‘Divided loyalty’ is a challenge of ‘balance’ for pharmacists

By Pat Kelly

The International Pharmaceutical Federation (FIP) has urged authorities internationally to develop a transdisciplinary code of ethics and urged every country to produce and develop an up-to-date code. A statement document by the FIP entitled Codes of Ethics for Pharmacists outlines the minimum obligations that should be included in such codes and is designed to guide national associations and regulators, as well as pharmacists themselves.

“Pharmacists are increasingly called upon to make difficult choices in positions where they must balance their obligations to individual patients with those to their employers or places of employment,” said Mr Andy Gray, Chairman of the FIP Code of Ethics Policy Committee.

This applies not only to pharmacists who are employed by corporate structures in community, hospital or industrial settings, but also to those employed

‘No reason’ why HPRA should not make more medicines available OTC

By Zach Kelly

The Irish Pharmacy Union (IPU) has called on the Health Products Regulatory Authority (HPRA) to make more medicines available without prescription, citing moves in other jurisdictions.

The Union is focusing on three medicines in particular: Low-dose aspirin 75mg; fluconazole for the treatment of thrush; and chloramphenicol eye-drops and ointment for treating bacterial conjunctivitis.

“These medicines are available directly from pharmacists in the UK and other jurisdictions,” commented Ms Kathy Maher, IPU President. “There is no reason why they should not also be available to people in Ireland. We are calling, therefore, for more medicines to be made available without prescription, which will empower people to take more care of their own health, with appropriate advice and support from their pharmacist.”

In July, the HPRA announced that a number of medicines should be reclassified to OTC and Ms Maher sees such moves as an important step in helping patients to manage their own health.

“Making it easier for people to access a wider range of medicines directly from their pharmacist would help them to safely manage their own health and wellbeing with the professional help of a trusted healthcare adviser. Pharmacists are uniquely positioned to advise on the treatment of minor ailments and to deliver on the Government’s healthcare strategy of supporting patients in better managing chronic illness.”

Shelf life in Bangkok

A delegate at the 74th International Pharmaceutical Federation (FIP) World Congress of Pharmacy in Bangkok peruses the products of another pharmacist in the exhibition hall. The FIP World Congress hosted more than 1,938 pharmacists from 95 countries across the world under the overall theme of ‘Access to Medicines and Pharmacists Today, Better Outcomes Tomorrow’.

See news coverage on p12-14

INSIDE: News p10, 12, 14, 16 | Smoking cessation p4, 6, 8 | Ebola p17
Name of product: Nexium Control 20 mg gastro-resistant tablets
Active ingredient: Esomeprazole
Product licence numbers: EU/1/13/860/001 and EU/1/13/860/002
Name and address of the company responsible for placing on the market and where additional information available: Pfizer Healthcare Ireland, Citywest, Dublin 24
Supply classification: Pharmacy Only
Indications: The short-term treatment of reflux symptoms (e.g. heartburn and acid regurgitation) in adults.
Side Effects: Common: headache, abdominal pain, constipation, diarrhoea, flatulence, nausea/vomiting. Uncommon: peripheral oedema, insomnia, dizziness, paraesthesia, somnolence, vertigo, dry mouth, increased liver enzymes, dermatitis, pruritus, rash, miliaria, angio-oedema. Rare: leukopenia, thrombocytopenia, hypersensitivity reactions, peripheral oedema, angio-oedema, rash, urticaria. Very rare: anaphylaxis, pancreatitis, hallucinations, haemolytic anaemia, agranulocytosis, severe hypomagnesaemia, severe hypokalaemia, cholestatic jaundice, aplastic anaemia, meningitis, Guillain-Barré syndrome, angio-oedema. Further hypersensitivity reactions reported are dermatitis herpetiformis, Henoch-Schönlein purpura, angio-oedema, severe hypomagnesaemia, severe hypokalaemia,otalgia, paraesthesia, somnolence, vertigo, dry mouth, increased liver enzymes, dermatitis, pruritus, rash, miliaria, angio-oedema. 
Precautions: Patients should consult their doctor if: They have 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 mask symptoms and delay diagnosis. They have had previous gastric ulcer or gastrointestinal surgery. They have been on continuous symptomatic treatment of indigestion or heartburn for more than 8 weeks. They have jaundice or severe liver disease. They are over 55 years with new or recently changed symptoms. They are over 60 years with a new indication for long-term prevention of ulcer disease. They have been on continuous symptomatic treatment of indigestion or heartburn for more than 8 weeks. They have been on long-term treatment of indigestion or heartburn for more than 8 weeks. They have had previous gastric ulcer or gastrointestinal surgery. They have been on continuous symptomatic treatment of indigestion or heartburn for more than 8 weeks. They have had previous gastric ulcer or gastrointestinal surgery. They have been on continuous symptomatic treatment of indigestion or heartburn for more than 8 weeks.
Dosage and Method of use: 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. Once complete relief of symptoms has occurred, treatment should be continued for at least 2 weeks. Due to the nature of the condition, patients should be advised to take the tablets for 2-3 weeks. The tablets should be taken on an empty stomach 30 minutes before meals. Dose adjustment is not required in patients with impaired renal function. The tablets should be swallowed whole. No other liquid should be used as the enteric coating may be destroyed. The tablets should be stored in the original package or equivalent. Contact your doctor before taking this medicinal product if you are taking any other medicinal products concomitantly. This medicinal product contains a 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. Esomeprazole 20 mg should be excluded. Esomeprazole is an OATP1B1 substrate. Where starting or ending treatment with irbesartan, the potential for interactions with medicinal products metabolised through CYP enzymes should be considered. For diabetes patients: Patients on esomeprazole should be instructed to consult a doctor if they have new or increased symptoms of hypoglycaemia. Patients should be instructed to consult their doctor if they experience any of the following: nausea, vomiting, diarrhea, constipation, abdominal pain, headache, rash, uterine bleeding, increased liver enzymes, dermatitis, pruritus, rash, urticaria. Patients should be advised to consult their doctor if they experience any of the following: nausea, vomiting, diarrhea, constipation, abdominal pain, headache, rash, uterine bleeding, increased liver enzymes, dermatitis, pruritus, rash, urticaria. Patients should be advised to consult their doctor if they experience any of the following: nausea, vomiting, diarrhea, constipation, abdominal pain, headache, rash, uterine bleeding, increased liver enzymes, dermatitis, pruritus, rash, urticaria. 
Contra-indications: Hypersensitivity to esomeprazole, substituted benzimidazoles or to any of the excipients. Esomeprazole must not be used concomitantly with nelfinavir.
Date: April 2014
For full product information please visit www.medicines.ie
1. IMS Data on file based on worldwide value sales.
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professional development

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CPD: Hypertension

Exputex™
Carbocisteine mucolytic syrup

COMPLETE WITH
CHILD RESISTANT
TAMPER EVIDENT
CAP

SUGAR FREE
✓ Non drowsy
✓ Mentholated
✓ 300ml - the lowest cost sugar free carbocisteine mucolytic syrup (on a ml per ml basis 250mg/5ml)¹

Prescribing Information
Please refer to Summary of Product Characteristics [SmPC].

Exputex® 250mg/5ml Oral Solution

Presentation:
Carbocisteine provided as 250mg/5ml oral solution.

Uses:
As a mucolytic adjunct for respiratory tract disorders characterised by excessive or viscous mucous.

Dosage and administration:
Oral.
Adults/Elderly:
Three 5ml spoonfuls three times daily initially. Reduce to two 5ml spoonfuls three times daily when a satisfactory response has been obtained.
Children:
6-12 years: 5ml spoonful (250mg) two to three times daily.
2-5 years: Half a 5ml spoonful (125mg) two to three times daily. Under 2 years: Not recommended.

Contraindications:
Hypersensitivity, patients with known active peptic ulceration.

Special Warnings and Precautions:
Patients with a history of peptic ulceration, avoid in patients with active ulceration, patients on a controlled sodium diet.

Contains parahydroxybenzoates (E215, E217 and E219), sunset yellow FCF (E110) and ethanol.

Interactions:
None listed.

Pregnancy and Lactation:
Not recommended.

Undesirable Effects:
Nausea, headache, gastrointestinal upset and skin rash.

Overdose:
No experience. Serious effects not expected.

Legal category:
S1B(E)

Product Authorisation number:
PA 488/14/1.

Product Authorisation holder:
Monmouth Pharmaceuticals Limited, Hampshire International Business Park, Chineham, Basingstoke, Hampshire, RG24 8EP, UK. Distributed by: Cahill May Roberts, Pharmapark, Chapelizod, Dublin 20. Further information is available from Shire Pharmaceuticals Limited, Hampshire International Business Park, Cippenham, Slough, Berkshire, RG16 1BN, UK. Adverse events should be reported to the Pharmacovigilance Unit at the Irish Medicines Board (IMB) (pharmacovigilance@imb.ie). Information about adverse event reporting can be found on the IMB website (www.imb.ie). Adverse events should also be reported to Shire Pharmaceuticals Ltd on +44 1256 894000.
When the smoke clears...

Pharmacists are increasingly being asked to play a greater role in front line public health delivery. Pat Kelly looks at how the sector is promoting smoking cessation for the overall benefit of public health and health services themselves.

The impact of smoking on public health is not a new phenomenon but an important element is the increased role being played by pharmacists in reducing mortality and improving quality of life for countless patients. As the health service comes under increasing pressure through manpower issues, the emigration of other healthcare professionals and budget constraints, pharmacists have increasingly been called upon to shoulder a greater burden in improving the lives of patients and take pressure off the hospital sector.

Tobacco use is the leading cause of preventable death in Ireland and each year, some 5,200 people die from smoking-related diseases in Ireland alone and one in every two smokers will die from a disease associated with the habit.

In March of this year, the Irish Pharmacy Union (IPU) launched a nationwide quit smoking pharmacy service for community pharmacists nationwide to coincide with Ash Wednesday, supported by the HSE and the Irish Cancer Society. Launched by then Minister for Health Dr James Reilly, the service highlighted the practical role pharmacists can play in promoting smoking cessation, from providing pharmaceutical therapies to recommending lifestyle changes and nicotine replacement therapies, which have been shown to more than double the chance of quitting.

Minister Reilly commented at the launch: “This is a great initiative by pharmacists who are using their training and skills to help smokers make that quit attempt. Let there be no doubt — the single best thing a smoker can do for their health is quit and community pharmacists are very well placed to provide smokers with both behavioural and pharmaceutical evidence-based cessation supports to make that quit attempt a successful one.”

These cessation supports range from advising a patient when they need to see a GP for prescription medication to help them kick the habit, to advice on managing cravings.

Pharmacies are on average open 50 per cent longer than GP surgeries and Ms Kathy Maher, President of the IPU, concurred with Minister Reilly that pharmacists play a vital role as they are among the most accessible healthcare professionals. “Pharmacists can help motivate people to quit smoking and to stay tobacco-free in the long term, helping them decide what method works best for them and offering advice on supports… we understand that giving up smoking is a real challenge but the health benefits are so great, it is well worth it. A smoker can get back 10 years of their life.”

While smoking is well known to be implicated in a person developing lung cancer, it is also culpable in cancers of the mouth, bladder, throat, stomach, cervix, pancreas and kidney. Smoking also significantly increases the risk of developing leukaemia and doubles the likelihood of stroke and coronary heart disease. Chronic bronchitis and emphysema are also risk factors for the smoker and Dr Stephanie O’Keefe, HSE National Director of Health and Wellbeing, emphasised that providing supports to help people quit is one of the most important functions of healthcare professionals.

“Every smoker should be prompted and supported to quit each time they come into contact with healthcare professionals.”

‘Smoking an average of 20 cigarettes a day over a 10-year period costs the equivalent of €34,675. This breaks down as €67 a week, €298 a month and equates to €3,476 a year, with such a smoker spending some €69,350 over a 20-year period’
New once-monthly Ability Maintena® (aripiprazole) reduces the risk of relapse for your patients

Recurring relapse in schizophrenia can lead to clinical deterioration and decreased functioning.1 Ability Maintena® can significantly reduce the risk of relapse during long-term treatment2,3* and maintain personal and functional benefits.4,5

Indications: Abilify Maintena® is indicated for the maintenance treatment of schizophrenia.1

Dosage: The recommended starting and maintenance dose is 400 mg (2 ml, IM). Titration of the dose of this medicinal product is not required. In patients who are taking concomitant strong CYP3A4 inhibitors and/or strong CYP2D6 inhibitors for more than 14 days, aripiprazole dose should be reduced to 300 mg.4,5

Contraindications: Aripiprazole is contraindicated in patients with known hypersensitivity to aripiprazole or any of the excipients.

Precautions: Caution must be exercised when considering the use of this medicinal product in patients with a history of cardiovascular disorders (myocardial infarction, arrhythmias, or hypertension), because aripiprazole can exacerbate cardiovascular symptoms.4,5

Interactions: Aripiprazole and concomitant use of potent CYP3A4 inhibitors e.g. ketoconazole, itraconazole, HIV Protease inhibitors or strong CYP2D6 inhibitors e.g. paroxetine, may increase the risk of adverse reactions including extrapyramidal and/or withdrawal symptoms that may vary in severity and duration.4,5

UNDESIRABLE EFFECTS: Adverse drug reactions were reported during clinical trials and/or post-marketing use of aripiprazole. Adverse drug reactions were reported during clinical trials and/or post-marketing use of aripiprazole. Adverse drug reactions were reported during clinical trials and/or post-marketing use of aripiprazole. Adverse drug reactions were reported during clinical trials and/or post-marketing use of aripiprazole.

services,” commented Dr O’Keefe.

“The pharmacy service complements QUITline, the online HSE QUIT.ie service and the network of smoking cessation services all over the country… we’re delighted to join-up our QUIT supports with this initiative from pharmacists.”

Apart from the evidence-based implications of smoking, in modern Ireland the financial impact has become more important than ever. Figures provided by the IPU show that smoking an average of 20 cigarettes a day over a 10-year period costs the equivalent of €3,675. This breaks down as €67 a week, €298 a month and equates to €3,476 a year, with such a smoker spending some €69,350 over a 20-year period.

For the health service itself, smoking is also a significant public health burden. The average cost of treating a smoker as an inpatient for a tobacco-related illness in an Irish hospital is €7,700, while the cost of premature deaths due to smoking-related diseases was more than €3.5 billion in 2009 alone.

