs more than advice on proper inhaler technique; the pharmacist needs to consider smoking and how she might be supported to stop.

Vision 2020 was essentially a bold statement of what the PSNI saw as the roles and responsibilities of community pharmacists 20 years into the future. By making this statement, it was hoped that we would choose the right policies and create a momentum that would eventually make the vision a reality and do so by the year 2020. Now that 2020 is here, and I must confess it has come much too fast, what has been the success and has it brought us to sun-lit uplands?

It's been a mixed bag. Some things have been successful, others have not and some have been delivered, but perhaps not successfully.

> *Apart from the loss of investment into community pharmacy, it also triggered a major workforce crisis, as 450 pharmacists have taken jobs that are 9-to-5 and with a decent pension. Now, in my world, try getting a day off at short notice!*

Using *Vision 2020*, the Department of Health (DoH) published its policy for community pharmacy, *Making It Better*, a few years into the new millennium. Sadly, discussions between DoH and the pharmacy negotiating body, now CPNI, hit a wall very early on. Negotiators wanted all-new commissioned activity — the clinical and public health services — to be paid as additional to the existing funding pot. DoH argued that it was a transition where there would be some new money but ultimately, it was necessary that fees for supplying medicines would need to be reduced to expand and fund new services. The next 20 years was a negotiating disaster; CPNI stalled where it could, DoH aggressively reduced funding, nearly bankrupting contractors. CPNI took three judicial reviews, losing in the end and paying a hefty legal bill. DoH got to such a point of frustration that CPNI was almost being ignored when, finally, in November 2018, a new contract was imposed and all the fighting just seemed to stop. The absence of a contract was causing considerable financial hardship and something had to give. Most contractors were happy to take what was on offer and see a way out of their hefty overdrafts.

The new contact is now commissioning services across the three domains. 'Living Well' is a public health service that supports pharmacists to engage in brief interventions on exercise, care in the sun, nutrition, and smoking. The smoking cessation service was a big win early on. The flagship of pharmacy public health is 'Health + Pharmacy'. Sadly, this impressive scheme has run aground, as contractors won't agree to some of the standards, such as a restriction on selling, confectionary, E-cigs and low-factor sunscreen. The minor ailments service, designed to keep patients out of GP practices and emergency departments, is part of 'Pharmacy First' and is currently allowing us to treat patients with cold and flu symptoms on the health service.

'Pharmaceutical Care', now called 'medicines optimisation', has been less successful for community pharmacy but has ensured a practice pharmacist in every GP surgery. Apart from the loss of investment into community pharmacy, it also triggered a major workforce crisis as 450 pharmacists have taken jobs that are 9-to-5 and with a decent pension. Now, in my world, try getting a day off at short notice!

Vision 2020 may have had an impact but perhaps things were moving this way anyway and we would have ended up here without it. Contractors did not buy into the vision as I would have wished and seemed too focused on monitored dosage systems, free prescription collection and delivery and investing in robotics. So, to say clinical services are now a part of the community pharmacists' role is wrong, and the dangers I saw back in the 1990s remain a problem for the sustainability of the network. Like UK society in 1984 and space in 2001, community pharmacy in 2020 is certainly not what was envisioned. ●

CONTRIBUTOR INFORMATION

Terry Maguire owns two pharmacies in Belfast. He is an honorary senior lecturer at the School of Pharmacy, Queen's University of Belfast. His research interests include the contribution of community pharmacy to improving public health.

A FRIEND INDEED?

Who will be the pharmacist's friend in Election 2020, asks ***Ultan Molloy***

As we settle into February, one can consider those New Year's resolutions that may have gone by the wayside already. The stress of the Christmas period in retail always delivers, in spite of our best efforts to manage it. A modest increase in front-of-house turnover following a six-month run-in and disproportionate return on staff time.

Perhaps it's taking us further away from the core job of safe and effective medicines. We are no doubt weeks away from another study showing that the majority of customers who presented at the counter requesting a codeine-containing medicine were asked an inadequate amount of questions to ensure, as best as possible, that the medicine was going to be appropriately used. We can't get it right all of the time of course, with the liars and the 'just give it to me' brigade, but that doesn't mean we can abdicate our responsibility for patient care.

Anyone reading this and thinking, 'sure, they'll just get it somewhere else' may as well be suggesting that pharmacy-only medicines be available off the shelf in supermarkets. Yes, it's easier not to collaborate with the visitor to the pharmacy and not to ask a few questions, and yes, there'll be money in the till after it, and yes, it's unlikely there'll be any repercussions, but the job is ask the questions. To collaborate and give of yourself and your time, and your staff time, so that there is clear value added. Much like the uptake of vaccination in a population required to prevent an outbreak, it's past time that we got to 80 per cent-plus uptake in application of knowledge, skills and a professional attitude at the counter in order to prevent an outbreak of 'sure, aren't they just shopkeepers!'

GENERAL ELECTION AND MAKING CHOICES

With Sinn Féin up 6 per cent in a recent poll, around the time one of their councillors noted the "Indian" heritage of our Taoiseach, the mind boggles. Dopamine, as the 'us and them' hormone, no doubt stirring the blood of many a brave Irish man and woman ready to fight for 'the cause'. Indeed. The 'whole country is in a state of chassis' smacks of the wisdom of protagonist Captain Boyle in Seán O'Casey's *Juno and the Paycock*. "No bread is better than half a loaf" being another one of the quotes from this genius. And who said most what you learn in your Leaving Cert isn't relevant?! There are the two quotes I learned, and both of them are relevant.

Actually, we are in really good shape as a country. One of the best in the world to live and work in. We are not at risk of starvation, like about 15 per cent of the world's population; indeed, we are among the most affluent 15 per cent. When your reference point is no running water or sanitation, infant mortality rates that remain inordinately high, no access to healthcare and life-saving medicines, then an attitude of gratitude can be more readily cultivated. Have a read of the book *Factfulness* if you'd like to feel better about your life, and to inoculate you from some of the sensationalist, emotive tripe we are fed by much of our media.

Yes, of course there will be richer and poorer than ourselves, but a myopic focus on what's not working at the expense of what is in order to determine policy is a fool's game. There will be always be more successful people, by societal and media expectations, than ourselves. Our reference point here is again critical, and where our focus lies. Do we consider what we are lucky to have, or feed anxiety by focusing on what we have not? There is an element of choice there to consider. Nor am I suggesting, of course, that we do not strive for better. That is why we were made.

So, who will be a friend to pharmacists and our profession of the candidates and parties in the next election needs to be teased-out. The tidal wave of Trumpish ignorance, bigotry, racism and warmongering, fuelled by the 'us and them' politics and media probing that appears to be gaining traction in the Western world, is concerning. Sinn Féin's focus on our Taoiseach's heritage smells of something different in Irish politics, or maybe it's there already. The Brits and 'we, ourselves' — Sinn Féin. Catholics and Protestants. Republicans and Unionists. Stoking those embers of a fractured and troublesome past is what I hoped we would be moving away from as a positively-evolving society. A party professing a wish for unity with a focus on difference. A tribal anti-vote, rather than a vote for something constructive, I can understand. It is just so far removed from a collaborative and wholesome way forward, but I am no doubt naive in my assessment and understanding of the perspective of many others. Getting one's kicks off the tribalism associated with the GAA and inter-provincial rugby just seems so much healthier!

WHAT'S IN IT FOR ME?

The real question at the end of all this is, do we represent ourselves well as a profession, day-to-day, in the dispensary and at the counter? Is patient care and safe and effective medicine use easily reconcilable with management, HR and business requirements in community pharmacy?

Are we being represented well by our representative body, as considered in my last article? I hope it was received in the good faith with which it was intended.

CHOICES

So, how will you vote, and what are your criteria? The politicians who engaged and responded to correspondence around the recently-proposed pharmacy cuts are perhaps a good starting point. The poster boys and girls who can't manage to reply to their constituents' emails should be kindly afforded the time to take an ECDL course after the next election. If you want the job, then do the work.

Do they have a constructive, can-do attitude, and a history of delivering in some capacity for their constituents and of course the country, with previous behaviour being the best predictor of future behaviour.

Do they share your values in terms of community, morality, or other considerations may be in the mix there too.

So best of luck with your choices for the election. Perhaps you'll have made your election choices by the time you've read this, given our publishing lag-time. There will be another one soon enough, no doubt! Best of luck also, though, in your choices day-to-day. Your choices to deliver positively for yourself, your family, your patients and customers, and your profession.

CONTRIBUTOR INFORMATION

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pharmacist CPD PharmacistCPD.ie

Within this CPD article, we will cover some common dermatological conditions seen and treated in primary care. On completion of this module, it is expected that the reader will have an enhanced understanding of dermatological conditions typically seen in the pharmacy, potential treatment options, and when it may be necessary to refer.

AUTHOR:
CIARA GAVIN MPSI

TRUE/FALSE QUESTIONS

Q1
Oral roaccutane is the first line of treatment for moderate acne.
True or false?

Q2
Topical antibiotics are often used in combination with benzoyl peroxide in the treatment of acne, as the combination reduces the risk of antibiotic resistance.
True or false?

Q3
Insecticides include malathion (Dermac-M) and permethrin (Lyclear), which work by poisoning the head lice by a chemical means.
True or false?

Q4
One fingertip unit — the distance from the tip of an adult index finger to the first crease — is sufficient to cover an area the size of the flat of one adult handprint (palm and fingers).
True or false?

Q5
Wet-combing is not an approved method for the treatment of head lice.
True or false?

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ACNE

Acne, or *acne vulgaris*, is a common skin condition, predominately affecting those between 10 and 30 years of age.[1]

Acne is considered to be an inflammatory process of the follicles of the skin[2] and is generally classified by severity in the following way:

- **Mild** — mostly whiteheads and blackheads, with a few papules and pustules.[3]
- **Moderate** — more widespread whiteheads and blackheads, with many papules and pustules.[3]
- **Severe** — lots of large, painful papules, pustules, nodules or cysts.[3]

There are four main factors which play a role in the development of acne lesions.[2] These are:

- Excess sebum production.[2]
- Disturbed keratinisation within the follicle.[2]
- Colonisation of the pilosebaceous duct by *Propionibacterium acnes*.[2]
- Release of inflammatory mediators into the skin.[2]

Acne lesions typically appear small and uniform in size, inflammatory papules and pustules, without comedones or cysts.[4] Acne scarring is common[5] and can be distressful for patients. Deep pustules and superficial pustules may cause scarring; this is either associated with collagen loss or increased collagen.[6] Scarring is best prevented by starting appropriate treatment without delay.[6] Treatment needs to address the four main factors in the development of acne, as mentioned above.[2] Topical therapy is the first-line option for mild-to-moderate acne.

(See **TABLE 1** for topical treatment options currently available.)