However, pharmacists are among the most dynamic driving forces striving to improve patients’ health and quality of life, reduce mortality and take pressure off valuable and much-needed healthcare resources.

Mr Fintan Moore, community pharmacist in Clondalkin and columnist, told Irish Pharmacist (IP) about some of his experiences in helping patients to achieve smoking cessation. “Between the smoking ban and greater awareness of the effects of smoking, I am seeing an increase in the number of people consulting about how they can quit,” says Mr Moore. “A lot of people also feel that if they have children, they should be making an effort to quit smoking.”

While some people may also ask about general health and lifestyle, Mr Moore says his preferred strategy is to deal with the issues of smoking cessation first and foremost and then deal with other lifestyle issues later, as necessary.

In terms of therapies, Mr Moore says that a treatment approach depends on how heavily a person smokes: “The inhalers are normally best for people who are termed ‘social smokers,’ for example,” he tells IP. “There are guidelines but sometimes there is no hard and fast rule. I have seen very heavy smokers quit successfully with products that are designed for lighter smokers, so it is variable from person-to-person.” The extent of side-effects is also a consideration and must be monitored, he adds.

“Also, if plain packaging comes in, as proposed, there may be fewer people taking up smoking over the next 10 years or so and we will have to see what happens in terms of regulation for electronic cigarettes.”

He pointed out that in terms of a greater future role for pharmacists in healthcare, the Healthy Ireland Initiative could take greater cognizance of pharmacists’ expertise. “There are approximately 30 people on the Council for this initiative and as far as I am aware, there is almost no pharmacy involvement and that’s certainly an omission,” he tells IP.

“Because there are so many pharmacies on so many corners all over the country, I would think that if they want to get a message across, that would be one significant way to do it.”

Community pharmacist and Honorary Treasurer of the IPU Mr Bernard Duggan also spoke to IP and confirmed that there has been an evident increase in the numbers of people seeking advice on the issue.

“A lot of patients come in seeking support when they are giving up smoking, both in terms of looking for information on the health benefits and also advice on the various options available in terms of nicotine replacement therapy products, on prescription or otherwise,” he confirmed.

I normally ask them whether or not they have experience in using a particu-
Evidence was based on a retrospective meta-analysis of 44 existing studies which included the following DMDs: IFNß-1a (Rebif®), IFNß-1a (Biogen Idec), IFNß-1b (Bayer), Glatiramer Acetate (Teva Pharmaceuticals) and Natalizumab (Biogen Idec)....

**INDICATIONS**

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**DOSAGE AND ADMINISTRATION**

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- Moderate quality evidence supports a protective effect of natalizumab and Rebif® against disability progression in RRMS in the short-term compared to placebo.

**PRECAUTIONS**

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- Thromboembolic events, glomerulosclerosis, seizures, transient ischaemic attacks, thrombotic events, thrombocytopenia, arthralgia, neuropathy, leg pain, myalgia.
- Nephrotic syndrome, glomerulosclerosis, seizures, transient neurological symptoms, thromboembolic events, thrombocytopenia, arthralgia, neuropathy, leg pain, myalgia.

**SIDE EFFECTS**

- Fever, pruritus, rash, erythematous/maculo-papular rash, alopecia, diarrhoea, vomiting, nausea, thrombocytopenia, anaemia.
- Very common: Injection site pain, myalgia, arthralgia, fatigue, rigors.

**REFERENCES**


**EMOTIONAL SUPPORT WHEN NEEDED**

**EMOTIONAL SUPPORT WHEN NEEDED**

**LEGAL CATEGORY**

- POM.

**MARKETING AUTHORISATION HOLDER AND NUMBERS**

- Merck Serono (Europe) Ltd, 51 Marsh Wall, London, E14 9TP; EU/1/98/063/007; 003; 006; 017; 013; 016; 010; 008; 009.

**For further information contact**

- Merck Serono, 4345 Kingwood Road, Citywide Business Campus, Dublin 24, Tel: +3531827000

June 2014 / Job No: REB14-0092

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June 2014 / Job No: REB14-0092
lar product and explain what supports are available to them, because the combination of supports and the pharmacological agent will ultimately lead to the patient quitting for good."

Lifestyle advice is also potentially helpful, said Mr Duggan, and in his opinion the pharmacist should take a holistic approach to helping the patient quit. "You would look at the lifestyle as well as the smoking habit itself, because that may have an effect on the type of therapeutic product you suggest. As a pharmacist, you also assess where people are in terms of actually wanting to quit because not everybody wants to quit right there and then and it's important to point out to people that when they do decide to quit, the community pharmacist is there to support them."

He explained to IP that the smoking cessation scheme is gaining traction, even at this early stage. "It's too early to get hard data on it but anecdotally, there is a lot of interest in the scheme and good success too."

From a broader healthcare perspective, Mr Duggan pointed out the greater role pharmacists are playing in front line healthcare delivery, taking pressure off the hospital services and GP surgeries.

"It's all about delivering healthcare at the least complex level and making it most accessible to the public," he says. "If you look at the Healthy Ireland strategy, one of the things that resonates is that they want people to give up smoking because it is one of the main lifestyle changes that people can make and will take pressure off secondary care services, which are stretched already."

"Pharmacists are accessible; we have the products and we have the training to help people to quit and achieve better healthcare outcomes."

He revealed that the IPU has called on the Government to introduce a Minor Ailments Scheme and this could encompass nicotine replacement therapy products.

"At the moment, if you are a medical card patient who wants to access certain nicotine replacement therapies, you need to go see a GP first for a prescription," he tells IP. "If the Minor Ailments Scheme was introduced, the pharmacist could still conduct a full assessment and supply a product under that scheme, freeing up time in GP surgeries, but the patient would still be getting the same service. The IPU has recently been met with the Oireachtas Health Committee and one of the things we discussed was the Minor Ailments Scheme and smoking cessation would fit very well into that."

The IPU has put in place supports for pharmacists who sign up to the smoking cessation initiative, including promotional material and a booklet which was produced in conjunction with the HSE.

"We have also developed a web-based clinical platform, IPU NET, and e-learning training for pharmacists so they can up-skill themselves in smoking cessation services.

"Ultimately, we want to see less people smoking and this is a chance people can really make if they get the right supports."

Now more than ever, pharmacists have good reason to intensify their efforts to help people kick the habit. Research by the Irish Cancer Society shows that 80 per cent of smokers in Ireland — estimated to number one million — would like to quit and pharmacists are best placed to help patients realise the benefits of lower blood pressure, improved circulation and breathing, improved fertility, younger-looking skin and whiter teeth. The sector is also helping to raise awareness that after 10 years as a non-smoker, the risk of heart attack is the same as a person who has never taken up the habit.

When the smoke clears, pharmacists' efforts deliver even more tangible benefits for patient's health and the service will be seen a milestone on the road to creating the ultimate goal of a tobacco-free Ireland.
Zantac 75mg Film-coated Tablets

Ireland’s No.1 H₂ Antagonist

Zantac 75mg Film-coated Tablets contain ranitidine hydrochloride. For the short-term symptomatic relief of acid indigestion and heartburn. Adults and children over 16 years: 1 tablet taken at onset of symptoms. Max 2 tablets in 24 hours. Seek medical advice if symptoms persist after 14 days. Do not give to children under 16 years.

Contraindications:
- Known hypersensitivity to ingredients.
- Renal impairment (creatinine clearance less than 50ml/min), hepatic impairment, history of acute porphyria, patients of middle age or older experiencing dyspeptic symptoms for the first time, patients with unintended accompanying weight-loss, concomitant use of other medications, pregnancy/lactation.

Side effects:
- Hypersensitivity reactions, G.I. disturbances, thrombocytopenia, agranulocytosis, changes in liver function tests.

Pharmacists are ‘astonished’ by medicines policy u-turn

THE new European Commission has taken office in a swirl of controversy as a seemingly innocuous reshuffle of responsibilities within the EU bureaucracy has sparked up roar.

When new Commission President, Mr Jean-Claude Juncker, announced his new line-up of European Commissioners in September. Buried in the small print was a plan to move responsibility for medicines policy out of the health and consumers directorate.

Instead of coming under the Health Commissioner, medicines will instead be a task for the Commissioner for the Internal Market and Industry.

This prompted more than 30 health organisations — including the European Association of Hospital Pharmacists and the Pharmaceutical Group of the European Union, which represents community pharmacists — to sign an open letter to Mr Juncker demanding a rethink.

However, the idea of moving medicines into the industry portfolio is not new and unlikely to be an accident. The switch reverses a 2009 decision to take responsibility for medicines away from the industry directorate and hand it to officials responsible for public health.

That decision had been celebrated by health professionals, patient groups and health NGOs but caused considerable anxiety for industry. Companies argued that EU powers in the field of health are limited — for example, they cannot influence prices or access to medicines at national level — whereas Brussels has considerable clout in enforcing the Single Market.

It makes sense, say industry sources, to have medicines controlled by a directorate with real powers, rather than the health directorate which must be careful not to tread on the toes of national health ministers.

This message was clearly conveyed to Mr Juncker who would have been in no doubt about the backlash that would ensue. The signatories to the open letter expressed ‘astonishment and concern’ at the move.

“The main driver of EU policies concerning pharmaceuticals and health technologies should be promoting and protecting health and patient safety,” the letter states. “The shift you are proposing sends the wrong signal to European citizens and patients – namely that economic interests come before their health.”

It says that the Commission’s five-year mandate will see delicate issues such as medicine pricing and information to patients climb up the agenda, pitting the interests of patients against those of industry.

The Juncker Commission is promising a more joined-up approach to policymaking, meaning the Health Commissioner could still have some input on medicines decisions taken by the Industry Commissioner. Whether this will be enough to appease irate health campaigners remains to be seen.

Pharmacists first to get new ‘European Professional Card’

WORKING in other EU countries could be about to get easier for pharmacists when a new European Professional Card (EPC) comes into operation.

The EPC is designed to boost mobility for highly-qualified workers and it is expected that pharmacists will be among the first wave of professionals to benefit, along with nurses, physiotherapists, mountain guides and estate agents.

The Pharmaceutical Group of the European Union (PGEU) which represents community pharmacy organisations opted in to the scheme, prompting the European Commission to recommend to national governments that pharmacists be among the first professions to try the EPC.

The Card is one of the key measures introduced under the new ‘Recognition of Professional Qualifications Directive’ and will effectively fast-track the registration process for pharmacists moving between EU member states.

New ‘.pharmacy’ internet addresses

A GLOBAL shake-up of internet domain names looks set to improve security for online pharmacies. Gone are the days when most web addresses had one of just a handful of endings ranging from .com and .org to .ie and .eu.

By opening up the possibility for new domain names, internet regulators have paved the way for .pharmacy addresses and thousands of others. This domain ending is controlled by the National Association of Boards of Pharmacy (NABP) in the US which will license its use to organisations meeting certain standards.

The first .pharmacy addresses will appear later this year in the US, and European organisations are expected to embrace the change in 2015.

The new domain name will be more secure than EU plans to add a security logo to legitimate pharmacy websites. The logo itself can be copied by unscrupulous online pharmacies whereas the .pharmacy domain name cannot be faked.

Meanwhile, the online medicines verification system introduced as part of an EU-wide crackdown on counterfeit medicines continues to gather pace. Luxembourg is the latest country to launch a pilot scheme which it hopes will link into a European hub.

The European system will eventually allow retail chemists to check whether a product is authentic by scanning its barcode, and will ensure the product has not been dispensed elsewhere in the EU.
“WHAT CAN BE DONE WHEN METFORMIN ALONE FAILS?”

“HOW CAN WE IMPROVE AND SUSTAIN GLYCAEMIC CONTROL?”

TREATING TYPE 2 DIABETES OFTEN MEANS FACING THE SAME CHALLENGES

“How can patients benefit further from their treatment?”

“How can we encourage a positive outcome?”
FIP Congress centered on theme of ‘Access to Medicines’

THE International Pharmaceutical Federation (FIP) held its 74th World Congress of Pharmacy recently, under the theme ‘Access to Medicines and Pharmacists Today, Better Outcomes Tomorrow’.

Some 95 countries were represented at the Congress, with more that 1,938 pharmacists and related professions in attendance in Bangkok, following on from last year’s Congress, which was held in Dublin.

The opening address was delivered by Dr Michel Buchmann, outgoing FIP President, who outlined his motivations during his four-year tenure, which included reforming pharmacy education, greater collaboration between healthcare professionals, integrating practice and science and more patient-centered roles within the profession.

However he also pointed to areas requiring further reform, such as a redistribution of roles in healthcare to achieve more effective public health, pointing out that there are too few studies focused on this area. “It is necessary to rearrange roles of health actors according to their competencies to effectively treat patients without additional costs, beyond hierarchy or traditions,” Dr Buchmann told the Congress.

He also drew attention to the increasing elderly population and the role pharmacists can play in caring for this patient group. “We face increased challenges in caring for those with chronic diseases, especially our elderly,” he said. “Not only are the numbers changing, but so is the way our populations live. The elderly are becoming more distanced from their families, becoming lonely and depending on their health professionals to provide care and close contact. So as all [people] around the world, we often see consultations and use of medicines increase.”

Dr Buchmann pointed out that even during his tenure, huge advances have been made in health technology and patients’ access to information but this has brought up new challenges, he pointed out. These include the rapid spread of misinformation; more informed patients becoming more demanding and impatient; less face-to-face communication; and increased trafficking of falsified medicines.

“The vast and growing knowledge in science has led to a gradual fragmentation into many different disciplines,” said Dr Buchmann. “These silos of information and specialisation often lead to many specialists working separately yet trying to collaborate to respond to the needs of a whole person.”

“Tomorrow’s pharmacists, scientists and practitioners will be important collaborators in health, working as integrators and translators of this vast knowledge to benefit patients.”

He went on to explain that major political and economic concerns are being raised by the escalating cost of healthcare delivery and this has changed the relationship between patients and healthcare professionals.

“Quality of care and quality of life are becoming important requirements in managing health,” said Dr Buchmann. “Yet some areas have advanced little, including the lack of balance between the availability of general practitioners compared with the plethora of specialists; disparities in access to care; and the huge waste that we know exists due to patients not adhering to their treatments.