Systemic treatment with oral antibiotics is used for moderate-to-severe acne, when topical preparations are not tolerated or ineffective, or when the site is difficult to access.[8] Co-cyprindiol is an alternative oral hormone therapy option available for women only,[8] while oral isotretinoin is reserved for use by consultant dermatologists.[9]

Oral antibiotic therapy

Tetracyclines (generally doxycycline or lymecycline) are oral antibiotics used for severe acne. They are generally given for at least two months; if there is no improvement after three months, an alternative antibacterial agent should be tried. Maximum improvement occurs between four-to-six months after commencing therapy but in more severe cases may require continued treatment for two years or longer.[8,9]

Minocycline is also effective for acne, however its use is limited by the greater association with risk of lupus erythematosus-like syndrome. It can also cause irreversible pigmentation.[8]

Erythromycin can also be used as an alternative to tetracyclines, however the spread of *propionibacteria* strains resistant to erythromycin also limit its response and use.[8]

HORMONE THERAPY

Co-cyprindiol (ie, Dianette) is licensed for women with moderate-to-severe acne that is not responding to topical therapy or oral antibiotics. The mode of action of co-cyprindiol and its benefit in acne is thought to occur due to decreased sebum secretion which is under androgen control.[8] It can take three-to-four months for the benefits to show with hormone therapy.[9]

Oral retinoid treatment

Isotretinoin is extremely effective for acne treatment.[9] Isotretinoin reduces sebum secretion, reducing acne effectively.[9]

Isotretinoin is a toxic medication and is limited to prescribing only under the supervision of a consultant dermatologist. Treatment is generally for 16 weeks and repeat courses are not normally required.[8]

Isotretinoin can cause severe dryness of the skin and mucous membranes and has been associated with nosebleeds and joint pain. It is teratogenic and cannot be given to women of child-bearing potential unless a detailed assessment is completed by the prescriber. Women must be registered with the pregnancy prevention programme and must practice effective contraction. Oral progestogen only

contraceptive is not considered effective.[8]

Prior to commencing treatment, women must have a negative pregnancy test. Pregnancy tests will be completed monthly during treatment and for five weeks' post completion of the course.[9]

As isotretinoin dries the skin, especially around the lips, it is good practice to recommend liberal application of moisturisers and lip moisturisers to prevent cracking.

Patients should be informed that often, acne becomes a little worse for a few weeks before improvement occurs.[9]

Some practical advice which can help your patients with acne includes:[3,4]

- Do not was the affected areas of the skin more than twice a day.
- Wash the affected areas with a mild soap or cleanser and luke-warm water. Very hot or cold water can make acne worse.
- Do not try to squeeze blackheads or spots; this can make them worse and cause permanent scarring.
- Avoid using too much make-up and cosmetics. If using products, water-based products are less likely to block skin pores.

CONTACT DERMATITIS

Background

Contact dermatitis is an allergic or irritant skin reaction caused by an external agent[10] and causes the skin to become itchy, blistered, dry and cracked.[11] There are two main types of contact dermatitis: Irritant contact dermatitis, and allergic contact dermatitis, with irritant contact dermatitis the most common.[10] Contact dermatitis accounts for between 4-to-7 per cent of dermatology consultations.[10] Irritant dermatitis is caused by a substance directly damaging the outer layer of skin, while allergic dermatitis is caused by a substance which activates an immune response affecting the skin.[1]

The terms 'dermatitis' and 'eczema' are often used interchangeably. In some cases, the term 'eczematous dermatitis' is used. Dermatitis can be acute or chronic, or both.

- Acute eczema (or dermatitis) refers to a rapidly-evolving red rash which may be blistered and swollen.
- Chronic eczema (or dermatitis) refers to a long-standing irritable area. It is often darker than the surrounding skin, thickened (lichenified) and much scratched.
- Subacute eczema is an in-between state.

Diagnosis

A full history for assessing a patient's dermatitis should be completed, with aim to identify:[10]

- Personal atopic history, including childhood dermatitis, asthma, hay fever.[10]
- Where did the initial symptoms begin and where did they spread?[10]
- Was there any link or association to application or use of a product, especially focusing on cosmetic, personal care, clothing, gloves, etc?[10]
- Wash products which come into contact with the skin, as the majority contain harsh emulsifiers/surfactants that can cause damage to the skin barrier.[10]
- If symptoms relate to a particular activity, such as hairdressing or holidays.[10]
- If symptoms relate to work or a specific work-related activity.[10]
- If symptoms get worse after sunlight exposure.[10]
- Do symptoms improve with environmental changes, ie, at weekends, holidays?[10]

Patch testing can be completed and is the gold-standard investigation in patients for whom allergic contact dermatitis is considered.[10]

TABLE 1: Topical treatment options currently available.[3,6]

Class	Mode of action	Helpful information
Retinoids	Anti-inflammatory, comedolytic, anti-comedogenic	▸ These work by removing dead skin cells from the surface of the skin which help prevent build-up within the hair follicles. ▸ Usually applied once a day before bed. ▸ Avoid excessive exposure to sunlight and UV. ▸ A six-week course is usually required.
Benzoyl peroxide	Antimicrobial, anti-inflammatory and comedolytic	▸ Apply 20 minutes after washing. ▸ Use sparingly, as using too much can irritate the skin. ▸ Your skin will become more sensitive to UV light, so advise sun cream. ▸ If it comes in contact with clothes or hair, it may have a bleaching effect. ▸ A six-week course is often required.
Antibiotics	Antimicrobial, anti-inflammatory (only to be used in combination with other topical agents)	▸ Clindamycin is 1% solution or gel, currently available in Ireland as a topical antibiotic. ▸ Topical antibiotics have both antibacterial and anti-inflammatory effects. ▸ These agents should not be used alone due to risk of antibiotic resistance. ▸ Often used in combination with benzyl peroxide. Combination products are available which may aid compliance. ▸ Usually six-to-eight week course is required.
Azelaic acid	Antimicrobial, anti-inflammatory, comedolytic	▸ Azelaic acid is often used as a treatment option when benzyl peroxide or topical retinoids are not suitable due to side-effects. ▸ Azelaic acid does not make skin sensitive to sunlight and therefore does not require additional precautions with UV light. ▸ A minimum four-week course is required before improvement is usually noted.
Salicylic acid	Anti-inflammatory, comedolytic	▸ Used mainly for its keratolytic effect. ▸ It is considered less effective than other options available.[7]

Treatment

By successfully identifying and avoiding irritants or allergens that trigger symptoms, the skin will clear up.[11] Skin protection can also help, such as wearing gloves to prevent exposure to the irritant. Replacement of soaps and detergents with emollients has been shown to be useful with contact dermatitis; even if these are not the agents to cause the dermatitis, they can compound the situation.[10]

The general principles for the management of dermatitis may be applied to all eczematous conditions. Cure of atopic dermatitis is said to be unrealistic, but good control can be achieved with proper management.

The objectives of treatment should be to reduce the signs and symptoms, to prevent or reduce recurrences, and to provide long-term management by preventing exacerbations.

If symptoms persist despite the allergen or irritant removal and use of skin protection, then studies support the use of topical steroids and topical tacrolimus in treatment of contact dermatitis.[10]

Topical corticosteroids or topical calcineurin (ie, tacrolimus) are the main treatment options for allergic contact dermatitis.[10]

Topical corticosteroids suppress the inflammatory reaction during use and will relieve symptoms.[8] It is important to differentiate the different areas of the body to be treated, as the potency of the topical corticosteroid used for treatment will depend on this.

The topical corticosteroid potency scale ranks from mild, to moderate, potent and very potent.[8]

One example from each class are:

- **Mild:** Hydrocortisone 0.1% cream.
- **Moderate:** Betnovate-RD-betamethasone 0.025%.
- **Potent:** Elocon-mometasone 0.1%.
- **Very potent:** Dermovate-clobetasol propionate 0.05%.

For more information on the categories of topical corticosteroids, please see the ***BNF*** or ***SPC***.[8]

Low-potency corticosteroids, ie, mild and moderate, should be used on areas of thinner skin, such as skin folds, neck and face.

High-to-mild potency corticosteroids, ie, potent and very potent, should be used on thicker-skinned areas such as torso, scalp, palms and soles.

Topical steroids should be applied thinly and sparingly to prevent excessive use and side-effects. The 'fingertip unit' is the unit of measurement often referred to when measuring the amount of steroid to use. One fingertip unit — the distance from the tip of an adult index finger to the first crease — is sufficient to cover an area twice the size of the flat of an adult handprint (palm and fingers).[8]

For example, one fingertip unit (FTU) should be sufficient to cover hands, elbows and knees with a topical corticosteroid.

HEAD LICE

Head lice, or *Pediculosis capitis*, is the collective term for insects that live close to the scalp of human heads.[12]

Life cycle of the head lice:[13,14,15]

- Head lice are spread most commonly by direct head-to-head contact. They cannot fly or jump.
- Adult head lice are 2-to-3mm long and usually pale grey.
- A female can live up to three-to-four weeks, laying approximately 10 eggs per day.
- Eggs are most easily seen along the hairline and the nape of the neck and behind the ears.
- A human's body heat allows for egg incubation and the egg will hatch between seven-to-14 days from being laid.
- A 'nit' is the term referred to as the empty egg once hatched.
- A 'nymph' is the name for a newly-hatched head louse. They continue to grow for nine-to-12 days, at which point they mate and females lay eggs.
- If not treated, this cycle repeats itself every three weeks.

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- Lice rarely survive more than 24 hours off a host head.

Head lice feed on human blood from the scalp; they do this by injecting small amounts of saliva and taking small amounts of blood.[13,14] The process of injecting the saliva causes the irritation, leading to itching associated with head lice.

Head lice should be treated as soon as detected to prevent spreading, but prophylactic treatment is not recommended.[4,12]

To check for head lice, the hair should be combed using a special 'detection comb' purchased in pharmacies.

The best process for comb identification is as follows:[12,16]

- Wash hair with ordinary shampoo.
- Apply lots of conditioner and comb through. This makes the lice wet and difficult for them to move.
- Using a 'detection comb', comb the hair at the roots and close to the scalp, downwards.
- A kitchen towel can be used to clean the comb immediately after each pass to remove lice and eggs to help identification.
- Work through the hair, section-by-section, checking the comb after each section.
- Rinse off the conditioner.

If head lice are identified, then the following treatment options are available: Insecticides, non-insecticides (physical insecticide); or wet-combing methods.[4,8] Head lice should be treated with lotion or liquid formulations, as shampoos are diluted too much in use to be effective. In general, two applications are required to complete a course of head lice treatment. Head lice treatment is generally effective against the live lice and not effective against the unhatched egg, therefore as we know from the life cycle above, treatment on day one should kill live lice and re-treatment on day seven should kill any nymphs before they have the opportunity to become fully grown and lay eggs (days nine-to-12).[4,8,12]

Insecticides include malathion (Dermac-M) and Permethrin (Lyclear) and work by poisoning the head lice by chemical means.[8,16] Resistance is a reported issue with insecticides, reducing their ability to work.[4,8]

Non-insecticides (or physical insecticides) include Dimeticone (Hedrin 4% lotion/spray, Lyclear lotion). Dimeticone is effective against head lice, as it acts on the surface of the organism and interferes with the water balance in lice by preventing the excretion of water.[8]

Isopropyl myristate/cyclomethicone (Full Marks Solution) is classed as a medical device but also works by physically coating the surface of the head lice and suffocating them. Due to this method of action, resistance is unlikely to develop in non-insecticide/physical insecticides.[16]

The wet-combing method, similar to that described in the technique used to identify head lice, can be used to mechanically remove head lice from the hair.[8,16] This process requires combing the wet hair meticulously with the 'detection comb' for at least 30 minutes at four-day intervals for a minimum of two weeks and continue until no lice are detected on three consecutive sessions.[8]

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MULTIPLE CHOICE QUESTIONS

MCQ 1

Match the potency to the steroid:

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Betnovate-RD-betamethasone 0.025
Elocon-mometasone 0.1%
Dermovate-clobetasol propionate 0.05%

Mild | Moderate | Potent | Very potent

MCQ 2

How many applications are recommended of topical lotions/liquids to treat head lice?

A One application.
B Two applications (seven days apart).
C Two applications (six months apart).
D Four applications (weekly).

MCQ 3

Which of the following is not recommended in the management of contact dermatitis?

A Avoiding irritants that trigger symptoms.
B Skin protection, such as wearing gloves to prevent exposure to the irritant.
C Replacement of soaps and detergents with emollients, even if these are not the agents that cause the dermatitis.
D Increasing exposure to irritants to encourage resistance to dermatitis.

MCQ 4

When choosing an antibiotic agent for the treatment of moderate acne, which of the following are recommended first-line? (Choose all that apply)

A Doxycycline.
B Minocycline.
C Erythromycin.
D Lymecycline.

MCQ 5

When counselling a patient newly commenced on isotretinoin, which of the following points is untrue?

A Acne can often initially become a little worse before improvement is seen.
B Use of progesterone-only contraception is sufficient.
C Liberal moisturising is advised due to dryness of the skin.
D Treatment can be initiated under the supervision of your GP.

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THE best start IN LIFE

An overview of infant health and nutrition and how the pharmacist can advise patients on giving their young children the best chance for good health as they grow

It is increasingly recognised that optimal delivery of paediatric care must be a collaborative effort between healthcare professionals from a range of disciplines. According to the HSE and the RCPI: "We earnestly believe that improving child health in Ireland will be realised by thinking differently, breaking traditional paradigms and joining together in a shared vision to tackle current and future challenges. This is the essence of this [paediatric] model of care."[1]

The Executive and the Faculty of Paediatrics at the RCPI also emphasise the need to plan ahead for increased incidence of obesity, diabetes, atopic disease and allergy, among others, and inflammatory bowel disease, and have stressed how "the future direction should be to provide as much care as close to home as possible, and to achieve this, we must strengthen both primary and community care of children and adolescents. We must learn from international experience and work together across disciplines throughout the country to develop a child health service that meets the current and future needs of our children."[1]

If this future direction for paediatric healthcare is planned and implemented properly, this means that pharmacists will be increasingly called upon as the most accessible source of primary care in the community, particularly in light of the expansion of the under-sixes contract with general practitioners. Within the EU, Ireland has the highest proportion of the population who are children — 25 per cent, compared with the EU average of 19 per cent. "Delivery of family-centered care as close to home as possible is at the centre of this model of care," that authors stated (**see SPOTLIGHT overleaf**).[1]

NUTRITION

Pharmacists, as well as other healthcare professionals, have a duty to encourage parents to make informed decisions based on evidence when it comes to breastfeeding and other nutritional options for their infants. A range of studies have shown the benefits of breastfeeding confers advantages in terms of growth, development and general health and can reduce the risk and/or severity of a number of diseases, including urinary tract infections, respiratory tract infections, otitis media, diarrhoea, and necrotising enterocolitis.[2]

In addition to essential nutrients, breast milk provides biochemical and immunological benefits, such as proteins, cytokines and hormones. However, breastfeeding is contraindicated in certain circumstances, such as when the infant's mother has untreated active tuberculosis, if the mother has been impacted by HIV, and if the infant has galactosaemia.[2] In the hospital setting, it is advised that barriers to breastfeeding include disruptive hospital policies, early discharge with inadequate follow-up procedures, and failure to place the infant at the breast immediately after birth. Mothers may also be prevented from breastfeeding by other factors, such as tiredness or insufficient time, embarrassment/inconvenience, pain in the nipples or breasts, and insufficient milk. Other barriers to breastfeeding include thrush, engorgement, mastitis and blocked ducts,[2] however these can be overcome if the mother receives the appropriate level of support.

If it is not possible to breastfeed a child, parents should be advised on the range of formulas that are available for infants, including follow-on formulas, special formulas for preterm infants, and infants with intolerance to cows' milk or allergies, although cows' milk is not suitable as a main source of nutrition for children under the age of 12 months.[2]

Iron deficiency can be common in infancy and can lead to delayed mental or motor development, as well as anaemia. Follow-on formulas

that are fortified with iron have been shown to improve levels of serum ferritin and haemoglobin and it has been suggested that inner-city infants who are not being breastfed should be prescribed iron-fortified formulas, as this has been shown to reduce declines in psychomotor development.[2]

ASSESSING THE PATIENT

While the pharmacist must establish the health status of the infant and mother in order to provide appropriate treatment or referral, this information should be obtained in a thorough but sensitive manner. As always, good communication is central to treatment and the PSI has stated that "pharmacists should be mindful of how they request information. It may be useful to explain to the patient why certain information is needed, ie, to be able to make a decision about the appropriate medicine and advice, or to recommend they need to see their doctor or another healthcare professional. It should be highlighted that if used correctly, medicines offer great benefit, but if used incorrectly, medicines have the potential to do harm."[3]

The range of potential conditions in infants is extensive and detailed analysis is beyond the scope of this article, but the pharmacist will typically deal with presentations such as infant acne, colic, the common cold, coughing disorders, nappy rash, ear infections, jaundice, milia, vomiting and colic, among others, such as plagiocephaly.[4]

Colic can be a particularly distressing condition for both parents and their infant and may be diagnosed as crying for more than three hours per day for more than three days a week. Pharmacists should advise parents that the symptoms of colic can be eased by taking a careful record of what the breastfeeding mother eats and drinks; potentially switching formula brands; feeding the baby the appropriate amount and not too quickly; avoiding caffeine and chocolate; holding the infant correctly; comforting the baby with skin-to-skin contact; and/or simethicone drops.[4]

Seborrheic dermatitis, or cradle cap, is another of the most common infant conditions. Patients can be advised that cradle cap can resolve after several months but at times can also affect the infant's eyelids, armpits, groin, and ears. Parents can be advised to gently wash the baby's head each day with a mild shampoo. However, pharmacists may also see cases of scalp ringworm or scalp psoriasis, the symptoms of which may sometimes by mistaken as cradle cap by parents.[5]

Gastrointestinal issues in infants can be difficult for a parent to identify, as small amounts are normally regurgitated by infants after feeding, particularly in the early months of life. The pharmacist is well placed to reassure parents, assist them in modifying their feeding technique and if necessary, provide advice on thickening the baby's formula mix. However, the pharmacist is also in a position to identify any underlying paediatric gastrointestinal problems, such as gastro-oesophageal reflux, and refer if necessary.

Pharmacists can be suspicious of gastro-oesophageal reflux if there is:

- Poor weight gain, possibly because significant volumes of milk are being regurgitated.
- Feed refusal or pain on feeding, possibly because of heartburn or oesophagitis.
- Blood-streaked vomit (possibly an indication of oesophagitis).
- Recurrent cough, wheezing or choking, possibly because of aspiration.
- Episodes of apnoea, possibly because of vagal reflex triggered by acid reflux.[6]

FUTURE INITIATIVE

It was recently announced that a new study is to look at the issue of 'everyday pain' in toddlers and young children, conducted by the Centre for Pain Research at NUI Galway. The definition of 'everyday pain' is described as bumps, scrapes and minor cuts and the study will explore how parents and their children respond to these events.[7]

The study will also examine how parents react to their child's everyday pain and how a child learns from this and the influence it may have, for better or worse. Ms Grace O'Sullivan at the Centre for Pain Research at NUI Galway and lead researcher of the study commented: "Previous research has shown that children experience a painful incident approximately every three waking hours. Parents often deal with multiple incidents each day, and this study may be of interest to parents who want to know a little more about how to assess their child's pain experiences."

Participants are currently being recruited and more information on the study can be found at ***www.nuigalway.ie/centre-for-painresearch/diarystudy***. ●

SPOTLIGHT

National Model of Care for Paediatric Healthcare Services in Ireland: Recommendations for Pharmacy

Increase paediatric pharmacy staffing levels, in order to provide safe, accessible and effective services.

Develop a robust national model of care for paediatric pharmacy.

Formalise links between local, regional and tertiary paediatric pharmacy units.

National guidelines or standards with regards to pharmacy resources for paediatric critical care should be developed.

Paediatric-specific policies are required for the provision of pharmacy services to children.

Increase pharmaceutical input to paediatric research and medicines management.

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NASAL CONGESTION IN THE PHARMACY

Nasal congestion in children and infants is one of the most common presentations in community pharmacy and can have a number of causes

One of the most common presentations in the community pharmacy is nasal congestion/obstruction. There is an extra challenge when congestion occurs in infants, as they are unable to accurately communicate their symptoms and/or the presence or absence of any accompanying pain.

Blockage of the nasal cavity can have a wide variety of causes. These include, but are not limited to:[1]

- **Common colds and flu:** Heavy deposits of mucus in colds and flu fill the nasal cavity.
- **Allergic rhinitis:** Pet dander or pollen in spring and summer also result in a build-up of mucus.
- **Non-allergic rhinitis:** More commonly caused by reaction to pollution, smoke or other such irritants.
- **Sinus or adenoid infections:** Infected mucus can cause sinusitis. Adenoids can also become infected, with similar results for the child. Referral to a family doctor may be appropriate in these cases.
- **Deviated nasal septum:** Can obstruct airways and may be a birth defect or occur as a result of nasal trauma. If this is particularly problematic for the child, a family doctor may decide to refer the patient for specialist care, where a surgical procedure may be recommended.
- **Large or swollen turbinates:** Nasal obstruction can result from these bones in the nose due to infection or allergies. Again, in these cases the pharmacist may decide to refer the patient.
- **Choanal atresia or pyriform aperture stenosis:** In choanal atresia, the nasopharynx is closed-off with either tissue or bone. When bilateral, this is usually discovered after birth but if it only occurs on one side of the nose, it is usually discovered later in life; pyriform aperture stenosis occurs when the bony nasal opening narrows and obstructs the nasal passage. Specialist medical intervention is usually required.
- **Nasal tumours or cysts:** Benign or malignant tumours and cysts are rare and most often affect one side of the nose.
- **Nasal polyps:** These normally affect the lining of the nose.
- **Large adenoids:** Enlarged tissue at the back of the nose.
- **Foreign bodies:** This occurs in younger children and can involve smaller objects such as a peanut, for example. Often accompanied by a foul-smelling discharge.