“All these challenges require clinical and economic adaptation that are both efficient and humane. Multidisciplinary teams have become indispensable to ensure the rational, efficient and co-ordinated use of all competencies available,” he added.

Dr Buchmann concluded by calling on pharmacists to “demonstrate your value as health professionals and scientists, through developing your skills and providing needed services and medicines to your fellow citizens and patients”.

“Share your pride in your profession so that all international and national leaders in the pharmaceutical sciences and in practice can easily convince decision-makers of the important role that we have to play in improving health.”

Survey reveals poor knowledge of antibiotic use among students

RESULTS of a survey presented at the 74th FIP World Congress showed an alarming lack of awareness on antibiotic use and highlighted the fact that this problem is not confined to less-educated members of society.

The survey — of 731 students at China’s Xi’an Jiaotong University — found that 40.2 per cent of students had self-medicated with antibiotics in the past six months. This rate of misuse is comparable to university students in Pakistan, at 35.2 per cent.

Some 59.2 per cent of the university students had bought their antibiotics without prescriptions and more than half the respondents — 56.5 per cent — stowed their antibiotics for immediate access and some 30.6 per cent used them for the common cold.

Some 36.5 per cent of the respondents had switched their antibiotics and 44 per cent had changed their dosage without advice from a healthcare professional.

The overall score rating students’ knowledge was four out of a possible score of 10, with more than 28 per cent under the impression that antibiotics are the same as anti-inflammatory drugs.

Prof Yu Fang, Associate Professor at the Xi’an Jiaotong University, commented: “Stricter and more practical regulations enforcing supervision of the sale of antibiotics in retail pharmacies is needed.

“Our findings highlight the urgent need for focused educational intervention, given that antibiotic resistance is one of the world’s most pressing public health problems.”

FIP elects its first woman President

THE FIP has elected its first ever woman President, Ms Carmen Peña, a community pharmacist in Madrid, Spain. Ms Peña has been with the FIP for more than 20 years and has been Vice-President since 2008. She succeeds outgoing President Dr Michel Buchmann and will serve a tenure of four years.

In a statement at the FIP World Congress, Ms Peña said pharmacists should be an active and effective force in shaping healthcare policies in their respective countries and offered the guidance and resources of the FIP to achieve this goal.

She also highlighted the FIP Education Initiative, an effort to transform pharmacy education to meet workforce and societal needs worldwide.

“Building a pharmaceutical workforce that is competent, sustainable, accountable and respected by society and by our colleagues in other health professions will make our countries’ health systems more efficient by lowering morbidity, mortality and cost,” she said.

Ms Peña is also President of the General Pharmaceutical Council of Spain, which represents more than 65,000 pharmacists.
IT’S TIME TO CHANGE THE CONVERSATION IN TYPE 2 DIABETES
‘Healthy Living’ pharmacy model preventing visits to GP surgeries

THE UK’s Healthy Living Pharmacy service — designed to help pharmacies provide public health services based on local need — is helping patients to avoid GP visits, according to new research presented at this year’s FIP World Congress.

Following a pathfinder programme in 2011, the Healthy Living pharmacies have been offering a range of services including sexual health, weight management, alcohol awareness and smoking cessation. There are a number of criteria the pharmacies must meet including in the areas of environment and workforce development, proactively promoting health and wellbeing and ‘engagement’. The participating pharmacies must also include a ‘health champion’, who has completed an accredited health improvement course.

The results showed that of the 1,304 patients surveyed, 60 per cent said they would have visited a doctor if they had not had access to the Healthy Living Pharmacy scheme.

In the 10 pathfinder sites, it was also found that pharmacist employers believed the initiative has a positive effect on staff productivity, retention and development.

“This initial evaluation indicates that Healthy Living pharmacies can be implemented in areas of different demography and geography,” according to Mr Mike Holden, author of a poster presented at the FPI Congress on the subject.

“The model appears to be a successful organisational development tool to maximise pharmacy’s contribution to improving the public’s health.

“Studies have also replicated the benefits of the ethos, practice and improved outcomes of these pharmacies.”

Olive oil shows promise in Alzheimer’s

RESEARCH presented at the FIP World Congress in Bangkok has indicated that biophenols found in olive oil show promise in the treatment of Alzheimer’s disease.

The data indicate that these biophenols inhibit β-secretase enzyme. Reducing β-secretase production is thought to inhibit extracellular deposits of amyloid beta peptide, implicated in the development of Alzheimer’s disease.

Dr Syed Haris Omar from the School of Biomedical Sciences, Charles Sturt University, Australia, told the Congress attendees: “Studies have indicated that consumption of olive biophenols can help to reduce the risk of dementia, as well as heart disease and stroke, but it is only relatively recently that scientists have been trying to explain how.”

He explained that in vitro and animal studies on transgenic mice show the promise of olive biophenols but further studies are required and standard olive oil tends not to contain the optimum biophenols but the right amount is found in the olive leaf, fruit and extra virgin olive oil.

“Due to their aromatic and volatile nature, biophenols are very unstable and are affected by processing and cooking,” he added.

Nasal aroma spray ‘could help treat anorexia’

RESEARCH presented at the 74th FIP World Congress has revealed that naturally-occurring fragrances found in plants are proving to be promising candidates for the treatment of anorexia.

Pharmaceutical researchers at Kyoto University in Japan tested different aromas on mice that had been fasting for one day and measured their food intake. Mice that were subjected to the aroma of benzylacetone, 1-phenyl-2-butatone or cinnamaldehyde ate considerably more that either a control group — some 20 per cent — or a group given the hunger-inducing hormone ghrelin, at 7 per cent.

While it was found to produce a sedative effect, benzylacetone stimulated a largely increased food intake. The substance is found in the smoke of heated agar wood and is sometimes used as a constituent ingredient in perfumes.

Prof Michiko Ito, Associate Professor at the School of Pharmaceutical Sciences in Kyoto University, commented: “Ghrelin and the stimulants of ghrelin receptors are being investigated in the treatment of anorexia.

“However ghrelin is a kind of peptide hormone that is very, very fragile and highly susceptible to heat. Handling ghrelin products is difficult and in trials, it has been given as intravenous infusion.”

He continued: “These compounds (such as benzylacetone) are mostly mono-, sesqui-terpenoids and phenylpropamoids. Although they are known to be harmful to skin and mucous membranes when applied in concentrated forms, the concentrations shown to be effective in our studies were all very low.”

Prof Ito suggested that it may be possible to administer such compounds via a nasal spray: “These fragrant compounds could be administered in a non-invasive way and are relatively inexpensive.”

Second edition of quality assurance framework for education launched

A NEW edition of the FIP’s global framework for pharmacy education has been launched at the Federation’s World Congress of Pharmacy and Pharmaceutical Sciences.

The framework is designed so that it can be adapted to suit individual national needs to help assure the quality of educational development in pharmacy. Two new elements of the edition include ‘pillars of quality’ and three ‘foundations’ of educational quality, namely science, practice and ethics.

The two new ‘pillars’ address the concept of social accountability, which is becoming more prominent in health professionals’ education.

“By failing to recognise and address context, all other pillars of quality can be compromised and making an impact is the final proof of quality in pharmacy education,” explained Mr Mike Rouse, FIP Education Initiative Quality Assurance Domain Lead.

“Many countries are introducing, expanding or undertaking major transformation of pharmacy education and they can use the framework as a starting point.”

A pharmacist could use the framework as a starting point. “With an understanding of the need for educational quality assurance and the concept of quality, the pharmacist can use the framework as a starting point.”

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References:


Advise 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. Asthma-related adverse events and exacerbations may occur during treatment. Patients should continue treatment but seek medical advice if asthma symptoms remain uncontrolled or worsen after initiation of Relvar. Systemic effects: Systemic effects of inhaled corticosteroids may occur, particularly at high doses for long periods, but much less likely than with oral corticosteroids. Possible Systemic effects include: Cushings syndrome, Cushingoid features, adrenal suppression, decrease in bone mineral density, growth retardation in children and adolescents, cataracts, glaucoma. More rarely, a range of psychological or behavioural effects including seizures,; hyperactivity; anxiety; depression or aggression (particularly in children). Increased incidence of pneumonia has been observed in patients with COPD receiving Relvar. Risk factors for pneumonia include: current smokers, patients with a history of prior pneumonia, patients with a body mass index <25 kg/m2 and patients with a FEV1 <50% predicted. If pneumonia occurs with Relvar treatment should be re-evaluated. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take Relvar. For patients with hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take Relvar. For patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take Relvar. For patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take Relvar.

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Steep rise in number of skin cancer cases in men

RATES of skin cancer cases in men have risen sharply and it was the most common form of male cancer dealt with by Vhi Healthcare in 2013. Since 2009, skin cancer cases have risen by 21.6 per cent in males, according to figures revealed by the health insurer.

The company said that in 2013, nearly 3,900 male patients were treated for the condition, compared to 3,200 men in 2009. This was followed by prostate cancer at 2,012 men, while 1,084 males were treated for colorectal cancer last year.

The fourth-most common cancer cause of its persistently dismal prognosis: in the public sector, military forces or by health insurers. “Divided loyalty is a challenge for all health professionals, including pharmacists,” continued Mr Gray. “Pharmacists must be allowed to provide independent professional judgements in the best interests of patients.”

Call for introduction of a pharmacy-based minor ailment scheme

By Pat Kelly

IN its pre-budget submission to Government, the Irish Pharmacy Union (IPU) has called for the introduction of a minor ailment scheme for medical card-holders. The Union claims this would enable such patients to have more timely access to healthcare at no extra cost to the State.

The Union has called for the introduction of a minor ailment scheme for medical card-holders. Ms Kathy Maher, IPU President. “We are calling on the Government to replicate such a scheme in Ireland. This would be a move to deliver on a more integrated healthcare model in line with the Government’s own Healthy Ireland framework.”

Wild berry extract could strengthen the effectiveness of pancreatic cancer drug

A WILD berry may strengthen the effectiveness of a chemotherapy drug commonly used to treat pancreatic cancer, reveals experimental research published online in the Journal of Clinical Pathology.

The findings prompt the researchers to suggest that adding ‘nutraceuticals’ to chemotherapy cycles may improve the effectivity of conventional drugs, particularly in hard-to-treat cancers, such as pancreatic cancer. They base their findings on the effectiveness of extract of chokeberry (Aronia melanocarpa) in killing off cancer cells.

The berry is high in vitamins and antioxidants, including various polyphenols–compounds that are believed to mop up the harmful by-products of normal cell activity. The researchers chose to study the impact of the extract on pancreatic cancer because of its persistently dismal prognosis: less than 5 per cent of patients are alive five years after their diagnosis.

They therefore cultured a well-known line of pancreatic cancer cells (AsPC-1) in the laboratory and assessed how well this grew when treated with either the chemotherapy drug gemcitabine, or different levels of commercially-available chokeberry extract alone, and when treated with both.

The toxicity of chokeberry extract on other normal lining cells was tested and found to have no effects up to the highest levels used (50µg/ml), suggesting that it may not be able to prevent the formation of new blood vessels (anti-angiogenic properties), a process that is important in cancer cell growth.

2014 Helix Health Pharmacist Awards

THE Helix Health Pharmacist Awards ceremony is rolling around again. The Awards — which have been in existence for 10 years — are aimed at raising funds for the Pharmacy Benevolent Fund and celebrating excellence across all disciplines of the pharmacy profession.

Eight awards will be presented in total at the 2014 Awards, which will take place in The Mansion House in Dublin’s city centre on the evening of Saturday, 29 November.

John Bowman is confirmed to MC proceedings once again and this year’s tickets for the awards ceremony are on sale now through www.pharmacistawards.com.

There was a huge response to the call for nominations over the summer and the judges will announce the shortlisted nominees at a special event in Dublin on October 15.

Along with Helix Health, sponsors of the 2014 Awards include Teva, Lundbeck Ireland, KrKa, Pinewood Healthcare and JPA Brenson Lawlor.

Follow the Pharmacist Awards on Twitter at @PharmacistAward or alternatively on Facebook at: www.facebook.com/TheHelixHealthPharmacistAwards.
Pharmacists on the Ebola front line

Pharmacists are as vulnerable as other healthcare professionals in treating the rampant Ebola outbreak in West Africa. Irish Pharmacist reports on some of the initiatives being undertaken and overseas pharmacists’ involvement in trying to halt the spread of the deadly disease.

At time of going to press, the death toll from the unprecedented Ebola outbreak in West Africa — the most widespread ever recorded — had reached 1,552 deaths from 3,069 confirmed cases, according to the World Health Organization (WHO).

Ebola typically has a mortality rate of 50-90 per cent and family members of healthcare workers are considered to be among those most at risk of infection. While pharmacists in Africa are well placed to recognise the disease, there is a problem with differential diagnoses as many of the early symptoms — fever, headache, muscle pain, sore throat, diarrhoea and vomiting — can be easily confused with tropical diseases such as dengue fever and malaria.

There are five strains of Ebola but the current one has been identified as Zaire ebolavirus.

The Royal Pharmaceutical Society’s publication The Pharmaceutical Journal has reported that Liberian pharmacists and pharmacy students are taking part in an initiative to visit pharmacies and offer advice on how to help halt the spread of the disease in the country’s capital city, Monrovia.

Drug counterfeiters rarely miss an opportunity to profit from misfortune and authorities are inspecting pharmacies to ensure that no bogus products are included in the range of medicines.

Liberia has the highest number of deaths and confirmed new cases and the WHO has reported that dangerously inaccurate advice is circulating on social media; two people in Nigeria died in recent months from drinking unsanitary salt water in the mistaken belief that it would prevent them contracting the disease.

The US Centers for Disease Control and Prevention (CDC) confirmed that “Ebola is spread through direct, unprotected contact with the blood or body fluids of an infected symptomatic person, contact with the body of someone who has died from Ebola, contact with infected animals and exposure to objects such as needles that have been contaminated with infected body fluids and tissues.”

Family members of healthcare workers are most at risk of infection

Ebola is also spread through sexual contact.

Contact with animals, raw, undercooked meat and eating or even handling meat from animals hunted for food also present serious risks of infection. The healthcare challenge is complicated by advice for patients to avoid hospitals where Ebola patients are being treated.

With such a fluid and ever-changing situation, exact numbers are hard to define, but the International Pharmaceutical Federation (FIP) has reported that pharmacists are among the casualties, with at least one pharmacist and four pharmacy technicians confirmed dead from the disease in Sierra Leone alone, all from the community pharmacy sector. This number is widely expected to rise as more concrete figures emerge across West Africa.