Treatments

For the above conditions that can be treated in the pharmacy, the pharmacist may prescribe medications sprayed into the problem area or oral medications. Other treatment options include nasal rinses and a 'watchful waiting' approach.[1]

According to a 2014 literature review, the most common causes of nasal obstruction and runny nose in children are usually viral infections or allergies.[2]

The authors concluded that nasal symptoms in children with allergic rhinitis or acute sinusitis showed significant improvement with nasal saline irrigation. "The use of isotonic and hypertonic saline solutions to relieve nasal congestion in infants and children is widespread; it is a safe and valuable therapeutic support, and can reduce the use of medications (antihistamines, decongestant, antibiotics, corticosteroids) during the treatment of URTIs," wrote the authors.[2]

Advice

Pharmacists can advise patients that drying-out the air in the home in an attempt to help ease the symptoms of a runny nose is incorrect. This actually has the opposite effect, as drying-out membranes only serves to further irritate them.[3]

Rather, parents can use a vaporiser or humidifier and a saline spray and ensure the child drinks plenty of fluids, as this thins-out the mucus and helps alleviate blocked sinuses. Chlorinated swimming pools should also be avoided, as the chlorine can irritate nasal passages.[3]

Decongestants are often prescribed by the pharmacist and similar to saline sprays, may also help to clear an allergen from the nasal passages. Isotonic sprays help to keep the cilia in the nasal passages healthy and help to humidify air travelling to the lungs, trap bacteria and improve sense of smell. Healthy cilia can also help protect the child against sinusitis and rhinitis.[4] Even when a physician has prescribed nasal steroid sprays, using an isotonic nasal cleansing spray can improve the efficacy of the steroids, as it can clear the nasal passages of debris and thick mucus. As with other treatments, it is important that parents are taught the correct application and the pharmacist is the most appropriate and ideally-placed healthcare professional to provide this guidance.[4]

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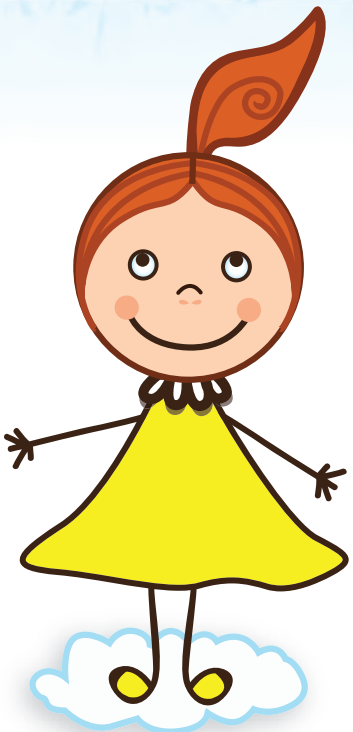

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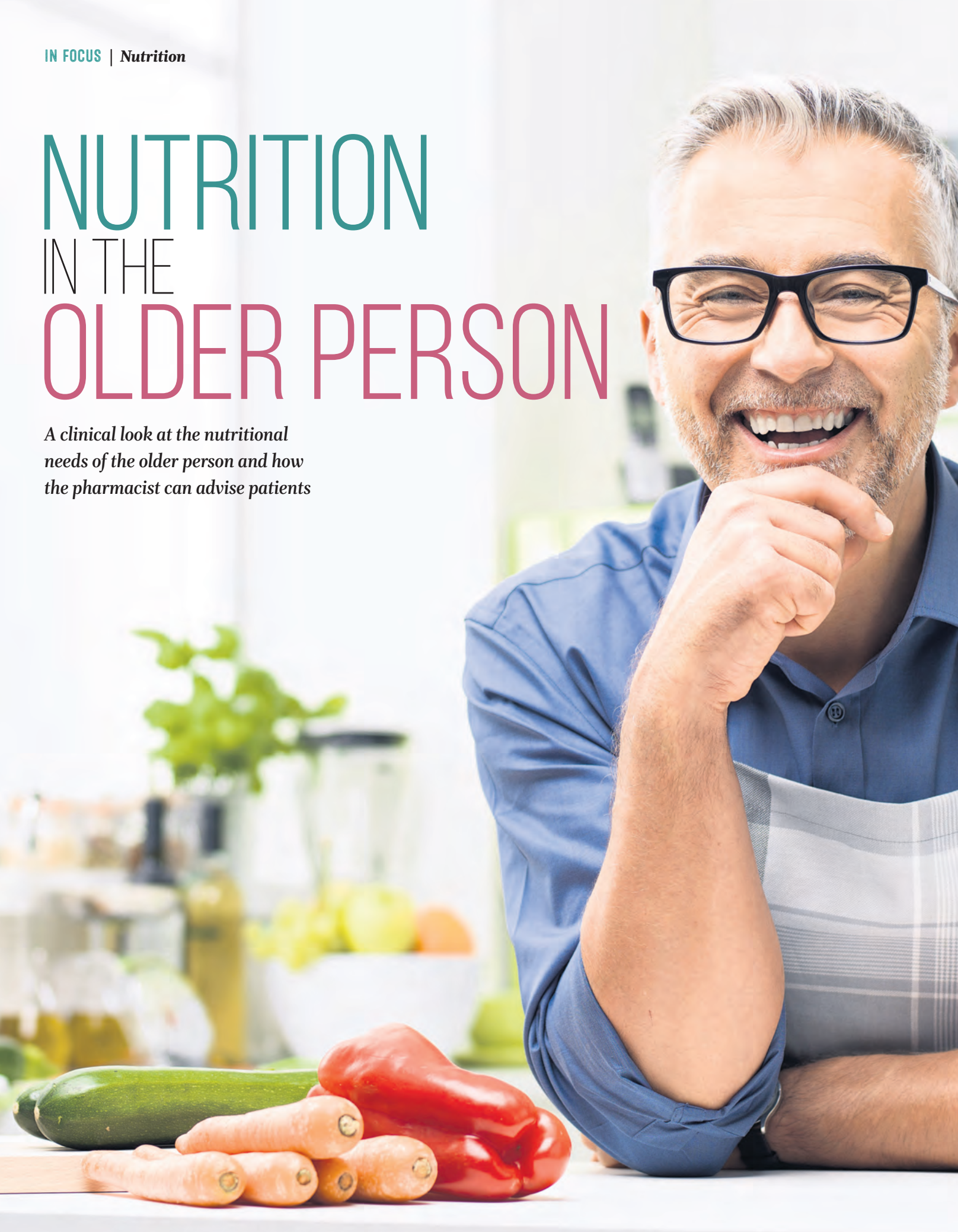
NUTRITION IN THE OLDER PERSON

A clinical look at the nutritional needs of the older person and how the pharmacist can advise patients



Eamonn Brady MPSI,
owner of Whelehans Pharmacies, Mullingar

WHAT IS MALNUTRITION?

Malnutrition is a state of nutrition in which a lack of protein, energy and other nutrients causes measurable adverse effects on tissue and/or body form, composition, function or clinical outcome. Malnutrition can be significant if a person has:

- A BMI of less than18.5kg/m^2.
- Had unintentional weight loss greater than 10 per cent within the last three-to-six months.
- a BMI less than 20kg/m^2 and has had unintentional weight loss greater than 5 per cent within the last three-to-six months.

People are also at risk of becoming malnourished if they have eaten very little or nothing for more than five days and/or this pattern is likely to continue. A UK study showed that among independent older people, 3 per cent of men and 6 per cent of women are underweight, and in nursing and residential care, these figures rise to 16 per cent and 15 per cent, respectively.[1]

NUTRIENTS IN THE OLDER PERSON

Nutrients are substances that are essential for growth and good health — they promote energy, they help to form body structures and they are involved in regulating body functions.[2] Protein, carbohydrate and fat are classified as **macronutrients** and primarily provide energy; protein also provides amino acids for synthesis. Minerals and vitamins are classified as **micronutrients** and play a key role in the body's structures and functions. Malnutrition may be divided into macronutrient and micronutrient deficiencies.[3] Macronutrient malnutrition is referred to as protein-energy malnutrition and is usually associated with a reduction in body mass index (BMI <20kg/m2). Micronutrient deficiencies may be more difficult to detect as they can occur in the presence of a normal body mass index (ie, vitamin D deficiency).

As people grow older, the bones and muscles in their body change, resulting in a decrease of lean body tissue and bone density. This leads to a reduction in basal metabolic rate (which depends on lean body mass), therefore energy requirements fall and hence appetite may lessen. Physical activity helps to lessen the reduction in lean body mass. Physical activity improves balance and reduces falls by keeping muscle strength. Body water content also declines with age and this can impair temperature regulation and increase susceptibility to dehydration. To maintain optimal health in senior years, it is important keep fit and healthy by eating foods high in vitamins and minerals, drinking water, and keeping as active as possible.

MORE ON NUTRIENTS

The older body finds it more difficult to absorb vitamins and minerals through food intake, especially vitamin D. Nutrients essential in the elderly are:

Vitamin B complex

- **Foods:** Whole-grain cereals, bread, red meat, egg yolks, green leafy vegetables, sweetcorn, brown rice, berries, and yeast.
- **Role:** B vitamins help energy release and are important for the central nervous system. Poor vitamin B status is known to adversely affect cognition in the elderly.[4]

Iron

- **Foods:** Liver, red meats, oily fish, nuts, eggs, pulses, and breakfast cereals.
- **Role:** Important for oxygen delivery in the body. Low iron levels cause anaemia; symptoms include lack of energy and shortness of breath.

Zinc

- **Foods:** Chicken, meat and fish.
- **Role:** Zinc is major component of over 300 enzymes and plays a vital role in carbohydrate metabolism, protein synthesis, wound-healing, the immune system, digestion, sugar level control, and the senses of taste and smell.

Calcium

- **Foods:** Milk, cheese, yoghurt, margarine and oily fish.
- **Role:** Maintains strong bones.

Vitamin C

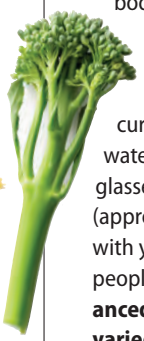
- **Foods:** Fruits and vegetables like oranges, melons, blackcurrants, grapes, tomatoes, red and green peppers and Brussels sprouts.
- **Role:** Vitamin C boosts the immune system. It is involved in producing protein and collagen (collagen is found in many parts of the body, including connective tissue which helps hold joints together). Vitamin C is a free radical which prevents against cancer and it helps the absorption of iron.

Vitamin D

- **Food:** Margarine, oily fish and sunlight.
- **Role:** Helps absorption of calcium, hence strengthens bones. Although it has not been proved, it has been said that vitamin D helps to have a positive effect on the ageing body, so much so that people with higher levels of vitamin D may age more slowly than those with a lower level. It is also possible that vitamin D could help protect the body from cancer and heart-related diseases.

Carbohydrates

- **Food:** Bread, rice, pasta, cereals and white sugar.
- **Role:** An important source of energy.



Folic Acid

- **Food:** Dark green vegetables, breakfast cereals, oranges, yeast extracts.
- **Role:** Most people assume folic acid is only needed during pregnancy. However, it is important at all ages to properly form red blood cells and for our bodies to metabolise protein for energy. Folic acid and other B vitamins have been shown to fight cardiovascular disease and to help prevent Alzheimer's, osteoporosis and cancer and it helps to stabilise mental health.

Protein

- **Food:** Milk, eggs, lean meat, chicken and fish.
- **Roles**
  - Required for building and repair of body tissues (including muscle).
  - Enzymes, hormones, and many immune molecules are proteins.
  - Essential body processes such as water-balancing, nutrient transport, and muscle contractions require protein to function.
  - Protein is a source of energy.
  - Protein helps keep skin, hair, and nails healthy.

Fats

- **Food:** Meat and dairy products. The general advice of using low-fat varieties is less applicable in older people where low weight can be an issue. Grill food wherever possible.
- **Role:** Another source of energy for the body. Fat also provides insulation for the body and is needed to store fat soluble vitamins: A, D, E and K. After the age of 75, the fat levels in the body decrease.

Water

Dehydration in the elderly often occurs as a result of not drinking enough water. It is important to drink at least eight glasses of water per day (approx 2 litres). As with younger people, a **balanced and varied diet** is the best way to ensure an elderly person gets all their essential nutrients.

STUDY EVIDENCE

According to a study carried out by the British Association for Parenteral and Enteral Nutrition (BAPEN) in 2007, more than one-in-four of all adults admitted to hospital, to a mental unit or a care home, is at risk of malnutrition.[5] This study concluded that "hospitals and care homes should implement nutrition screening on admission to ensure that all those at risk — no matter their age or physical appearance — are identified and an appropriate and individual nutritional care plan is provided."[5]

CAUSES OF MALNUTRITION

There are many causes of malnutrition. These can include:

- **Reduced intake:** Poor appetite due to illness, food aversion, nausea or pain when eating, depression, anxiety, side-effects of medication or drug addiction.
- **Diminished sensory ability**: Taste changes, less smell perception, hard of hearing, reduced appetite.
- **Inability to eat:** This can be due to restrictions imposed by surgery or investigations, reduced levels of consciousness; confusion; difficulty in feeding oneself due to weakness, arthritis or other conditions such as Parkinson's disease, dysphagia, vomiting, painful mouth conditions, poor oral hygiene or dentures.
- **Gut:** Changes in the gut microflora can affect digestion and absorption of nutrients. With a reduced immune system, there may be bacterial overgrowth in the gut, or conversely, the use of antibiotics may reduce the beneficial gut flora, leading to diarrhoea or constipation (probiotics such as acidophilus may help counteract this). With the ageing process, there is also reduced efficiency of motility of gut muscle.
- **Drug use:** Drugs can affect the absorption and metabolism of some nutrients. As a population, older people use a large percentage of prescribed medication, and many are often using more than one drug, as well as some over-the-counter medicines. Clinical effects of these drugs on an already less efficient metabolism can be loss of appetite and taste changes from chemotherapy and analgesics, or specific nutrient interactions, for example hypokalaemia with loop diuretics and hypocalcaemia from corticosteroids.[6] Tetracycline and ciprofloxacin affect absorption of calcium and magnesium.
- **Lack of food availability:** Poverty; poor-quality diet at home, in hospital or in care homes; problems with shopping and cooking.
- **Impaired absorption:** This can be due to medical and surgical problems effecting digestion and stomach, intestine, pancreas and liver.
- **Altered metabolism:** Increased or changed metabolic requirements related to illness, ie, cancer, surgery, organ dysfunction, or treatment.
- **Excess losses:** Vomiting; diarrhoea; stomas; losses from nasogastric tube and other drains or skin exudates from burns.

CONSEQUENCES OF MALNUTRITION

- Increased risk tof infections.
- Delayed wound-healing.
- Impaired respiratory function.
- Muscle weakness and depression.

> *The best indicators of poor nutrition are measurements of weight and height. Other measures in specialist circumstances include skin-fold thickness, arm circumference and grip strength measurements*

DETECTION OF MALNUTRITION

Although biochemical measurements can contribute to nutritional assessment, none can reliably measure nutritional risk, ie, a low serum albumin is almost always a marker of a fluid overload rather than a marker of malnutrition.

The best indicators of poor nutrition are measurements of weight and height. Other measures in specialist circumstances include skin-fold thickness, arm circumference and grip strength measurements. These generally need an experienced assessor. These measurements can then be used with the following questions:

- Has your patient been eating a normal and varied diet in the last few weeks?
- Has your patient experienced intentional or unintentional weight loss recently? Obesity or fluid balance changes and oedema may mask loss of lean tissue. Rapid weight loss is a concern in all patients, whether obese or not.
- Can your patient eat, swallow, digest and absorb enough food safely to meet their likely needs?
- Does your patient have an unusually high need for all or some nutrients? Surgical stress, trauma, infection, metabolic disease, wounds, bedsores or history of poor intake may all contribute to such a need.
- Does any treatment, disease, physical limitation or organ dysfunction limit your patient's ability to handle the nutrients for current or future needs?
- Does your patient have excessive nutrient losses through vomiting, diarrhoea, surgical drains, etc?
- Does a global assessment of your patient suggest under-nourishment — low body weight, loose-fitting clothes, fragile skin, poor wound-healing, apathy, wasted muscles, poor appetite, altered taste sensation, altered bowel habit. Discussion with relatives may be important.
- In light of all of the above, can your patient meet all of their requirements by voluntary choice from the food available?

Understanding that asking these questions takes a significant amount of time and expertise, a number of screening tools have been developed to help identify whether a patient is at risk of malnutrition. Examples include the **Mini Nutritional Assessment (MNA)**[7] and the **Malnutrition Universal Screening Tool (MUST)** developed by BAPEN. Performing a routine nutritional 'screening' should result in early identification of patients who might have otherwise been missed.

NURSING CARE STRATEGIES

A Collaboration

1. Refer to dietitian if patient is at risk for or has under-nutrition.
2. Consult with pharmacist to review patient's medications for possible drug-nutrient interactions.
3. Consult with a multidisciplinary team specialising in nutrition.
4. Consult with social worker, occupational therapist, and speech therapist as appropriate.

B Alleviate dry mouth

1. Avoid caffeine; alcohol; tobacco; and dry, bulky, spicy, salty, or highly-acidic foods.
2. If patient does not have dementia or swallowing difficulties, offer sugarless hard candy or chewing gum to stimulate saliva. Biotene and Bioxtra gels, mouthwashes and chewing gum can relieve dry mouth.
3. Keep lips moist with petroleum jelly.
4. Encourage frequent sips of water.

C Maintain adequate nutritional intake

Daily requirements for healthy older adults include 30kcal per kg of body weight and 0.8-to-1g/kg of protein per day, with no more than 30 per cent of calories from fat. Carbohydrate, protein, and fat requirements may differ, depending on degree of malnutrition and physiological stress.

D Improve oral intake

1. Mealtime rounds to determine how much food is consumed and whether assistance is needed.
2. Limit staff breaks to before or after patient mealtimes to ensure adequate staff are available to help with meals.
3. Ask family to bring favorite foods from home when appropriate.
4. Ask about and aim to fulfill patient food preferences.
5. Suggest small, frequent meals with adequate nutrients to help patients regain or maintain weight.
6. Provide nutritious snacks.
7. Help patient with mouth care and placement of dentures before food is served.

E Provide conducive environment for meals

1. Remove bedpans and urinals from room before mealtime.
2. Administer analgesics and antiemetics on a schedule that will diminish the likelihood of pain or nausea during mealtimes.
3. Serve meals to patients in a chair if they can get out of bed and remain seated.
4. Create a more relaxed atmosphere by sitting at the patient's eye level and making eye contact during feeding.
5. Order a late food tray or keep food warm if patients are not in their room during mealtime.
6. Do not interrupt patients for round and non-urgent procedures during mealtimes.

F Specialised nutritional support[8]

1. Start specialised nutritional support when a patient cannot or will not eat adequately and if the benefits of nutrition outweigh the associated risks.
2. Prior to initiation of specialised nutritional support, review the patient's advanced directives regarding the use of artificial nutrition and hydration.

Provide oral supplements

Supplements should not replace meals but rather be provided between meals, but not within the hour preceding a meal and at bedtime.[9]

ORAL NUTRITIONAL SUPPLEMENTS

The type of oral nutritional supplements (ONS) most commonly prescribed in the community are the 'sip feeds', which include ready-made milk-, juice- and yoghurt-based or savoury drinks. Other formulations available include dessert-type products and powder supplements that are made up into a drink/added to drinks or food. These products contain different amounts and types of vitamins, minerals and/or macronutrients.

Although ONS are widely used, currently, the evidence base for their usage is mixed. The American Dietetic Association has stated that the best nutritional strategy for promoting optimal health and reducing the risk of chronic disease is to have a varied diet.[10] Long-term usage might result in reduced food intake.[11] A UK study also showed no association between ONS and improvements in either mortality or functional outcomes.[11]

Food is the best vehicle for appropriate nutrient consumption.[12] According to the National Medicines Information Centre in St James's Hospital, Dublin, no studies have yet determined the optimum usage of ONS in terms of the most appropriate patients, the optimum dose and duration of use.[13] Despite lack of evidence, ONS has a role in many circumstances; therefore, it is important to liaise with nutrition specialists such as dieticians before ONS can be recommended. For the added reason of the high cost of ONS to the State, the HSE recommends that ONS are only commenced after the patient is assessed by a dietician. ●

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Ciara Gavin MPSI

Making headway in MIGRAINE

A clinical overview of the characteristics of migraine, its effect on a patient's quality of life and how the pharmacist can help to alleviate the symptoms

Migraine is a chronic, genetically-determined, episodic neurological condition.[1,2] About one-third of migraine sufferers experience transient neurological symptoms, known as auras — this group are referred to as 'migraine with aura' or 'MA',[1] although aura can occur without headache.[2]

Migraines, although complex, are considered a common neurological condition.[3] The World Health Organisation classified migraines as the seventh-most disabling disease worldwide, the fourth for women, and the sixth-highest cause of years lost due to disability worldwide.[3,4] As this statistic shows, female gender is a risk factor for migraines. Other risk factors include family history of migraine, high caffeine intake, and stress.[2,5]

Migraines can have the following features:[6]

- The pain can be located as unilateral or bilateral.
- The pain can be described as 'pulsating'.
- The intensity of the pain a person feels is considered moderate or severe.
- The pain is aggravated by routine activities of daily living.
- Usually, the patient will complain of sensitivity to light and/or sound, nausea and/or vomiting.
- A migraine headache typically lasts four-to-72 hours in adults.
- Can be episodic (occurring less than 15 days per month), or chronic (equal to or more than 15 days per month for more than three months).

Migraines with aura[6] include visual symptoms such as flickering lights, spots or lines and/or partial loss of vision; sensory symptoms, such as numbness and/or pins and needles; and/or speech disturbance.

Symptoms can occur with or without headache. These symptoms are:

- Fully reversible.
- Develop over at least five minutes.
- Last five-to-60 minutes.

Some women are affected by **menstrual-related migraine.**[6] These migraines predominantly occur between two days before and three days after the start of menstruation in at least two out of three consecutive menstrual cycles.[2,6]

ACUTE TREATMENT

Treatment options remain the same, whether treating a migraine with or without aura.