In Liberia, pharmacists have been overwhelmed by patients seeking essential medicines after a second outbreak there and the Liberian Medicine and Health Regulatory Authority has been conducting widespread awareness campaigns for pharmacists, with the Pharmaceutical Society of Ghana taking similar steps.

Mr Luc Besancon, CEO and General Secretary of FIP, commented: “Pharmacists, as the first point of care for many people, have an important role to play in such emergencies, not only in terms of vigilance but also on a wider scale, such as raising awareness and knowledge and providing advice to travellers.”

Such awareness and knowledge are now crucial and in Sierra Leone, a lot of chlorine and chlorine-containing products are being used by fearful members of the public as an antiseptic. However many people were incorrectly mixing the chlorine and in some cases this resulted in toxicity and in cases where too little chlorine was used, the mixture was ineffective.

Authorities have organised teams to visit towns in the region in an effort to educate and inform people on the correct mixing technique and amounts.

However healthcare workers in Liberia and Sierra Leone have reported to aid agencies that personal protection equipment is in extremely short supply and is becoming more scarce as the disease continues to spread. Already-fragile health systems in these countries are ill-equipped to deal with the scale of the epidemic and the WHO has called for a co-ordinated international response — a move that has only happened twice before, with the swine flu pandemic in 2009 and the more recent polio outbreak.

While all drug treatments are in the earliest stages of development, the drug ZMapp was successfully administered to two aid workers and a clinical trial is due to begin soon of an experimental vaccine by pharmaceutical company GlaxoSmithKline.
The plight of the modern pharmacist

Dear Editor,

As a retired pharmacist (or ‘chemist’, as we were known) I still enjoy reading my copy of Irish Pharmacist online every month. However I do find some of the circumstances in which modern pharmacists must work very demanding and I have a certain amount of sympathy for those operating in today’s environment.

Life was more simple in years gone by. For example there was no threat to business viability or patient safety via mail order pharmacy. This was expertly outlined by your columnist David Jordan recently in your July issue.

The prescription charge and greater demands on pharmacists to grow their role in healthcare provision must also be stressful.

It does not seem that pharmacists will be reimbursed for the extra work they do beyond dispensing, at least not without a fight but it should not have to come to that.

Today’s pharmacists will no doubt also be called upon to support the introduction of free GP care in some way, shape or form. But you might take comfort from the fact that this is unlikely to be happening anytime soon.

Then there are the issues of reference pricing and generic medicines. And on top of this, most of today’s pharmacists have to deal with falling sales. All of this and more makes me long for the simpler times.

I don’t know if I would pursue a career in pharmacy in today’s environment and I sympathise with those who choose to do so in this day and age.

Yours sincerely,

John McMahon,
Former pharmacist in Co Dublin on self-imposed exile in Spain.

With great power...

Q: What do pharmacists, Dexy’s Midnight Runners and Batman have in common?
A: They are all honoured on 25 September.

At time of going to press, World Pharmacists Day is underway. The theme of which is Access to Pharmacist is Access to Health. Through no fault of the organisers, they must share that particular spot on the calendar with ‘World Comic Book Day’ and ‘World One-Hit Wonder Day’.

That particular date was chosen because that is the date on which the International Pharmaceutical Federation (FIP) was established.

But there may be a tenuous synchronicity at play, as pharmacists are emerging as an increasingly potent force for healthcare justice — although developing ‘superpowers’ to prescribe would be even more useful in the fight against healthcare inequality.

The day itself was being marked in Portugal with the launch of a year-long campaign on the responsible use of medicines, while in Zimbabwe, pharmacists were due to mark the occasion with a walk to Africa Unity Square in Harare, followed by media interviews and speeches. This provides a good opportunity for Irish pharmacists to pause and consider their colleagues in West Africa, some of whom are dying as they struggle to control the rampant Ebola outbreak (see p17).

The theme of the day — now in its fourth year — makes the point that ‘access’ has a broader meaning than simply having a pharmacist on every corner. “Access to health is not just an economic issue,” commented new FIP President Ms Carmen Peña, “it is also about access to medicines — which has big research and evidence elements — access to correct information and advice and access to education.”

Also on the subject of World Pharmacists Day, IPU President Ms Kathy Maher added: “When it comes to debating reform and improvement of the health service, we [pharmacists] don’t feature to the extent that we should. Pharmacists are frustrated, as we can play a critical role in healthcare delivery. This approach is working in other countries but it seems that the powers that be in Ireland are blind to our potential, resulting in missed opportunities, wasted resources and underperformance — all to the detriment of patients.”

Here’s hoping the day’s events helped to raise a more general awareness of the importance of the profession in a time of gradual but unprecedented change in healthcare.

As our co-celebrants on 25 September would point out, Peter Parker’s mentor and father-figure, uncle Ben, once famously said: “With great power comes great responsibility.”

Pharmacists are already shouldering the responsibility; now it’s time they were also given the power, in the form of proper resources and recognition. Hopefully World Pharmacists Day is another step in that direction.

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The Helix Health Pharmacy Awards are on the way again and there has been an enormous response to the call for nominations. Broadcaster John Bowman will MC the event in Dublin’s Mansion House on 29 November, where eight awards will be presented and vital funds will be raised for the Pharmacy Benevolent Fund.

This year promises to be bigger and better than ever. To check out more details and book your ticket, visit www.pharmacistawards.com and see the next issue of Irish Pharmacist for the soon-to-be-announced shortlisted nominees.

Pat Kelly,
Email: pat@greenx.ie

[Image of letter to the editor]
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I am sceptical when there is little clinical evidence to back up animal work, no matter how positive it might seem. Could the aroma of raspberries help customers lose weight?

Dr Des Corrigan examines the evidence for raspberries in weight loss.

I recently spotted products labelled ‘Raspberry Ketones’ in a pharmacy and I was intrigued to know what the intended use might be. Traditionally, raspberry leaf in the form of a tea, tincture or tablet is used during pregnancy to facilitate easier childbirth. While there is some limited evidence from in vitro studies of an effect on uterine tissue, the clinical evidence is limited to a single RCT involving 192 pregnant women, half of whom took raspberry leaf extract (1.2gram) daily from the 8th month until the onset of labour. There were no significant differences in a whole range of labour outcomes between the raspberry and placebo groups. The EMA has recently published its Community Herbal Monograph on the leaf and recognises three separate indications involving symptomatic relief of minor spasm associated with menstrual periods; of mild inflammation of the mouth or throat; and of mild diarrhoea, respectively.

A lot of work has gone into the chemistry of the leaves but no compounds have been identified as being responsible for the claimed effects during pregnancy. Work has also been done on the aroma and flavour constituents of the berries themselves and this led to the isolation and identification of the aforementioned raspberry ketone (RK), which is responsible for the unique smell of raspberries. These ketones are now widely used in fragrances and as a food flavouring. Chemically, RK is 4-(4-hydroxyphenyl)butan-2-one and when its structure was elucidated, it was realised that it was similar to that of capsaicin (from chilli peppers) and synephrine (a stimulant phenethylamine from orange peel) — particularly bitter.

In that study, 70 obese subjects were enrolled in an industry-sponsored, randomised, placebo-controlled, double-blind trial of a multi-ingredient supplement (which included RK) for eight weeks, alongside a calorie-restricted diet and exercise training. For the 45 participants who actually completed the study, there were significant differences in body weight, fat mass, hip and waist girth and energy levels between the treatment and placebo groups. Now, there are a number of problems with this study.

Firstly, it is only a single study. Secondly, there was a high level of dropouts from both arms, which reduces the power of the study and means that it is difficult to evaluate the clinical significance of the findings. Thirdly, and perhaps most important of all, the treatment was a multi-ingredient supplement which apart from RK also contained caffeine, capsaicin, garlic, ginger and a standardised extract of Citrus aurantium (bitter orange)-containing synephrine, which, being chemically related to ephedrine and amphetamine, has been shown to increase resting metabolic rate and to enhance weight loss in clinical trials. It is suggested that garlic and ginger influence adiponectin secretion, reduce body fat accumulation and decrease circulating insulin.

Both caffeine and capsaicin increase energy expenditure by up to 13 per cent. Because of the fact that all of the constituents seem to have potential effects on weight, it would not be possible to isolate the contribution of any single component such as RK. Thus, it is not possible on the basis of this solitary trial to state that RK contributes to weight loss in humans. In the meantime, what of the safety of RK? The clinical study did not show any differences in adverse events between the treatment and placebo and the fact that RK has been used as a food flavouring for many years is reassuring, although combinations involving caffeine and synephrine would be worrisome.

On the basis of the animal studies, it does appear to have potential, which needs to be studied in large-scale well-designed studies where RK is used as a mono-component. Only then can pharmacists be assured that preparations containing RK will benefit patients who need to lose weight as part of a calorie-controlled diet linked to an exercise programme.

In the case of RK, there is very little clinical evidence to back up the animal work, no matter how positive it might seem. Traditionally, raspberry leaf in the form of a tea, tincture or tablet is used during pregnancy to facilitate easier childbirth. While there is some limited evidence from in vitro studies of an effect on uterine tissue, the clinical evidence is limited to a single RCT involving 192 pregnant women, half of whom took raspberry leaf extract (1.2gram) daily from the 8th month until the onset of labour. There were no significant differences in a whole range of labour outcomes between the raspberry and placebo groups. The EMA has recently published its Community Herbal Monograph on the leaf and recognises three separate indications involving symptomatic relief of minor spasm associated with menstrual periods; of mild inflammation of the mouth or throat; and of mild diarrhoea, respectively.

A lot of work has gone into the chemistry of the leaves but no compounds have been identified as being responsible for the claimed effects during pregnancy. Work has also been done on the aroma and flavour constituents of the berries themselves and this led to the isolation and identification of the aforementioned raspberry ketone (RK), which is responsible for the unique smell of raspberries. These ketones are now widely used in fragrances and as a food flavouring. Chemically, RK is 4-(4-hydroxyphenyl)butan-2-one and when its structure was elucidated, it was realised that it was similar to that of capsaicin (from chilli peppers) and synephrine (a stimulant phenethylamine from orange peel) — particularly bitter.

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Managing hypertension

BY FIONA CLANCY, CLINICAL TRIALS PHARMACIST, OUR LADY’S CHILDREN’S HOSPITAL, CRUMLIN

Introduction

Hypertension (HTN) is one of the most preventable causes of premature morbidity and mortality worldwide. It is estimated to cause 7.5 million deaths annually, about 12.8% of the total of all deaths globally. The overall international prevalence of raised blood pressure (BP) in adults aged 25 and over is around 40% worldwide, with prevalence among men being slightly higher than that among women.

In a survey carried out in 2007 by the Department of Health and Children on a group of individuals over 45 years old, 60% of 1,207 respondents who underwent a clinical examination had high blood pressure. By 2020, the number of adults aged 45+ with HTN in Ireland is expected to rise to more than 1.2 million.

Blood pressure is determined by the rate of blood flow produced by the heart (cardiac output), and the resistance of the peripheral blood vessels to blood flow (peripheral resistance). Blood pressure readings are stated as ‘systolic over diastolic’, with measurements expressed in terms of millimetres of mercury (mmHg). The diastolic pressure represents the pressure during ventricular relaxation in diastole (when the heart relaxes and refills), while the systolic pressure represents the peak pressure due to ventricular contraction during systole (when the heart pumps blood out).

Hypertension causes pathological changes in the vasculature and hypertrophy of the left ventricle of the heart. As a result, it is a major risk factor for a range of conditions including stroke (ischaemic and haemorrhagic), myocardial infarction (MI), heart failure, chronic kidney disease and peripheral vascular disease. If not managed appropriately, the progressive rise in BP can bring about a treatment-resistant disease. If not managed appropriately, the progressive rise in BP can bring about a treatment-resistant disease. It is estimated to cause 7.5 million deaths annually, about 12.8% of the total of all deaths globally. The overall international prevalence of raised blood pressure (BP) in adults aged 25 and over is around 40% worldwide, with prevalence among men being slightly higher than that among women.

Causes

For 90-95% of patients diagnosed with HTN there is no known cause. This is termed primary hypertension and the cause of this is unknown but it is likely that genetic factors play a part. In the remaining 5-10% of cases, HTN is secondary to another disease process, e.g. renal, endocrine disorder.

Diagnosis and Classification

Blood pressure is normally distributed in the population and there is no natural cut-off point above which hypertension definitively exists and below which it does not. For the purposes of simplification of diagnosis and treatment decisions, the European Society of Hypertension (ESH) and European Society of Cardiology (ESC) provide definitions and classifications of HTN, as outlined in Table 1. Hypertension rarely has any symptoms. For the normotensive patient, it is recommended that they would have their BP measured at least once every five years. This should be carried out more frequently if BP is close to 140/90 mmHg.

Measuring Blood Pressure

- Use a validated and regularly calibrated BP monitor with an appropriate-sized cuff for the patient.
- The patient should be seated in a quiet area such as a reading chair, with the arm resting on a table or armrest at heart level. The cuff should be placed on the upper arm. The bladder should encircle the arm to a point just above the cubital fossa, with the patient's arm at heart level. The bladder should be large enough to encircle at least 80% of the arm. The bladder should be inflated to a pressure of 100 mmHg above the patient’s systolic pressure.
- The patient’s arm should be outstretched, level with the heart, and supported by resting it on a table. The patient should be seated in a quiet area such as a reading chair, with the arm resting on a table or armrest at heart level. The cuff should be placed on the upper arm. The bladder should encircle the arm to a point just above the cubital fossa, with the patient's arm at heart level. The cuff should be inflated to a pressure of 100 mmHg above the patient’s systolic pressure.

Table 1: Definitions and classification of BP levels in untreated individuals. The BP category is defined by the highest level of BP, whether systolic or diastolic. Isolated systolic hypertension should be graded 1, 2, or 3 according to systolic BP values in the ranges indicated.