Combination therapy consisting of:

- Oral triptan + an NSAID[6,7,8] (NSAID options include: Aspirin, ibuprofen 300-400mg up to four times a day, naproxen 500mg up to twice a day, diclofenac 50-to-75mg maximum of 150mg in 24 hours).
- Oral triptan + paracetamol.[6,7]

▸ For patients who prefer monotherapy, then consider treatment with an oral triptan alone, NSAID, aspirin or paracetamol.[6,7]

▸ Patients should consider an antiemetic in addition to other treatment, even in the absence of nausea and vomiting.[6] Antiemetics are considered for their nausea and/or for the prokinetic effect, such as: Domperidone 10mg up to three times a day; metoclopramide 10mg up to three times a day; or prochlorperazine 3-6mg as a buccal preparation (max 12mg/day) — unlicensed.[7,8]

▸ Do not offer ergots or opioids for the acute treatment of migraine.[6]

▸ For those who cannot tolerate oral preparations for the treatment of acute migraine, consider:

- Non-oral preparation of metoclopramide or prochlorperazine[6] and a non-oral NSAID or triptan.[6]

Triptans

Triptans are 5HT 1B/1D receptor agonists. Their action is due to vasoconstrictive effects on blood vessels.[7] There are seven triptans available in Ireland — these are: Almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, and zolmitriptan.[7,8]

Triptans should be used at the start of the headache phase of a migraine, as there is no evidence of efficacy if taken during the preceding aura.[7] Triptans can be associated with overuse headaches and therefore are reserved to be used no more than two days a week and no more than 10 days per month.[2,7]

The choice of triptan to use is dependent on cost, route, formulation available and patient-dependant factors. Patients' response to triptans is a key factor; some patients may experience recurrence headaches within 24-to-48 hours and respond to a second dose, while others respond better to a change in formulation.[2,7]

Example scenarios:

Patients suffering early nausea and vomiting may benefit from treatment with non-oral triptan formulations, such as:[7]

- Sumatriptan nasal spray 10mg, or
- Zolmitriptan 5mg nasal spray, or
- An orodispersible triptan formulation, such as zolmitriptan 2.5mg melts or rizatriptan 10mg wafers.

Patients may be suffering recurrence of headaches, therefore a longer-acting oral triptan may be more beneficial, ie:[7]

- Naratriptan 2.5mg.
- Almotriptan 12.5mg.
- Frovatriptan 2.5mg.

INFORMATION ON TRIPTANS

The side-effects for triptans include dizziness, drowsiness, flushing and nausea.[7,8] The side-effects tend to be related to the speed of onset of medication action; therefore people taking subcutaneous sumatriptan report more adverse effects than oral sumatriptan. Triptans with longer half-lives and slower onset of action, ie, naratriptan and frovatriptan, have fewer side-effects.[7] Subcutaneous sumatriptan has the most rapid onset of action and greatest efficacy, but the most adverse effects.[9]

Dizziness and sedation occur more with rizatriptan and zolmitriptan than with sumatriptan and naratriptan.[7] For specific information related to product side-effects, access the medications' SPC.

Triptans are not recommended in those with uncontrolled hypertension, cardiovascular and/or cerebrovascular disease due to the 5HT1B receptors present on vascular smooth muscles.[7]

PREVENTIVE THERAPY

Along with encouraging reduction of modifiable risk factors, such as reduced stress and reduction in caffeine intake, patients should be encouraged to keep a headache diary in order to record the frequency, duration and severity of headaches, help identify triggers and assess the effectiveness of treatment.[6]

If a prescriber deems it necessary due to interference with quality of life, pharmacological prophylactic therapy can be considered.

Treatment options include:

- Antiepileptic drugs:[6,11] Topiramate and valproate have been shown to reduce migraine frequency by 50 per cent in some cases.
- Antidepressants:[6,11] Amitriptyline has been shown to reduce migraine frequency by 50 per cent.
- Beta blockers:[6,11] Propranolol and atenolol have been shown to be beneficial in migraine prevention.
- Some studies show the benefit of ACE and ARB inhibitors and calcium channel blockers in migraine prophylaxis, including the more commonly-seen candesartan.[11]

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Triptan treatment options[8,10]

Triptan	Formulation	Notes
Zolmitriptan	Film-coated tablets/ orodispersible tablets	**Dose:** 2.5mg as early as possible after onset of migraine headache. If symptoms of migraine recur within 24 hours following an initial response, a second dose may be taken. If a second dose is taken, it should not be taken within two hours of the first dose. If the patient has not responded to the first dose, a second dose should not be taken for the same attack.
Zolmitriptan	Nasal spray	**Dose:** 5mg nasal dose is administered into one nostril. This provides a particularly rapid onset of relief of migraine, with the first signs of efficacy apparent within 15 minutes of dosing. If symptoms persist or return within 24 hours, a second dose can be given. If a second dose is given, it cannot be taken within two hours of the initial dose.
Sumatriptan	Nasal spray, dispersible and non-dispersible tablets and subcutaneous injection	**Dose:** ORAL: 50mg-100mg initially, followed by 50-100mg after two hours if needed if migraine recurs. Maximum 300mg per day. SUBCUTANEOUS: 6mg initially, followed by 6mg after at least one hour if needed if migraine recurs. Maximum 12mg per day. NASAL SPRAY: 10-20mg dose into one nostril. The dose may be repeated once after at least two hours if the headache recurs, with no more than two doses of 20mg in 24 hours.
Almotriptan	Tablets	**Dose:** 12.5mg dose as soon as possible, followed by 12.5mg after two hours if needed if migraine recurs. Do not take a further dose for the same attack. Maximum 25mg in 24 hours.
Eletriptan	Film-coated tablets	**Dose:** 40mg taken initially, followed by 40mg after two hours if the headache recurs. Dose should not be taken if no response to first dose. Increased if necessary to 80mg, dose to be taken for subsequent attacks if 40mg dose inadequate. Maximum 80mg per day.
Frovatriptan	2.5mg tablets oral	**Dose:** 2.5mg as soon as possible, followed by 2.5mg after two hours if required if migraine recurs. Maximum 5mg per day.
Naratriptan	2.5mg tablets	**Dose:** 2.5mg followed by 2.5mg after at least four hours if required, only if migraine recurs, not if no response to initial treatment. Maximum 5mg per day.
Rizatriptan	Orodispersible tablets 10mg	**Dose:** 10mg dose as soon as possible after onset, followed by 10mg after two hours if migraine recurs. Maximum 20mg in 24 hours.

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Zomig® ZOLMITRIPTAN Rapimelt

Headache response achieved as early as **30 minutes**.[1]*

Convenient and discreet to use. Can be taken without water.[2]

Zomig® ZOLMITRIPTAN Tablet

For patients who prefer conventional tablets, Zomig 2.5 mg tablets are also available.[3]

Zomig® Rapimelt Dosing: 2.5 mg recommended dose rapidly dissolves when placed on tongue. If satisfactory relief is not obtained with Zomig 2.5 mg dose, 5 mg doses can be taken for subsequent attacks. (See SmPC for full dose information).[2]

Zomig Tablets and Zomig Rapimelt Orodispersible Tablets Prescribing Information. Refer to the Summary of Product Characteristics (SmPC) before prescribing. **Presentation:** Zomig 2.5 mg (yellow) film-coated tablets contains 2.5 mg of zolmitriptan. Zomig Rapimelt 2.5 mg (white) orodispersible tablets contain 2.5 mg of zolmitriptan. **Indication:** Zomig Tablets and Zomig Rapimelt are indicated for the acute treatment of migraine headache with or without aura. **Dosage and method of administration:** *Zomig Tablets:* swallow whole with water. *Zomig Rapimelt:* Take orally. Dissolves rapidly when placed on the tongue and swallowed with patient's saliva. Drink of water is not required. *Dosage:* The recommended dose of Zomig Tablets / Rapimelt to treat a migraine attack is 2.5 mg. It is advisable to take Zomig as early as possible after the onset of migraine headache. If symptoms recur within 24 hours following an initial response, a second dose may be taken. If no response to first dose, it is unlikely that a second dose will be of benefit in the same attack. A second dose should not be taken within 2 hours of the initial dose. If unsatisfactory relief with 2.5 mg dose, 5 mg dose can be considered for subsequent attacks. Total daily dose should not exceed 10 mg. Not indicated for prophylaxis of migraine. *Paediatric population (0 – 17 years inclusive):* not recommended. *Elderly (over 65 years):* not recommended. *Hepatic impairment:* no dose adjustment in mild or moderate impairment. In severe impairment, maximum dose of 5 mg in 24 hours is recommended. *Renal impairment:* No dosage adjustment if creatinine clearance is more than 15 ml/min. **Contraindications:** Hypersensitivity to ingredients, moderate or severe hypertension and mild uncontrolled hypertension, concurrent administration of ergotamine, derivatives of ergotamine, sumatriptan, naratriptan and other $5HT_{1B/1D}$ receptor agonists, patients with history of cerebrovascular accident or transient ischaemic attack, creatinine clearance less than 15 ml/min. Should not be given to patients who have had myocardial infarction or have ischaemic heart disease, coronary vasospasm, peripheral vascular disease or patients with symptoms or signs consistent with ischaemic heart disease. **Special warnings and precautions:** only use where clear diagnosis of migraine. Care should be taken to exclude other potentially serious neurological conditions in patients not previously diagnosed as migraineurs and in those who present with atypical symptoms. Not indicated in hemiplegic, basilar or neurological conditions. Cerebral haemorrhage, subarachnoid haemorrhage, stroke, and other cerebrovascular events have been reported in patients treated with $5HT_{1B/1D}$ agonists. Should not be given to patients with symptomatic Wolff-Parkinson-White syndrome or arrhythmias associated with other cardiac accessory conduction pathways. In very rare cases, coronary vasospasm, angina pectoris and myocardial infarction have been reported. In patients with risk factors for ischaemic heart disease, cardiovascular evaluation prior to treatment is recommended. Heaviness, pressure or tightness over the precordium have been reported. If symptoms consistent with ischaemic heart disease occur, stop zolmitriptan and carry out appropriate evaluation. Transient increases in systemic blood pressure have been reported in patients with and without a history of hypertension. Do not exceed recommended dose. Rare reports of anaphylaxis/ anaphylactoid reactions. Serotonin Syndrome has been reported with combined use of triptans, Selective Serotonin Reuptake Inhibitors (SSRIs) and Serotonin Norepinephrine Reuptake Inhibitors (SNRIs). Careful observation of the patient is advised for signs of serotonin syndrome, if concomitant treatment with Zomig and a SSRI or SNRI is necessary particularly during treatment initiation and dosage increases. Undesirable effects maybe more common with concomitant use with St John's wort. Diagnosis of medication overuse headache should be suspected in patients who have frequent daily headaches despite (or because of) regular use of headache medications. *Zomig Tablets:* Should not use with hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption. *Zomig Rapimelt:* Inform patients with phenylketonuria that Zomig Rapimelt contains phenylalanine. **Interactions:** no clinically relevant differences in pharmacokinetics in studies with caffeine, ergotamine, dihydroergotamine, paracetamol, metoclopramide, pizotifen, fluoxetine, rifampicin and propranolol. Advisable to wait at least 24 hours following use of ergotamine before administering Zomig due to the theoretical possibility of increased risk of coronary vasospasm. Wait at least 6 hours following Zomig before administering ergotamine products. Avoid concomitant use of other $5HT_{1B/1D}$ agonists within 24 hours of Zomig. 5 mg Zomig maximum in 24 hours in patients taking MAO-A inhibitors. Do not use together if dose of mocobemide is higher than 150 mg b.i.d.. 5 mg Zomig maximum in 24 hours when taking cimetidine. Similar dose reductions recommended in CYP 1A2 inhibitors (fluvoxamine and quinolone antibiotics). Following administration of Rifampicin, no clinically relevant differences in pharmacokinetics of Zomig or its active metabolite. Serotonin syndrome reported with combined use of triptans, SSRIs and SNRIs. Zomig could delay absorption of other drugs. **Pregnancy and lactation:** Use in pregnancy only if the expected benefit is greater than any possible risk to the foetus. Caution when administering to women who are breast-feeding. Avoiding breast-feeding for 24 hours after treatment to minimise infant exposure. **Driving and using machines:** no significant impairment of performance of psychomotor test with doses up to 20 mg. Caution in patients performing skilled tasks as drowsiness and other symptoms may occur during migraine attack. **Undesirable effects:** typically mild/moderate, transient, not serious and resolve spontaneously without additional treatment. *Common (≥1/100, <1/10):* Abnormalities or disturbances of sensation, dizziness, headache, hyperaesthesia, paraesthesia, somnolence, warm sensation, palpitations, abdominal pain, dry mouth, nausea, vomiting, dysphagia, muscle weakness, myalgia, asthenia, heaviness, tightness, pain or pressure in throat, neck, limbs or chest. *Other important undesirable effects:* tachycardia *(uncommon ≥1/1000, <1/100),* anaphylaxis/anaphylactoid reactions, hypersensitivity reactions, angioedema *(rare ≥1/10,000, <1/1000),* angina pectoris, myocardial infarction, bloody diarrhoea, gastrointestinal infarction or necrosis, gastrointestinal ischaemic events, ischaemic colitis, splenic infarction *(very rare <1/10,000).* Additional information is available on request. **Overdose:** Monitor patients for at least 15 hours or while symptoms / signs persist. No specific antidote. In severe intoxication, intensive care procedures recommended, including establishing and maintaining a patent airway, ensuring adequate oxygenation and ventilation and monitoring and support of cardiovascular system. Effect of haemodialysis or peritoneal dialysis on serum concentrations of zolmitriptan is unknown. **Legal classification:** POM. **Marketing Authorisation numbers and pack sizes: Zomig 2.5mg tablets:** PA 2242/4/1, 6 pack. **Zomig Rapimelt 2.5mg orodispersible tablets:** PA 2242/4/2, 6 pack. **Marketing Authorisation Holder:** Grünenthal Pharma Ltd., 4045 Kingswood Road, Citywest Business Park, Citywest, Co. Dublin, Ireland. **M-ZMG-IE-11-18-0001. Date of Preparation: November 2018**. **References: 1.** Rapoport et al. Zolmitriptan conventional and orally disintegrating tablets achieve headache response as early as 30 minutes post treatment: results of a pooled data analysis. Cephalalgia 2003;23:581-762 (P718 - P5N97). **2.** Zomig 2.5 mg Rapimelt Summary of Product Characteristics. **3.** Zomig 2.5 mg Tablets Summary of Product Characteristics. *Reduction in migrane headache intensity from moderate to severe to mild or no pain, Zomig 2.5 mg vs placebo. **Date of Preparation:** September 2019. M-ZOM-IE-09-19-0002.