<table>
<thead>
<tr>
<th>Category</th>
<th>Systolic BP (mmHg)</th>
<th>Diastolic BP (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Optimal</td>
<td>&lt;120</td>
<td>&lt;80</td>
</tr>
<tr>
<td>Normal</td>
<td>120–129</td>
<td>80–84</td>
</tr>
<tr>
<td>High normal</td>
<td>130–139</td>
<td>85–99</td>
</tr>
<tr>
<td>Grade 1 hypertension</td>
<td>140–159</td>
<td>90–99</td>
</tr>
<tr>
<td>Grade 2 hypertension</td>
<td>160–179</td>
<td>100–109</td>
</tr>
<tr>
<td>Grade 3 hypertension</td>
<td>≥180</td>
<td>≥110</td>
</tr>
<tr>
<td>Isolated systolic hypertension</td>
<td>≥140</td>
<td>&lt;90</td>
</tr>
</tbody>
</table>

Managing Blood Pressure Monitoring (ABPM)

The ESH/ESC regard the clinic BP measurement as the gold standard but recognise the utility of ABPM in certain situations, eg suspected ‘white coat’ hypertension. These guidelines suggest that it may be of particular use in patients with readings which are borderline hypertensive in the clinic including evidence of validation of blood pressure measurement equipment.

The current National Institute for Clinical Excellence (NICE) and British Hypertension Society (BHS) guidelines recommend that if BP is measured in the clinic as ≥140/90 mmHg, the patient should undergo ambulatory blood pressure monitoring (ABPM) in order to confirm a diagnosis of hypertension.

Management

Drug treatment should be initiated promptly in patients who are diagnosed with Grade 3 hypertension and patients with Grade 1 or 2 hypertension who are at high or very high total CV risk. In patients with a lower risk, drug treatment may be delayed for some weeks or months (depending on grade of hypertension), while trying lifestyle measures. Appropriate lifestyle changes can prevent hypertension, delay the need for pharmacological intervention and contribute to a reduction in BP for those on drug therapy.

It is recommended that systolic BP should be lowered to <140 mmHg and diastolic BP should be lowered to <90 mmHg in all hypertensive patients. Evidence is only missing in the elderly patient, in whom the benefit of lowering systolic BP to <140 mmHg has not been tested in randomised trials.

Lifestyle

The following guidance is appropriate for all patients with hypertension:

- **Salt:** Intake should be limited to 5-6g per day. Patients should avoid added salt and high salt food, with particular emphasis on an awareness of “hidden salt” such as that in processed food, eg bread, cereals.
- **Alcohol:** The HSE and Irish Heart Foundation recommend that for those who drink alcohol, consumption should be limited to a maximum of 11 standard drinks in a week for women, and up to 17 standard drinks in a week for men, with drinks spaced out over the week.
- **Diet:** Increase consumption of fruit and vegetables and low-fat dairy products
- **Weight:** Body Mass Index (BMI) should be reduced to <88 kg/m². Waist circumference of <102 cm in men and <88 cm in women is recommended.
- **Exercise:** At least 30 minutes of moderate aerobic exercise on 5-7 days per week.
- **Smoking:** All smokers should be advised to quit and offered assistance.
Pharmacological
A patient-centred approach is favoured for pharmacological management of HTN. Therapy is likely to be long-term and patient acceptability is key for treating an asymptomatic disease. ESH/ESC guidelines present a hierarchy of drugs, beta-blockers (BBs), calcium channel blockers (CCBs), angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs) do not differ significantly in efficacy and are all suitable for HTN management, either alone, or in combination. The focus should be on selecting drugs appropriate to concomitant conditions, based on clinical trial evidence. Some examples are outlined in Table 2.

Table 2: Drugs to be preferred in certain conditions

<table>
<thead>
<tr>
<th>Condition</th>
<th>Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microalbuminuria</td>
<td>ACE inhibitor, ARB</td>
</tr>
<tr>
<td>Previous stroke</td>
<td>Any agent effectively lowering BP</td>
</tr>
<tr>
<td>Previous MI</td>
<td>BB, ACE inhibitor, ARB</td>
</tr>
<tr>
<td>Angina Pectoris</td>
<td>BB, CCB</td>
</tr>
<tr>
<td>Heart Failure</td>
<td>Diuretic, BB, ACE inhibitor, ARB, mineralocorticoid receptor antagonist (spironolactone, eplerenone)</td>
</tr>
<tr>
<td>Atrial fibrillation, prevention</td>
<td>Consider ARB, ACE inhibitor, BB or mineralocorticoid receptor antagonist</td>
</tr>
<tr>
<td>Atrial fibrillation, ventricular rate control</td>
<td>BB, non-dihydropyridine CCB</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>ACE inhibitor, ARB</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>Methylpoda, BB, CCB</td>
</tr>
<tr>
<td>Black patients</td>
<td>Diuretic, CCB</td>
</tr>
</tbody>
</table>

Conversely, certain drugs are to be avoided in certain conditions e.g. thiazide diuretics in gout; BBs in asthma; ACE inhibitors/ARBs in pregnancy, hyperkalaemia; CCBs in AV block, heart failure.

Most patients will require a combination of two drugs or more to achieve BP control. Therapy will generally be initiated with a single antihypertensive agent. In patients with markedly high baseline BP or at high CV risk, it may be appropriate to initiate treatment with a two-drug combination. Doses of a single drug or two-drug combination can be stepped up as necessary. If targets are not achieved, a different two-drug combination may be introduced, or a third drug added. The use of combination tablets may improve adherence due to the reduced pill burden.

Certain combinations have more favourable evidence, as illustrated in Figure 1. Evidence of favourable results from clinical trials has been obtained, particularly for the combination of a diuretic with an ACE inhibitor, ARB or CCB. The only combination that cannot be recommended on the basis of trial results is that of two blockers of the renin-angiotensin system (i.e. ACE inhibitor/ARB/Direct renin inhibitor) as this combination is associated with end-stage renal disease. The combination of a BB with a diuretic is associated with an increased risk of development of new-onset diabetes. In 15-20% of patients, a combination of three drugs will be necessary for BP control, with the most rational combination being a blocker of the renin-angiotensin system, a CCB and a diuretic (Figure 1).

Unlike the ESH/ESC recommendation for all major classes of antihypertensive agents to be considered in HTN management, the BHS and NICE recommend the use of an ACE inhibitor/ARB or CCB as a first-line agent on the basis of age or ethnicity, as shown in Figure 2. NICE guidelines do not consider BBs to be a first-line agent in the treatment of HTN except in those with an intolerance or contraindication to ACE inhibitors and ARBs, in women of child-bearing potential or people with evidence of increased sympathetic drive. NICE guidance favours the use of thiazide-like diuretics in preference to thiazide diuretics. (Figure 2)

Calcium Channel Blockers
Calcium Channel Blockers (CCBs) act by reducing the influx of calcium into vascular smooth muscle cells by interfering with voltage-operated L-type calcium channels in the cell membrane. Contraction of the vascular smooth muscle is dependent on free intracellular Ca²⁺ concentration. Reduced intracellular Ca²⁺ causes relaxation of arteriolar smooth muscle and decreased peripheral vascular resistance. Calcium channel blockers may be classified as dihydropyridine derivatives, e.g. amlodipine, lercanidipine; or non-dihydropyridine (rate-limiting) eg verapamil, diltiazem. Amlodipine is a preferred agent due to its long half-life and once-daily dosing. Dihydropyridines may bring about adverse effects such as headache, flushing, tachycardia and oedema. These effects may decline with time. Non-dihydropyridine CCBs also act as vasodilators but these agents slow the heart rate (negative chronotropic effect) and decrease myocardial contractility (negative isotropic effect) and should be avoided in patients with compromised left ventricular function and used with extreme caution in combination with BBs.

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Benefit from Benetor®

For the Effective Management of Essential Hypertension

❤ Greater BP reduction vs. other ARBs¹-⁷
❤ Effective BP control maintained over 24 hours¹,⁸
❤ Proven achievement of recognised BP targets⁹,¹⁰

* vs. losartan, valsartan and candesartan

ABBREVIATED PRESCRIBING INFORMATION. BENETOR® 10, 20, 40mg film-coated tablets (olmesartan medoxomil). Refer to Summary of Product Characteristics (SmPC) before prescribing. Presentation: Film-coated tablets containing 10mg, 20mg, 40mg olmesartan medoxomil. Uses: Treatment of essential hypertension. Dosage: Recommended starting dose: one 10 mg tablet daily. Administer once a day, at the same time each day, with or without food. Take tablet with sufficient fluid and do not chew. Where blood pressure (BP) not adequately controlled, increase dose to 20 mg once daily as tolerated. If additional BP reduction required, increase dose to maximum 40 mg daily or addition of hydrochlorothiazide therapy. Older people: No dose adjustment generally required. If up titration required to maximum daily dose (40 mg), closely monitor BP. Children and adolescents (below 18 years): Not recommended. Renal impairment: Mild to moderate: Maximum dose 20 mg once daily. Severe: Not recommended. Hypokalemia: Mild: No dose adjustment required. Moderate: Initially one 10 mg tablet daily; maximum dose 20 mg once daily. Closely monitor BP/renal function in heathy-capped patients already receiving diuretics and/or other antihypertensive agents. Severe: Not recommended. Contraindications: Hypersensitivity to any ingredient, 2nd and 3rd trimesters of pregnancy, biliary obstruction. Warnings/precautions: Pregnancy: Contraindicated in 2nd and 3rd trimesters. Do not initiate during pregnancy. Patients planning pregnancy should change to alternative antihypertensive treatment. Stop BENETOR immediately if pregnancy diagnosed and start alternative therapy, if appropriate. Should exposure occur from 2nd trimester, recommend ultrasound check of renal function/skull closely monitor infant for hypotension. Periodic monitoring of serum potassium and creatinine levels recommended. Severe: Not recommended. Renovascular hypertension: Increased risk of severe hypotension and renal insufficiency when patients with bilateral renal artery stenosis or stenosis of the artery to a solitary kidney are treated with medicinal products that affect the renin-angiotensin-aldosterone system (RAAS). A similar effect may be anticipated with angiotensin II receptor antagonists. Intravascular volume depletion: Correct sodium and/or volume depletion before starting treatment. Aortic or mitral valve stenosis (obstructive hypertrophic cardiomyopathy): Special caution recommended. Primary aldosteronism: Not recommended. Hyperkalemia: Risk increased (may be fatal) in older people; patients with renal insufficiency, diabetes, concomitant use with potassium-lowering medicines, and/or patients with intercurrent events. Close monitoring of serum potassium levels is at risk patients recommended. Hypokalemia: Severe: Late hepatic impairment: Not recommended. Ethnic differences: BP-lowering effect of BENETOR® may be reduced in black patients. General: Combination of lithium and BENETOR® not recommended. In patients with severe congestive heart failure or underlying renal disease including renal artery stenosis, treatment with drugs that affect RAAS has been associated with acute hypotension or, rarely, acute renal failure. The possibility of similar effects cannot be excluded with angiotensin II receptor antagonists. As with any antihypertensive agent, excessive blood pressure decrease in patients with ischaemic heart disease or ischaemic cerebrovascular disease could result in a myocardial infarction or stroke. Contains lactose. Patients with rare hereditary problems of galactose intolerance, Lapp-lactase deficiency or glucose-galactose malabsorption should not take product. Interactions: Concurrent use of lithium, NSAIDs, potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium and drugs that may increase serum potassium levels not recommended. BP-lowering effect of BENETOR® may be increased by concomitant use of other antihypertensive agents. Effects on ability to drive and use machines: BENETOR® has minor or moderate influence on the ability to drive and use machines. Dizziness or fatigue may occasionally occur in patients taking antihypertensive therapy, which may impair the ability to react. Side effects: Classification very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000). Common: Abdominal pain, arthritis, back pain, blood creatine phosphokinase increased, blood urea increased, bronchitis, chest pain, cough, diarrhoea, dizziness, dyspnea, fatigue, gastritis, headache, heartache, hepatic enzymes increased, hypertriglyceridaemia, hyperuricaemia, influenza-like symptoms, nausea, pain, peripheral oedema, pharyngitis, rhinitis, skeletal pain, urinary tract infection. Uncommon: Alcoholic dermatis, anaphylactic reaction, angina pectoris, asthma, exanthema, face oedema, malaise, myalgia, pruritus, rash, thrombocytopenia, urticaria, vertigo, vomiting. Hypotension in Older people. Rare: Acute renal failure, angioedema, blood creatinine increased, hyperkalaemia, hypotension, lethargy, muscle spasm, renal insufficiency. Please consult the SmPC for the full list of reported side effects. Pack Sizes: Blister containing 28 film-coated tablets. Legal Category: POM. Product Authorisation Numbers: PA 1595/1/3. 3. Product Authorisation Holders: Daiichi Sankyo Ireland Ltd., Riverside One, Sir John Rogerson’s Quay, Dublin 2. BENETOR® is a registered trademark, the property of Daiichi Sankyo Co., Ltd., Tokyo, Japan. Additional information is available on request from: Daiichi Sankyo Ireland Ltd. Building 1, Swift Square, Northwood Road, Santry, Dublin 9. Telephone: (01) 489 3000. Fax: (01) 489 3033. Email: medinfo@daiichi-sankyo.ie Date of Preparation: February 2014.