SAME-SAME, BUT

The Ford Mondeo has been around for almost 30 years and now the American marque has given the stalwart family saloon a contemporary hybrid engine to appeal to the surge in customer demand for electrically-assisted cars, writes Morgan Flanagan Creagh

Though late to the game, this Mondeo Hybrid Electric Vehicle (HEV) estate offers an alternative for a motorist with a family who doesn't want a crossover or a diesel engine. The Mondeo was once one of Ford's best-selling cars, however it's now slid down to 49th place and with 3/5 of Ireland's top-selling cars being crossovers (here comes a sentence I never thought I'd write), how about standing out from the crowd and embracing the counter-culture by driving a Mondeo?

The hybrid Mondeo, aside from being electric motor-powered, torque-filled, with silent acceleration, felt exactly like a Mondeo. No weird stuff or surprises; you don't have to lick the steering wheel to activate the handbrake or anything like that. It was almost exactly what you expect, like a pub carvery dinner, only this time made with a plant-based beef alternative. Think Coke Zero, only a Ford Mondeo. Personally, I like estates, though they have never sold particularly well in Ireland compared to the UK or mainland Europe. I tested the diesel saloon Mondeo in 2018 and described it as "the ultimate all-rounder for your family's needs" and in terms of hybrid estate cars, the Mondeo doesn't have much competition in its price segment.

Inside was spacious, comfortable and the trim was unmistakably Ford-ish. The long boot, however, wasn't as deep as its diesel brother because the batteries are located beneath and thus reduce the overall capacity, however it still

DIFFERENT

TECH SPECS

FORD MONDEO TITANIUM ESTATE - HYBRID

- 2.0 Automatic HEV 187 PS
- CO2 emissions (g/km) 126-140
- Colour: Moondust silver

FEATURES ON TITANIUM HEV

- 16" alloy wheels
- Power folding door mirrors
- SYNC 3 with 8" touchscreen
- Parking sensors – front and rear
- Keyless entry
- Cruise control + speed limiting device
- Traffic sign recognition
- Lane keeping aid

offers 403 litres with the back seats in place and 1,508 litres with them folded down. This car also offers a specially-developed exhaust gas heat recovery system that enables faster cabin warming for those chilly winter mornings.

This Mondeo HEV is a usable, practical daily driver that offers a low entry price point, as well as a Government VRT rebate and €180 annual road tax. The electric motor uses regenerative braking technology to capture up to 90 per cent of the energy normally lost during braking in order to replenish the battery, meaning you don't need a home charging port to top-up your electric motor. It uses a 2.0-litre non-turbo petrol engine that utilises an Atkinson combustion cycle system to produce 184hp. The hybrid powertrain combines the Atkinson cycle petrol engine; electric motor; generator; 1.4 kWh lithium-ion battery; and a Ford-developed power-split automatic transmission, for a very futuristic hybrid offering.

According to research conducted by easytrip.ie, one-in-four motorists are considering buying a new car in 2020 and 36 per cent of them want a hybrid. For this very reason, I'd be surprised if it didn't outsell its diesel brother, in fact Roelant de Waard, Vice President, Marketing, Sales and Service, Ford of Europe, said the "Mondeo Hybrid offers a compelling alternative to diesel powertrains" and he expects "the Hybrid to account for up to 50 per cent of sales".

The entry price for the Mondeo is €32,580, however the starting price for the test model I drove, the 'Titanium estate HEV', is €35,247. My test car had some optional extras too, putting the price up to €36,197.

The Ford Mondeo HEV is a safe pair of hands, it's well built and historically, its motors have been reliable and long-lasting. It's not a show-stopping car, but it's a very dependable workhorse and with the hybrid-assisted fuel consumption figures of almost 70mpg (4.2l/100km), it will be a frugal too. If you're the type of person who doesn't take well to change, then this is the perfect car for you to safely dip your toe into the future of motoring without the scary prospect of plugs, charging points or Prius ownership.

DISTRIBUTION AGREEMENT

Accord and Adienne enter into exclusive distribution agreement for Tepadina

Accord Healthcare Limited ('Accord') and Adienne Pharma and Biotech SA ('Adienne') have entered into an exclusive licencing and distribution agreement for the commercialisation of Tepadina (thiotepa) 15mg and 100mg lyophilised powder for concentrate for solution for infusion. Adienne is also working on new delivery presentations for Tepadina and other oncology and cytotoxic drugs to improve and enhance the healthcare professional and patient experience.

The new delivery presentations for Tepadina will be commercialised by Accord in Ireland, across Europe and India. With this new partnership, Accord secures exclusive rights to market, commercialise and sell Adienne's chemotherapy brand Tepadina, which will be supported by an expert sales force and a seasoned marketing team that has successfully launched multiple oncology products in Europe. Accord will begin selling Tepadina across select markets in the European region, such as Ireland, Italy, Spain, UK, Benelux and Portugal.

Additional markets will be included in 2020, with the aim of Accord becoming the sole distributor across all European markets by early 2021. Adienne will continue to be the marketing authorisation holder in the territories and will be responsible for the manufacture and supply of the product. Tepadina is indicated in combination with other chemotherapy medicinal products, in the conditioning regimens before autologous and allogeneic haematopoietic stem cell transplantation to treat haematological diseases and solid tumours, both in the adult and paediatric populations. It has been granted orphan drug designations by the European Medicines Agency (EMA) and by the US Food and Drug Administration (FDA).

Dr Antonio Francesco Di Naro, founder, owner and President of Adienne, said: "We are very pleased to have established this collaboration with Accord, whose established track record of successful marketing of complex oncology and specialty products gives us confidence that they are the best partner for our Tepadina product. Accord has a remarkable commercial team and infrastructure in place, and we are highly confident in their ability to successfully leverage that platform with us."

Mr James Burt, Executive Vice President, Europe and MENA, Accord, said: "We are committed to bringing complex, added-value products to improve the lives of cancer patients. This agreement builds on our oncology platform, adding to our extensive oncology experience in Europe, where we supply more than 35 oncology products across the region. We are excited to take over the commercialisation of this product, which will provide tangible advantages to patients and healthcare providers, and we look forward to a mutually beneficial and successful collaboration with Adienne."

MS INDEX

MS Index highlights severe lack of specialist healthcare services for people living with MS in Ireland — The FutureProofing Healthcare MS Index focuses on the treatment of MS across 30 European countries, with Ireland ranking in bottom third overall

A severe lack of specialist services and healthcare specialists — such as neurologists, physiotherapists, occupational therapists and psychologists — is impacting the level of care and quality of life for people living with multiple sclerosis (MS) in Ireland and their families. That's according to the FutureProofing Healthcare MS Index, in which Ireland ranked 22nd out of 30 European countries.

A series of panel meetings have taken place at which Irish healthcare experts and people living with MS have interrogated the data in an Irish context and called for urgent action to be taken to address the deficit of specialist services and access to information for people affected by the disease in Ireland. These panels have included former Tánaiste and Minister for Health Mary Harney; GP and media commentator Dr Nina Byrnes; Chief Executive of MS Ireland, Ms Ava Battles; and Ms Rebecca Maguire, Lecturer in Psychology at Maynooth University.

The MS Index — which was led by an independent panel of experts, in partnership with Roche — gives an in-depth analysis of the state of care for MS in 30 European healthcare systems, based on data from reputable public sources such OECD, Eurostat, MS Barometer and *The Lancet*. The Index measures each country's performance based on three Vital Signs, with each made up of a number of individual measures.

Key findings of the FutureProofing Healthcare MS Index for Ireland:

1. Diagnosis and Outcomes: Ireland performed worse than 24 other European countries for this vital sign. The Index explored a number of measures within this vital sign which led to this score, including the severe shortage of neurologists per capita in Ireland, and a low number of MRI units available. While the country performed moderately well on outcomes, the Index found that only one-quarter of people living with MS in Ireland are in the workforce.