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uncertain. Long-term administration leads to a fall in peripheral vascular resistance. This, combined with reduced cardiac output, is likely to account for the reduction of BP in hypertensive patients. Certain BBs are more selective for receptors in the heart. These are termed ‘cardioselective’ and include atenolol and bisoprolol. Non-selective agents, eg propranolol, have more adverse effects associated with them, eg tiredness, cold hands and feet and masking of hypoglycaemia in type-1 diabetics. BBs are contraindicated in asthma.11,12 Questions have been raised in recent years regarding the use of BBs as first-line agents in the treatment of HTN. They have a slight inferiority compared to other drugs in stroke prevention but show significantly better efficacy in prevention of coronary events and heart failure. They have a higher efficacy than other agents in patients with a recent coronary event.11

Diuretics

Thiazide diuretics increase sodium excretion and urine volume by blocking renal tubular sodium reabsorption. The result of this is a reduction in circulating blood volume in the short term, with the longer term effect being a reduction in peripheral resistance due to subtle alterations in contractile responses of the vascular smooth muscle. Thiazide (eg bendroflumethiazide, hydrochlorothiazide) and thiazide-like diuretics (eg indapamide, chlorothalidone) have historically been the cornerstone of antihypertensive treatment and are still viewed by the ESH/ESC as a suitable first-line choice.21 It is worth noting that one randomised controlled trial, ACCOMPLISH, did show superiority of a CCB over a thiazide in combination with an ACE inhibitor, however these results do require further replication.21 The efficacy of thiazides and thiazide-like diuretics is decreased in renal impairment. In this case it may be appropriate to substitute a loop diuretic. Adverse effects of thiazides include hypokalaemia, acute gout (due to hyperuricaemia) and new onset diabetes (due to hyperglycaemia).21,12 Metabolic effects are dose-dependent and less likely to occur with the lower doses used now compared to those used previously.21

Others

Aliskiren is a direct renin inhibitor. It binds to the active site of renin to block conversion of angio- tensinogen to Ang I, thereby reducing the production of Ang II. It may be used alone or in combination with other antihypertensive drugs. The ALTITUDE clinical trial on diabetic patients taking aliskiren in combination with another renin-angiotensin system blocker was terminated early as a result of adverse events. Concomitant use of aliskiren with ARBs or ACE inhibitors is contraindicated in patients with diabetes mellitus or renal impairment.21,24

Alpha blockers, eg doxazosin, are most often used in multiple drug combinations in cases of resistant hypertension. They may be an appropriate choice in hypertensive males with benign prostatic hyperplasia as they can improve urinary outflow.21,25 Methyldopa is a centrally acting antihypertensive drug. It is now mainly only used in pregnancy.

Additional Therapies to reduce cardiovascular risk

Lipid lowering agents

Statin therapy should be considered in hypertensive patients with established cardiovascular disease, type 2 diabetes or an estimated 10-year risk of cardiovascular death >5% (based on the SCORE chart).13

Antiplatelet therapy

Low-dose aspirin should be prescribed in hypertensive patients with previous cardiovascular (CV) events. It should be considered in hypertensive patients who have reduced renal function or a high CV risk. Blood pressure should be controlled prior to the introduction of aspirin. The risk of gastrointestinal adverse events should also be taken into consideration.10,11

Special populations

Elderly

Elderly patients have a high prevalence of hypertension. They are also at increased overall risk for CV events. The HYVET trial in patients over 80 years with systolic BP >160mmHg demonstrated benefit in reducing systolic BP to between 150 and 140mmHg, showing reduced risk of death from stroke, death from any cause and heart failure. It should be noted that the patient population studied was healthier than normal at baseline so the evidence should be extrapolated to more frail patients with caution.21 All antihypertensive agents are recommended and can be used in the elderly and the ESC guidelines state that the choice of the drugs should not be guided by age. In the case of isolated systolic hypertension, diuretics and CCBs may be preferred.10,13

Diabetes

Control of blood pressure is more difficult in patients with diabetes27 but that a reduction to <130/80mmHg should be adopted in patients at high cardiovascular risk (CV hypertension is common in diabetic patients and is associated with development of macrovascular and microvascular complications). Progressive diabetic nephropathy can lead to a reduction in renal function. Nephropathy is indicated by the detection of small amounts of albumin in the urine (microalbuminuria). Increased concentration of albumin in the urine is indicative of a progression to proteinuria, which may in turn progress to end-stage renal disease requiring dialysis.

Antihypertensive therapy is recommended in patients with systolic BP ≥140mmHg. Evidence-based targets in patients with diabetes are systolic BP goal <140mmHg and diastolic BP goal between 80-85mmHg. All classes of drugs may be used in treating hypertension in diabetes, with due consideration given to individual patient comorbidities. Combination therapy will generally be required. An ACE inhibitor or an ARB should generally be included, especially in the presence of proteinuria or microalbuminuria.11

Oral Contraceptive Users

The use of oral contraceptives (OCs) is associated with some small but significant increases in BP, on average an increase of 5/3mmHg.11 Oral contraceptives should be selected and initiated based on the potential risks and benefits for the individual woman111 (ISSN: *1558-3597*, “PMID”: “19147038”, “abstract”: Contraceptive hormones, most commonly prescribed as oral contraceptives. Oral contraceptives are not recommended for use in women with uncontrolled hypertension and there is evidence that discontinuation of combined OCs in women with hypertension may improve the BP control.20 Women who are over the age of 35 and who smoke should be prescribed OCs with caution.10

Pregnant women

Hypertension in pregnancy carries risks to both mother and baby. Raised BP detected before 20 weeks’ gestation usually indicates pre-existing chronic HTN that may not have been previously diagnosed. Hypertension diagnosed after 20 weeks may still indicate previously undiagnosed chronic HTN or it may be gestational hypertension. Women with elevated BP measurements in pregnancy are at increased risk of pre-eclampsia and foetal intrauterine growth restriction.1,20 Drug treatment is recommended in severe hypertension (systolic BP>160mmHg or diastolic BP>110mmHg). Treatment may also be considered in women with persistent BP elevation ≥150/95mmHg, or if otherwise clinically indicated.21 The preferred drugs for treatment in hypertension in pregnancy are labetalol, methyldopa and nifedipine. There is some controversy surrounding the utility of low-dose aspirin for the prevention of pre-eclampsia.21 (Cochrane Controlled Trials Register and Embase.included STUDIES: Randomised trials involving women at risk of pre-eclampsia, and its complications, allocated to antiproliferate drugs definition of pre-eclampsia, according to the guidelines of the International Society for the Study of Hypertension in Pregnancy.)

Exclusion criteria were: omitting at least one of the inclusion criteria, trials involving women with pre-eclampsia at trial entry, studies investigating hypertensive disorders other than pre-eclampsia, prophylaxis of intrauterine growth restriction with low-dose aspirin or vitamins C/E, non-randomised studies and data reported in graphs or percentages. The incidence of pre-eclampsia, perinatal outcomes and adverse effects attributable to LDA and VCE were compared between treated women and placebo. Inter-studies heterogeneity was tested. P<0.05 was considered significant. Pooled odds ratios (OR Women who are considered at high-risk of pre-eclampsia may be advised to take aspirin 75mg daily from 12 weeks until the birth, provided they are at low risk of gastrointestinal haemorrhage).21

Practice Points

• Counsel patients starting on a new antihypertensive agent and offer Medicines Use Review for those on existing therapies. Educate the patient about how the medication works to treat their condition and why and how taking the medication may benefit them. Advise on potential adverse effects and the importance of regular BP monitoring.

• Offer support and advice to patients who report adverse effects and address any issues with the prescriber, referring the patient to see them if necessary. Any suspected adverse effects should be reported to the Health Products Regulatory Authority (formerly the IMB).

• Compliance aids like blister packing may be useful for certain patients particularly in the context of polypharmacy.

• Advise on modification of lifestyle factors where appropriate, eg smoking cessation support.

• Provide information leaflets like those from the Irish Heart Foundation or refer patients to the website.
HYPERTENSION

Conclusion

Hypertension is a major risk factor for stroke, MI and heart failure and therefore should be appropriately managed, in the context of overall cardiovascular risk. Lifestyle measures are an important adjunct to pharmacological management. Patient acceptability of anti-hypertensive treatment is important for adherence so adverse effects should be taken into account and treatment modified accordingly. Combination tablets may be useful in improving adherence. Sustained BP lowering and maintenance should be the goal.

Useful Resources

Guidelines


Patient Information

1. Irish Heart Foundation website: High Blood Pressure (Hypertension) http://www.irishheart.ie/open/g24/high-blood-pressure-7-19.66.html
2. Irish Heart Foundation leaflet: Manage your Blood Pressure and Reduce your Risk of Heart Disease and Stroke: http://www.irishheart.ie/media/pub/informationleaflets/blood_pressure_newpdf.pdf

Bibliography


Assessment questions

Please read the questions below and decide, based on your reading, if the answers are true or false

1. In the majority of cases, the cause of hypertension is unknown.
2. In patients with markedly high baseline BP or at high CV risk it may be appropriate to initiate treatment with a two-drug combination.
3. A combination of an ACE inhibitor and an ARB is recommended in cases of resistant hypertension.
4. BBs no longer play a role in the pharmacological management of hypertension.
5. Hypertension diagnosed in pregnancy after 20 weeks is defined as gestational hypertension.

True
False
False
True
False
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For the Effective Management of Essential Hypertension

- Greater BP reduction vs. other ARBs
- Effective BP control maintained over 24 hours
- Proven achievement of recognised BP targets

* vs. losartan, valsartan and candesartan

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ABBREVIATED PRESCRIBING INFORMATION. BENETOR® 10, 20, 40mg film-coated tablets (olmesartan medoxomil). Refer to Summary of Product Characteristics (SmPC) before prescribing. Presentation: Film-coated tablets containing 10mg, 20mg, 40mg olmesartan medoxomil. Uses: Treatment of essential hypertension. Dosage: Recommended starting dose: one 10mg tablet daily. Administer once a day, at the same time each day, with or without food. Take tablet with sufficient fluid and do not chew. Where blood pressure (BP) is not adequately controlled, increase dose to 20 mg once daily as optimal dose. If additional BP reduction required, increase dose to maximum 40 mg daily or addition of hydrochlorothiazide therapy. Older people: No dose adjustment generally required. If up titration required to maximum daily dose (40 mg), closely monitor BP. Children and adolescents (below 18 years): Not recommended. Renal impairment: Mild to moderate: Maximum dose 20 mg once daily. Severe: Not recommended. Hepatic impairment: Mild to moderate: Maximum dose 20 mg once daily. Severe: Not recommended.

Indications: BENETOR® is indicated for the management of essential hypertension in adults. BENETOR® is contraindicated in patients with bilateral renal artery stenosis or stenosis of the artery to a solitary kidney are treated with medicinal products that affect the renin-angiotensin-aldosterone system (RAAS). A similar effect may be anticipated with angiotensin II receptor antagonists.

Contraindications: Contraindicated in patients with bilateral renal artery stenosis or stenosis of the artery to a solitary kidney are treated with medicinal products that affect the renin-angiotensin-aldosterone system (RAAS). A similar effect may be anticipated with angiotensin II receptor antagonists. Intravenous volume depletion: Correct sodium and/or volume depletion before starting treatment. Aortic or mitral valve stenosis (obstructive hypertrophic cardiomyopathy): Special caution recommended. Primary aldosteronism: Not recommended. Hyperkalemia: Risk increased (may be fatal) in older people with renal insufficiency, diabetes, concomitant use with potassium-lowering medicines, and/or patients with intercurrent events. Close monitoring of serum potassium levels in at risk patients recommended. Hepatic impairment: Severe hepatic impairment: Not recommended. Ethnic differences: BP-lowering effect of BENETOR® may be reduced in black patients. General: Combination of lithium and BENETOR® not recommended. In patients with severe congestive heart failure or underlying renal disease including renal artery stenosis, treatment with drugs that affect RAAS has been associated with acute hypertension or, rarely, acute renal failure. The possibility of similar effects cannot be excluded with angiotensin II receptor antagonists. As with any antihypertensive agent, excessive blood pressure decrease in patients with ischaemic heart disease or ischaemic cerebrovascular disease could result in a myocardial infarction or stroke. Contains lactose. Patients with rare hereditary problems of galactose intolerance, Lapp-lactase deficiency or glucose-galactose malabsorption should not take product.

Effects on ability to drive and use machines: BENETOR® has minor or moderate influence on the ability to drive and use machines.

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References:

Date of Issue: March 2014. DSIE/BEN66.
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Once again unto the airwaves

Summer’s ‘slow news days’ found Terry Maguire once again on UK national radio, this time to tackle the issue of stock shortages.

There were plenty of ‘slow news days’ in the late, lazy days of summer, as being on local radio twice in a fortnight is most unusual. It’s always good to get community pharmacy onto the airwaves, reminding the public how important and essential we are. The public need to be made aware that we work very hard on their behalf, delivering their medicines and advising on their common ailments and their general health; this is who we are and this is what we do and we don’t say it often enough or loudly enough.

My first interview at BBC’s Belfast HQ involved answering listeners’ questions on the week’s biggest headline: ‘Aspirin Reduces Cancer Risk!’ Below the myriad headlines reporting on the paper published by Cuzick et al in the Annals of Oncology, journalists were insisting that those of us over 50 are verging on moral bankruptcy when we fail to do the right thing by not taking an aspirin a day. On air I tried to qualify the hyperbole and put back some balance into the story but my telephone audience were already committed aspirinophiles and they fought back aggressively. "This man [me] is wrong; we should all be taking an aspirin a day to stop us getting cancer and heart disease," snapped Desmond from Dundonald.

My objectives when agreeing to do this interview were two-fold. First, I wanted to ensure that the risks associated with long-term aspirin use were discussed and understood — the study did not identify the most effective daily dose and if this turns out to be 325mg, then the risk of gastric bleed after 10 years’ use is increased by some 70 per cent. We might have 7–9 per cent less cancers but a lot of deaths from bleeding ulcers. Hard choice?

Secondly, I wanted to reinforce the public health messages that we already have very safe ways to massively reduce our risk of developing cancers, diabetes, cardiovascular disease and stroke — and that is, stopping smoking, taking more exercise, eating the right amount and quality of calories and managing stress. How perfectly dull and boring that sounded when I said it and I almost heard my audience expel a collective sigh of ennui.

I suppose that’s the rub. There is less interest in natural ways to support better health, particularly those that require denial and effort. Popping a pill is so much more convenient and properly scientific.

No-one was denying that the results of this study were encouraging. The methodology was a little unusual in that the quality of the data cannot be judged and thus there might be some bias in the way studies that addressed the impact of aspirin on cancer were not included. Some questions, such as the best dose, remain unanswered.

As pharmacists, we shouldn’t yet recommend public dosing with aspirin but perhaps we are potential risk to patients; and a Member of the Local Assembly (MLA) who had recent, personal and painful experience of medicine shortages, having had to return to his GP on three occasions before the required medicine was obtained and he got relief from a painful neck. And off course me, mainly there because no-one else in the pharmacy world was available to make a comment on a story that was broken in the Belfast Telegraph by the MLA, which has a canny eye, no doubt, on next May’s local elections.

Stock shortages have been the bane of pharmacy life north of the border and across the rest of the UK for about five years...
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**Dr Alan Ruth** looks at how a complaint by a customer can be used as an opportunity to learn and improve service.

"Your most unhappy customers are your greatest source of learning."

**Bill Gates**

According to the 2013 Annual Report of the Pharmaceutical Society of Ireland (PSI), a total of 48 formal complaints were received last year, concerning pharmacists and retail pharmacy businesses. In addition, 103 'expressions of concern' were received. These expressions of concern related to situations where a formal complaint was not received in writing. The majority of complaints (69 per cent) and expressions of concern (75 per cent) were from members of the public and the majority of each related to behaviour/professionalism issues.

The fact that expressions of concern were not put in writing should not be interpreted as necessarily making them less serious than complaints. For most businesses, only 10 per cent of complaints are ever articulated by customers. The other 90 per cent manifest themselves in various damaging ways, e.g. 'customer defections' (lost customers) and negative word of mouth.

This article concerns complaints made by customers to a pharmacist or other staff member in community pharmacy.

**Viewing complaints as gifts**

It's important to realise that a customer who complains is probably interested in continuing their relationship with your pharmacy and will probably do so if you effectively handle their complaint.

Research has shown that 60-70 per cent of customers who complain will do business again with the business with which they had the problem, provided their concerns are resolved. Indeed, 95 per cent of complaining customers say they would be willing to do business again if their complaints are resolved quickly.

Complaints have been described as 'gifts' that business owners should welcome, in that they are important for a number of reasons, including:

- You won't know how to improve your service if you don't know what's wrong.
- Customer complaints can give you ideas for improved or new services.
- Complaints provide valuable information about what's important to customers.
- Complaints are also 'gifts' in the sense that the vast majority of customers don't complain; they just take their business elsewhere.

**Successfully handling complaints**

Successfully handling complaints is a crucially important activity because handling them poorly can give customers negative feelings about your pharmacy. Effective handling of complaints not only resolves a customer's immediate problem, but it is an excellent way to keep customers satisfied and build customer loyalty. Community pharmacists should think in terms of the 'lifetime value' of a satisfied and loyal customer, rather than think only in terms of the value of a single transaction.

**Some guidelines**

**Allow the customer to get it off their chest.**

A complaining customer is often annoyed or angry. They should be encouraged to talk so as to reduce tension and provide details of the nature of their complaint. The person dealing with the complaint should only ask questions if it is necessary to obtain all relevant information. Any complaint, no matter how trivial it may seem, is important to the person doing the complaining.

**Listen and empathise**

Listening attentively will serve to calm the customer down and demonstrate concern on the part of the person dealing with the complaint. Full concentration should be given to what the customer says, so as to determine the facts and avoid making assumptions. It's important that the person dealing with the complaint indicates that they understand how the customer feels. Phrases such as the following can be helpful:

- "I can understand how you must feel."
- "That must have been very annoying."
- "This must have really inconvenienced you."

As a business owner, your goal is to solve the problem, not to argue. The customer needs to feel that you're on his or her side.

**Thank the customer and apologise**

Thank the customer for bringing the complaint to your attention and apologise. Tell the customer you're thanking them because you care about relationships with customers and her/his complaint will provide an opportunity to address something that isn't working as well as it could be.

Don't say it's your fault or blame anyone, just say, "I'm sorry about that". If a customer senses that you are genuinely sorry, it will usually defuse the situation. Promise that you will do whatever you can, as quickly as possible, to solve the problem.

**Don't take it personally**

An angry or upset customer may make unfounded remarks. It may be tempting for the person handling the complaint to interrupt the customer and defend themselves, or indeed, respond angrily. This temptation should be resisted. A better approach is to remain calm, listen and try to see the complaint from the customer's perspective.

**Don't say anything that will further annoy the customer**

The person dealing with the complaint should avoid saying anything that will get the customer even more annoyed. Obvious examples are:

- "Nobody has ever complained about this before."
- "I'm sorry but that's not my responsibility."

**Decide if the complaint is justified**

Having established the facts, the person dealing with the complaint should decide whether or not the complaint is justified. If it is, the person dealing with it should strive to resolve the complaint fairly. If the fault lies with the customer, it's best to let him or her down gently to allow them save face. The customer isn't always right but he/she shouldn't be told they're wrong — unless of course, you don't want them to come back!

If a customer has used a product incorrectly, the correct manner should be explained. An apology could be given to the customer for the inconvenience in having to return to the pharmacy.

**Resolve the complaint quickly**

A quick response to deal with a complaint demonstrates genuine concern and a desire to deal with the problem as a matter of urgency. The person dealing with the complaint should suggest a solution and attempt to elicit the customer's agreement to this. If a customer doesn't like the solution suggested, they should be asked what they would consider to be a fair settlement.

If the customer seems unreasonable, it may be best to give them a full refund.
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Taking care of business

Operating without the basic data is a recipe for disaster, says David Jordan

Before I first qualified, it would be safe to say that chemists were seen as just another shopkeeper, albeit with specialised knowledge. By the time that I graduated, a process of change was underway. A lot of pharmacists put a lot of effort into altering the public’s perception of the profession. Our image as healthcare professionals reached a zenith in or about the turn of the century. Since then I fear that the drift has been back to shopkeepers. This has been as a result of the recession, the actions of the HSE and the behaviour of some of our colleagues. So this month I’m going to look at the business of pharmacy.

If money out is greater than money in, then you will be the most professional pharmacist in the poorhouse. You might even need the help of the Pharmacy Benevolent Fund, a very worthy charity which I expect you will all support by going to the Helix Health Pharmacist Awards — the only pharmacy awards where all the proceeds go to charity.

Much as some of us like to see ourselves as professionals, we still have to run our pharmacies along business lines. If money out is greater than money in, then you will be the most professional pharmacist in the poorhouse. You might even have need the help of the Pharmacy Benevolent Fund, a very worthy charity which I expect you will all support by going to the Helix Health Pharmacist Awards in the Mansion House on 29 November — the only pharmacy awards where all the proceeds go to charity.

I’ll start by asking a few basic questions. If you have heard these questions before, then you are already one step ahead of the posse. If you know the answers for your own pharmacy, then skip ahead to the bottom of the page where I write “that’s all for this month, folks!” and have an early cuppa. I’ll presume that for these questions that you operate your pharmacy as a limited company. If not, then it is time to look for a new accountant or advisor.

Okay, pencils at the ready: What was your net profit for last year? What is your projected net profit for this year? Do you prepare monthly profit and loss accounts?

You most probably know the first and could probably make a good stab and the second. You may think that this is basic stuff but there are those who don’t know the answers. You need this intelligence about your business to survive.

You will always find those who say, ‘sure, isn’t there enough cash there to put something away at the end of the year?’ Or ‘the accountant looks after all that for me’. These are like the customer who refuses all offers of free blood pressure screenings, insisting that he is fine. Right up to the day of the stroke or heart attack. To keep with our hypertensive patient, what is he doing that gives him blood pressure? What can he do to reduce his risk? We need all the information to be able to come up with a proper plan of action.

Next questions: What is your percentage margin (net or gross) and how does it compare to national and local averages? Of every euro that a customer hands across the counter, how much goes into your suppliers’ pockets, how much to overheads and how much ends up in your pocket? This only relates to customers getting something at the till. How many people cross the threshold of your pharmacy every day, week, year? How many pass the threshold without coming in? What can you do to transform those who pass, to those who cross, to those who buy something? How many patients collecting prescriptions buy something else?

And while on spending, what is the average spend per customer and what is the breakdown between OTC, FOS and Rx? Do you have any metrics that you use to judge performance on a day-to-day basis? I use the number of GMS scripts. Because my pharmacy is prescription-based and mainly GMS, this gives me a surprisingly accurate read of daily, weekly and monthly sales.

Last few questions. What’s your best seller? By volume, by value or by profit? Is there any niche product that you could sell that would generate more footfall? Preferably something that fits in with a pharmacy. Think outside the box. How about a newsagent? Low margins but loads of footfall every day.

Hands up here — I don’t know the answers to all these questions about my own pharmacy but I’m doing my damndest to find out.

You might be surprised to learn that a lot of this information is already out there. First port of call is your own disposable computer and EPOS. What, you don’t have an EPOS? That’s like giving up smoking — it’s a no-brainer. Next you get a student on work experience or a pre-reg to count every person who walks past and into the pharmacy. Depending on your layout, it may also be possible to count how many of these actually go to the till.

Outside bodies have a lot of intelligence relating to Irish pharmacy as well. Some of it relates to your pharmacy and a lot of it is part of a bigger picture. Your wholesalers and the HSE are the first that spring to mind. They will only share it in a very limited way and usually long after the event.

You can be sure that the multiples, both in pharmacy and general retail, have done this work about their own business and probably your pharmacy, if they see it as a direct competitor.

As individuals and as a profession, we must have this information at our fingertips and we need it in a timely manner. There are very few of us who could gather this — a national organisation is needed. How about the IPU?

A good many years ago the IPU decided to take control of the price list. This is so long ago that many of us take it for granted. But then it was a key move which strengthened pharmacists’ hands immensely. Now they are moving to gather all the economic data on Irish pharmacy into one place and to use it for the benefit of members, both nationally and individually. You may already heard about Health Market Research Ireland, the joint initiative between the IPU and National Pharmacy Association in Portugal, which will shortly be introducing a state-of-the-art business intelligence service for pharmacies. I don’t have enough space here to go into the detail of it. That will have to wait until another day. Suffice to say I will be signing up.

If you are running your business without this basic intelligence, then you are operating on a wing and a prayer. That’s what our politicians did for the last God knows how many years — and look how we ended up.

Now, for those who skipped ahead — that’s all for this month, folks!
Solpadeine Soluble Tablets (P) contain Paracetamol, Codeine Phosphate Hemihydrate and Caffeine. For the treatment of acute moderate pain not relieved by other analgesics such as paracetamol or ibuprofen alone; for symptoms of headache, including migraine, toothache, backache, common cold, influenza, menstrual pain, musculoskeletal pain. Adults and children 12 years and over: 2 tablets in water three to four times in 24 hours as required; not more frequently than once every four hours. Maximum 8 tablets in 24 hours. Children under 12 years: Not recommended. Do not take for more than 3 days without consulting a doctor. Do not take any other paracetamol or codeine containing products concurrently. Avoid excessive caffeine intake. Can cause addiction. Use for 3 days only. In case of overdose, seek immediate medical advice, even if the patient feels well.

Contraindications:
- Lactation
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- Known CYP2D6 ultra-rapid metabolisers
- Patients under 18 years who undergo tonsillectomy or adenoidectomy for obstructive sleep apnoea syndrome
- Rare hereditary fructose intolerance.

Precautions:
- Caution in renal or hepatic impairment, non-cirrhotic alcoholic liver disease, obstructive bowel disorders, previous cholecystectomy, acute abdominal conditions, pregnancy, hypertension, oedema. Interaction with coumarins (including warfarin), domperidone, metoclopramide, colestyramine, monoamine-oxidase inhibitors. Side effects: anaphylaxis, bronchospasm, dependency or worsening of headache following prolonged use, dizziness, GI disturbances, hepatic dysfunction, thrombocytopenia.

Published Under

International Pharmaceutical Federation World Congress

Attendees at the 74th International Pharmaceutical Federation World Congress in Bangkok

Ms Carmen Peña, new FIP President; Mr Luc Besançon, FIP General Secretary and CEO; and Dr Michel Buchmann, outgoing FIP President

Mr Mike Rouse, FIP Education Initiative Quality Assurance Lead

Ms Wei Wen Chong, National University of Malaysia

Ms Arijana Mestrovic, Head of the Education Centre Department of Competency Development, Atlantic Farmacia

Mr Thomas Menighan, American Pharmacists Association, addresses the Council meeting

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Indications: in combination with trastuzumab and docetaxel for the treatment of adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease. Dosage and Administration: Please refer to Perjeta Summary of Product Characteristics (SmPC) for full guidance. Perjeta is for use in adults only. Treatment should be initiated under the supervision of a physician experienced in the administration of anti-cancer agents. Perjeta should be administered by a health care professional prepared to manage anaphylaxis and to its environment with full resuscitation facilities immediately available. Administer an antienzyme (I) infusion (not as an IV push or bolus) through a dedicated line. Patients treated with Perjeta must have HER2-positive tumour status, defined as a score of 1+ by immunohistochemistry (IHC) and/or a ratio of ≥1.8 by in situ hybridisation (ISH) assessed by a validated test, refer to SmPC for further details. The recommended initial loading dose is 490 mg administered as a 60 minute intravenous infusion followed every 3 weeks thereafter by a maintenance dose of 420mg administered over a period of 30-60 minutes. When administered with Perjeta the recommended initial loading dose of trastuzumab is 8mg/kg body weight administered as an intravenous infusion followed every 3 weeks thereafter by a maintenance dose of 6mg/kg body weight. When administered with Perjeta the recommended initial dose of docetaxel is 100mg/m² administered over 60 minutes. The dose of docetaxel may be escalated to 100mg/m² on subsequent cycles if the initial dose is well tolerated. The medical problems should be administered sequentially Perjeta and trastuzumab and Perjeta and docetaxel are given in the order of the patient receiving docetaxel, the docetaxel should be administered after Perjeta. An observation period of 30-60 mins is recommended after each Perjeta infusion before commencement of any subsequent infusion with chemotherapy or docetaxel. If a patient develops an infusion related reaction interrupting or slowing the infusion may help control symptoms; resume when symptoms abate. Treatment-related adverse experiences, neutropenia, anaemia, rash, pyrexia, asthenia, arthralgia and myalgia may also help alleviate symptoms. Discontinue if patient experienced (NCI-CTCAE grade 4) reaction (anaphylaxis), bronchoospasm or acute respiratory distress syndrome, refer to SmPC for further details. Not recommended in patients <18 years of age. Dose adjustments are not needed in patients with mild or moderate renal failure. No data is available in patients with severe renal impairment or hepatic impairment. Administer until disease progression or unmanageable toxicity. Refer to SmPC for guidance on missed doses. Dose modifications: Dose reduction not recommended. Patients may continue treatment during periods of reversible chemotherapy-induced mycophenolate but should be monitored for complications of neutropenia, for docetaxel dose modifications to be recommended, refer to SmPC if trastuzumab is discontinued. Perjeta treatment should be discontinued. If docetaxel is discontinued, continue treatment with Perjeta until disease progression or unmanageable toxicity. Left ventricular dysfunction: Perjeta and trastuzumab should be withheld for at least 3 days if signs and symptoms suggestive of congestive heart failure, a drop in left ventricular ejection fraction (LVEF) by ≥10% or a LVEF of <40% associated with a ≥10% points below pre-treatment values. Treatment with Perjeta and trastuzumab may be resumed if LVEF has recovered to ≥10% or 40-45% associated with ≥10% points below pre-treatment values. Repeat LVEF assessment within 3 weeks. If LVEF does not improve or further decline consider discontinuation of Perjeta and trastuzumab, refer to SmPC for further details. Contraindications: Severe hypersensitivity reactions (NCI-CTCAE Grade 4) to any of the ingredients. Warnings and Precautions: Please refer to the Perjeta SmPC for further information. Perjeta has not been studied in patients with a pre-treatment LVEF value ≤50%, a prior history of congestive heart failure (CHF), LVEF declines to ≥10% during prior trastuzumab or adjuvant therapy, or conditions that could impair left ventricular function such as uncontrolled hypertension, recent myocardial infarction, serious cardiac arrhythmia requiring treatment or a cumulative anthracycline exposure to >360mg/m² of doxorubicin or its equivalent. Patients who have received prior anthracyclines or prior radiotherapy to the chest area may be at higher risk of LVEF declines. Assess LVEF prior to initiation of Perjeta and at regular intervals for at least three months during treatment. If LVEF is <40% or 40-45% associated with ≥10% points below the pretreatment value, Perjeta and trastuzumab should be withheld and a repeat LVEF assessment performed within approximately 3 weeks. If the LVEF has not improved, or has declined further, discontinuation of Perjeta and trastuzumab should be strongly considered. Perjeta has been associated with infusion and hypersensitivity reactions. Close observation of the patient during and for 60 minutes after the first infusion and during and for 30-60 minutes after subsequent infusions is recommended following the administration of Perjeta. If an infusion reaction occurs, the infusion should be slowed down or interrupted and appropriate medical therapies should be administered. Patients should be evaluated and carefully monitored until complete resolution of signs and symptoms. Permanent discontinuation should be strongly considered for any patient who experiences a severe (NCI-CTCAE Grade 4) infusion reaction. Patients treated with Perjeta, trastuzumab and docetaxel are at increased risk of febrile neutropenia compared with patients treated with placebo, trastuzumab and docetaxel, especially during the first 3 cycles of treatment. Higher incidences of febrile neutropenia in Perjeta treated patients may be associated with the higher incidences of myelotoxicity in these patients. Symptomatic treatment for myelotoxicity and diarrhoea should be considered.