2. Support and Management: Ireland lagged significantly behind most other Western European countries for this Vital Sign. This can be put down to multiple areas of weakness outlined by the Index in this area, including both a shortage of healthcare professionals and lack of access to rehabilitation services.

3. Daily Living: Ireland ranked 21st in Europe for this vital sign, which was calculated based on measures including availability of flexible working conditions, sick pay, disability benefits, youth support, and cost of housing. The Index found that the length of statutory sick pay and level of disability benefits are relatively short/low in Ireland, while there is a moderate ability for people with disabilities to set their own flexible working arrangements.

Speaking about the findings, Ms Battles said: "Ireland's performance in the MS Index is quite poor, which is unsurprising due to the chronic lack of specialist services available to people living with MS in this country. Ireland has two neurologists per 100,000 people, which — along with the UK — is the lowest seen across all 30 countries. There is also no rehabilitation centre available for people with MS in Ireland. However, it's also clear from analysing the Index findings that there is a severe lack of data available at national or European level to allow us to get an accurate picture of the state of care for people living with MS. That is something that needs to be addressed, potentially through a patient register, similar to that which we have for other disease areas, such as the National Cancer Registry."

Speaking about the findings, Mr Pierre-Alain Delley, General Manager of Roche Products (Ireland) Limited, said: "The purpose of this Index is to gather data from across Europe for the first time to allow us to gain a deeper understanding of the challenges faced by people living with MS and their families. By working with partners and experts and most importantly, patients, Roche is committed to co-creating truly patient-centric healthcare systems and we hope this Index will serve as a vehicle to drive these much-needed initiatives."

The FutureProofing Healthcare MS Index has aggregated over 660 data points on 18 individual healthcare measures from reputable public sources, such as WHO, OECD and Eurostat across 30 European countries.

Review the **MS Index** data by visiting **www.futureproofinghealthcare.com/multiple-sclerosis-index**.
Join the conversation using **#FutureProofIndex** and follow on
twitter.com/FutureProofHlth
facebook.com/futureproofing-healthcare
instagram.com/futureproofhlth

An overview of key findings from the Index can also be viewed in this short video, which you are welcome to share: **http://bit.ly/MSIndexIRE**

LICENSE EXTENDED

Toujeo (insulin glargine) EU licence extended for use in adolescents and children from the age of six years with diabetes mellitus

The EU licence extension of Toujeo was supported by positive results from the EDITION JUNIOR trial.

Sanofi Ireland has announced that the European Commission (EC) has expanded the current indication for Toujeo (insulin glargine 300 units/mL) to include children and adolescents with diabetes. This licence extension means that Toujeo will now be available to all eligible diabetes patients from six years and above in Ireland. The new indication follows positive results in a phase 3 trial that found children and adolescents living with type 1 diabetes achieved comparable reduction in average blood sugar (HbA1c) and similar risk of low blood sugar events with Toujeo when compared to insulin glargine 100 Units/mL (Gla-100). Around 2,750 children and adolescents under the age of 16 in Ireland are currently living with type 1 diabetes. The incidence of type 1 diabetes is increasing by 3 per cent each year in Europe, and Ireland has one of the highest rates of type 1 childhood diabetes in Europe. Concerns over the number of adolescents living with type 2 diabetes are growing. Becoming overweight or obese can contribute to developing type 2 diabetes and in Ireland, 17 per cent of seven-year-olds are overweight or obese.

Dr Alok Gupta, Consultant Paediatric and Clinical Director, Darent Valley Hospital UK and Co-Chair for London and South East Coast Children Diabetes Regional Networks UK, said: "Diabetes is a long-term condition which is becoming more common in the UK and Ireland. It can have a major impact on the life of a young person, as well as those around them. Based on trial data, we can see that Toujeo may present a valuable treatment for many children and adolescents living with diabetes in the UK and Ireland. The licence decision is welcome news as it expands the treatment options we have available for this patient population."

EDITION JUNIOR is the first randomised, controlled trial comparing Toujeo vs Gla-100 in this group of patients. The study met its primary endpoint of demonstrating non-inferiority vs Gla-100 change in HbA1c from baseline at week 26. Toujeo provided similar glycemic control to Gla-100 in children and adolescents with type 1 diabetes, as well as similar risk of low blood sugar events (hypoglycemia). The percentages of patients who experienced severe hypoglycemia and who experienced high blood sugar (hyperglycemia) with ketosis were numerically lower with Toujeo vs Gla-100 (6% vs 8.8% and 8.2% vs 11.4%, respectively). As these are serious short-term complications, these findings may be clinically important for people with type 1 diabetes.

Prof Mike Baxter, Medical Therapy Expert for Sanofi, said: "Sanofi is committed to supporting people with diabetes in controlling their condition and reaching their treatment goals. The decision to extend the licence indication to children and adolescents expands the population of patients who can benefit from Toujeo and provides a new treatment option for many young people living with diabetes."

About Toujeo (insulin glargine 300 units/mL): Toujeo (insulin glargine 300 units/mL) is a solution for injection that contains the active substance insulin glargine. It is a long-acting human insulin analogue indicated for the treatment of diabetes in adults, adolescents and children from six years old. It is available in pre-filled SoloStar and now DoubleStar pens (for those requiring at least 20 units per day).

About EDITION JUNIOR: The EDITION JUNIOR study compared Toujeo to Gla-100 in 463 children and adolescents (aged 6 to 17 years) treated for type 1 diabetes for at least one year and with HbA1c between 7.5 per cent and 11.0 per cent at screening. Participants continued to use their existing mealtime insulin.
The study met its primary end-point, confirming non-inferior reduction of HbA1c with Toujeo vs Gla-100 after 26 weeks (mean reduction 0.4% vs 0.4%; difference: 0.004%, 95% CI -0.17 to 0.18; upper bound was below the pre-specified non-inferiority margin of 0.3%). Over the same period, a comparable number of patients experienced one or more anytime (24h) documented low blood sugar (hypoglycemia) events (Toujeo 97.0% vs Gla-100 97.8%). Numerically fewer patients using Toujeo experienced severe hypoglycemia, or experienced one or more episodes of high blood sugar (hyperglycemia) with ketosis vs Gla-100 (6% vs 8.8% and 8.2% vs 11.4%, respectively). The number of adverse events was comparable between the two treatment groups (65.2% vs 65.8% of patients reported any treatment-emergent adverse event). No unexpected safety concerns were reported, based on the established profiles of both products. The study design includes a further six-month safety follow-up period, which will be reported separately.

APPOINTMENTS

Pharmaforce announces appointment of recruitment specialist as Pharmed Group expansion continues

Contract sales outsourcing and recruitment experts Pharmaforce has further accelerated its growth plans with the appointment of Ms Alison Conroy as 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 Alison Conroy

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.

PRODUCT LAUNCH

Capasal shampoos

During winter, changes in temperature from cold winds, hot central heating and layers of woolly or fleecy clothes may make dry and itchy skin conditions worse. A number of triggers may irritate the skin and scalp and can cause flare-ups. These include stress and other environmental factors. These seasonal triggers may lead to an increase in patients coming into pharmacy asking for recommendations for dry, scaly scalp conditions. Dermal are promoting the Capasal shampoo range with advertising to the general public in national newspapers, supplements and magazines. Capasal shampoo comes in two formulations:

Capasaltm therapeutic shampoo is a specially formulated medicinal shampoo for the treatment of dry scaly scalp conditions such as seborrhoeic dermatitis, psoriasis and dandruff. It has a triple-action formulation to remove scales and relieve itching, with coconut oil to condition the hair.

Capasaltm herbal shampoo with 2% tea tree oil and coconut oil is an alternative to medicinal coal tar shampoos to help manage dandruff.

For patients with dry scaly scalp conditions, remember Capasal shampoo with moisturising coconut oil.

STUDY

Positive and negative wellness outcomes

A study carried out by the JE Cairnes School of Business and Economics at NUI Galway has examined how fitness apps can affect the wellbeing of the user. The research focused on identifying how the social features of fitness apps predict the type of passion (harmonious and obsessive) a person has for physical exercise and what the resulting positive and negative implications are for their wellbeing. Modern physical fitness apps such as Strava, Nike+, MyFitnessPal, RunKeeper, and Fitocracy are gamified to provide rewards to users based on the tracking and analysis of their digital trace data, ie, the number of steps walked per day, calories burned, or average speed of a cycle or run. The research found that fitness apps can lead to both positive and negative wellbeing outcomes, depending on the person's social motivation for using the app. People who use fitness apps for reciprocation (ie, giving encouragement to other exercisers) are more likely to have a harmonious passion for their exercise and ultimately lower life stress. In contrast, people who use the app for social recognition (ie, to receive praise and public endorsements) are more likely to develop an obsessive passion for physical exercise and suffer higher life stress in the long run.

Lead author of the study, Dr Eoin Whelan, Senior Lecturer in Business Information Systems, JE Cairnes School of Business and Economics at NUI Galway, said: "The majority of exercisers are now using digital technology to track and share their workout data in order to support their fitness goals.

"But these fitness apps can be a double-edged sword. Our study suggests fitness sharing apps can certainly help seed and sustain exercise routines, but there is a danger that some users may develop obsessive tendencies, which need to be avoided. [...] Fitness app social features which promote self-recognition, such as posting only positive workout data or photos, can be linked to maladaptive perceptions of exercise and burnout in the long run. In contrast, fitness app social features which promote reciprocation, such as giving support and commenting on colleagues' activities, are likely to lead to adaptive outcomes."

The study also flags to employers the risks and responsibilities of giving employees free fitness apps and incorporating them as part of employee wellness programmes. "Our results shed light on the dark side of fitness app engagement, in that they may indirectly lead to greater burnout. If the organisation supports fitness app use among employees, they should also be responsible for ensuring the employee maintains control over their exercise patterns. One possible solution could be for the organisation to monitor the exercise log files of employees and assess these for signals of exercise obsession," says Dr Whelan. The full study was published in the journal Information Technology and People. It was authored by Dr Whelan with Mr Trevor Clohessy, Department of Business Information Systems, Galway-Mayo Institute of Technology.

PRODUCT LAUNCH

New 'Measure Me' BMI app developed by Children's Health Ireland at Temple Street

The 'Measure Me' app has been developed to calculate the body mass index (BMI) standard deviation score (SDS) and to identify if a child is a healthy weight or overweight.

Parents and healthcare professionals need to know whether their child/paediatric patient is overweight so that they can address the issue as soon as possible. Unfortunately, the measurement of weight alone is not helpful for parents/healthcare professionals in terms of working out whether their child is at the correct weight.

This is because height is also required but while in adults the BMI can be calculated relatively easily, in children the BMI SDS must be calculated as children are still growing.

The sooner a child who is overweight is diagnosed, the easier it is to help that child achieve normal weight. This app facilitates earlier diagnosis, allowing parents and healthcare professionals to work together to reduce the number of children who become overweight.

The 'Measure Me' app has been developed by Children's Health Ireland at Temple Street and University College Dublin. It has been unconditionally supported by Consilient Health.

The app is available to download on a mobile or tablet by entering 'Measure Me' in the Apple iStore or the Google Play Store.

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