Drug Interactions: No formal interaction studies have been performed. No pharmacokinetic interactions were observed between Perjeta and docetaxel, trastuzumab, or between Perjeta and docetaxel in the pivotal trial. No evidence of effects of Perjeta on the PK of docetaxel, gemcitabine, erlotinib and capecitabine. Fertility, Pregnancy and Lactation: Avoid during pregnancy unless potential benefit outweighs risks. Women of childbearing potential should use effective contraception while receiving Perjeta and for 6 months following the last dose of Perjeta. A decision should be made to discontinue breast-feeding or to discontinue treatment taking into account the benefit of nursing for the child and the benefit of Perjeta therapy for the woman. Side-effects and adverse reactions: Please refer to the Perjeta SmPC for further information. In the pivotal clinical trial Perjeta was given in combination with docetaxel and trastuzumab, it is therefore, difficult to ascertain the causal relationship of an adverse event to a particular medicinal product. The safety of Perjeta-in phase II and III studies was generally consistent with that observed in the pivotal trial, though the incidence and most common AEs varied depending on whether Perjeta was administered as monotherapy or in combination with anti- HER2-anticipating agents. Very common reactions: Upper respiratory tract infection, nasopharyngitis, febrile neutropenia, neutropenia, leucopenia, anemia, hypertension, anaphylaxis, reactions, infusion related reactions, cytokine release syndromes, decreased appetite, insomnia, peripheral neuropathy, peripheral sensory neuropathy, headache, dizziness, dyspnoea, larynx oedema, dyspnoea, cough, diarrhea, dermatitis, nausea, constipation, dyspepsia, alopecia, rash, diarrhoea, pruritus, dry skin, myalgia, erythema, mucositis/mucosal inflammation, pain, oedema, diarrhea, cough, dysgeusia.

Dear Healthcare Professional, 

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We are pleased to inform you that Perjeta® is now available in the following countries:

Roche Products (Ireland) Limited

404 Lake Drive, Citywest, Naas Rd, Dublin 24. Telephone: (01) 6400700 Fax: (01) 6400791 Date of Preparation: November 2013.


4. Roche Registration Limited, 6 Columbia Road, London E3 2AP, UK.

5. Cochrane Library: The Pharmacovigilance Section Roche Products (International) Limited Telephone: (01) 6400700 Fax: (01) 6400793 Email: ineland_drug_surveillance_centre@roche.com Website: www.medicines.ie Email: info@pharmacovigilance@roche.com Additional information will be requested during a PERJETA-exposed pregnancy.

Enhanced Safety Reporting for Potential Perjeta-Exposed Pregnancies

Perjeta should be avoided during pregnancy. There is limited amount of data from the use of Perjeta in pregnant women and the safe use of Perjeta during pregnancy and lactation has not been established.

Verify pregnancy status prior to the initiation of Perjeta. Women of childbearing potential should use effective contraception while receiving Perjeta and for 6 months following the last dose of Perjeta.

Monitor patients who become pregnant during PERJETA therapy or within 6 months following the last dose of PERJETA closely for oligohydramnios.

If PERJETA is used during pregnancy or if a patient becomes pregnant while being treated with PERJETA or within 6 months following the last dose of PERJETA, immediately report exposure to the local Roche Adverse Event Line at Tel: (01) 6400702 Fax: (01) 6400791 Email: ineland_drug_surveillance_centre@roche.com

Out of Hours: 01201945.

Additional information will be requested during a PERJETA-exposed pregnancy.

GermENCHEN to better understand the safety of PERJETA and to provide appropriate information to Health Authorities, Healthcare Providers and patients.

Date of Issue: June 2014

P13/05/14

*First licensed. HER2 dimerisation inhibitor (HDI) for the first-line treatment of HER2-positive metastatic breast cancer (mBC)1,2,3

Breast cancer is one of the most common cancers among women in Ireland. About one-in-12 women will develop breast cancer in their lifetime and it is more common in women aged 50 and over.

In Ireland, there are approximately 2,800 cases of invasive and 340 in situ breast cancer diagnoses in women annually. It is the second-highest cause of invasive cancer deaths in women after lung cancer. In 2012, 675 women died from breast cancer. However the five-year relative survival rate has increased to 85 per cent in recent years.

October is breast cancer awareness month and pharmacists can have a significant impact on raising awareness of the disease and on the lives of patients being treated for breast cancer, through offering tailored support, advice and information.

The Irish Cancer Society breast cancer awareness campaign for October 2014 is called ‘Paint it Pink’ and it is calling on men and women throughout Ireland to come together this month in the fight against breast cancer by doing something big or small to ‘Paint it Pink’ on 3 October, and raise money for the Society’s work across breast cancer funding vital research, advocacy and services to those affected by breast cancer.

Irish Cancer Society Chief Executive Officer Mr. John McCormack said the campaign is all about doing something to ‘Paint it Pink’ this October, sharing pictures of your activity online, and texting the word ‘Pink’ to 50300 to donate €4 to the Society. “We can’t continue our work in the fight against breast cancer without raising significant funds, so we hope men and women across the country will get behind the campaign and ‘Paint it Pink’ with us. It is through campaigns such as ‘Paint it Pink’ that we can continue to fund and support exciting initiatives such as BREAST-PREDICT.”

**Awareness**

Most pharmacies will carry leaflets from the Irish Cancer Society and other associations like the Marie Keating Foundation, highlighting what women should look out for regarding potential symptoms of breast cancer. Pharmacists can order breast cancer leaflets and booklets from the Irish Cancer Society’s website, which can be displayed this month as well as throughout the year.

All pharmacists should familiarise themselves with the contents of these leaflets and of the local breast cancer screening services, ie BreastCheck, in their area.

Screening saves lives by catching cancer early and every 500 women screened will ensure that one life will be saved. BreastCheck is the Government-funded programme providing breast screening and invites women aged 50 to 64 for a free mammogram on an area-by-area basis every two years. However, women between the ages of 60 and 69 have the second-highest incidence of breast cancer and the second-highest risk of dying from the disease so there have been numerous calls to roll-out the free breast cancer screening scheme to women aged between 65 and 69. In addition, for those women who have been identified to be carriers of certain genetic mutations, HIQA has concluded that surveillance for women aged 30 to 49 using MRI is cost-effective.

For women who have been identified to be carriers of certain genetic mutations, HIQA has concluded that surveillance for women aged 30 to 49 using MRI is cost-effective.

It is something that they should go away and have checked, so being open, confident and reassuring about such discussions is vital, as is direct referral to their local GP to get checked out, noted Ms Elizabeth Laing, a community pharmacist based in Sligo.

**Treatment**

Pharmacists deal regularly with patients who have been diagnosed with breast cancer and who come in for various prescription medicines and advice.

“So sometimes we see them even before they have formally started treatment, and it...
is good to reassure them that we have seen and dealt with lots of patients in their situation who have come through the other side,” Ms Laing told Irish Pharmacist.

She said as well as explaining about how and when exactly to take the various medications they have been prescribed correctly, it is important to explain why the medications have been prescribed, ie some medications are to offset the adverse effects of chemotherapy, like developing nausea and mouth ulcers or oral thrush, for example.

“For the first two doses of chemotherapy they can feel quite well, but after the third and the fourth dose, as they get further into treatment, they can feel sicker and sicker and it is important that they know that in advance so they take the anti-nausea medications, for example,” Ms Laing commented.

Medication side-effects can be a significant issue for breast cancer medications and generate a lot of queries for Irish pharmacists. Beyond the obvious side-effects from chemotherapy, tamoxifen can also cause menopausal symptoms and other side-effects.

It is important that pharmacists are proactive in tackling the side-effects of cancer medications, given the risks patients face if they do not take them. The issue of poor long-term treatment adherence with breast cancer medications (50 per cent or worse in some studies) was raised in a special meeting and report by the Irish Platform for Patients’ Organisations, Science and Industry (IPPOS) last year.

However Ms Laing said in her experience, medication compliance is very good in cancer patients, given the fear of what could happen if they do not take the drugs properly and in full.

Women who survive breast cancer are also faced with the impact on their reproductive life. Treatment can often reduce fertility and menopausal symptoms and chemotherapy-induced amenorrhoea are significant issues for survivors. Stress and depression are also significant risk factors in these patients.

To help these patients and their families, a holistic approach to care is needed, with just as much focus on their emotional as their physical needs. Addressing quality of life issues can be instrumental in helping the patient move through the treatment process. It is vitally important to convey that there are things patients can do that will help them feel better, both physically and emotionally, and that these things are worth pursuing.

This includes reminding breast cancer patients that a healthy diet, lifestyle, some exercise as well as rest, and keeping in touch with family and friends when they feel able can help them more in their fight against cancer as opposed to ‘just taking to the bed’.

### Services

Some pharmacies in Ireland offer more specialised breast cancer services for their patients. For example, Lynch’s Pharmacy in Douglas, Cork, offers its patients a free 30-minute consultation that covers ‘what is breast cancer?’, how it is treated and how to live with it — essentially, a breast cancer management programme. This consultation would include comprehensive information on the drugs to use to treat breast cancer, particularly chemotherapy and hormonal therapies and aromatase inhibitors, and what side-effects to expect, as well as what natural or OTC remedies can be taken to address nausea.

Pharmacists should ask if breast cancer patients are taking any herbal medicines because they could contain active ingredients that could interact with prescribed medicines and cause dangerous adverse reactions.

### Irish Cancer Society national clinical study aimed at improving outcomes for breast cancer patients

To mark the launch of their new breast cancer campaign, ‘Paint it Pink’, the Irish Cancer Society recently announced the roll-out of a national clinical study by its first Collaborative Cancer Research Centre, BREAST-PREDICT.

The research is aimed at understanding how aspirin may improve outcomes in breast cancer patients. This follows on from a recent research breakthrough funded by the Irish Cancer Society and Health Research Board, which found that women who had been prescribed aspirin regularly before being diagnosed with breast cancer were less likely to have cancer that spread to the lymph nodes than women who were not on prescription aspirin.

The next step in this research will be to investigate how aspirin may have this effect. To answer this question, Irish Cancer Society BREAST-PREDICT researchers are looking to gather information on exposure to this medicine from almost 3,000 breast cancer patients around the country. Patients participating in this study will be asked to answer some questions on their recent exposure to aspirin, information that can then be analysed by researchers. Scientists will also carry out laboratory-based studies to examine the mechanisms by which this drug might act to reduce the risk of breast cancer spreading.

This study is just one of a number of clinical studies run by the national cancer clinical research organisation, the All Ireland Co-operative Oncology Research Group (ICORG), which will enable Irish Cancer Society BREAST-PREDICT researchers to study tissue and blood samples from breast cancer patients across Ireland. In addition to funding the BREAST-PREDICT Collaborative Cancer Research Centre, the Irish Cancer Society also provides core funding to ICORG every year to allow clinical trials to take place across Ireland in the area of breast cancer and many other cancers. Through clinical trials run by ICORG, Irish Cancer Society BREAST-PREDICT researchers now have access to tumour and serum samples from over 1,000 breast cancer patients for their research studies. These samples can be used to improve understanding of how the individual characteristics of each tumour can dictate how likely a patient is to experience a recurrence, or how responsive they will be to a particular treatment.

The samples collected are from patients undergoing treatment for breast cancer. Scientists can profile these samples in order to understand how tumours can adapt and evolve in response to treatment, and to understand why certain patients develop resistance, while others are cured. Irish Cancer Society BREAST-PREDICT researchers are also working on identifying biomarkers that could indicate the presence of breast cancer, or the most appropriate treatment for a specific patient. It is hoped that this research may make personalised medicine a reality, whereby each breast cancer patient would have their treatment plan tailored for them based on the unique characteristics of their tumour.

Commenting on the roll-out of the study, Irish Cancer Society Acting Head of Research Dr Sinéad Walsh said: “The Irish Cancer Society firmly believes that excellent cancer research goes hand-in-hand with excellent cancer care and so we are delighted with the progress of the clinical research being conducted by our first Collaborative Cancer Research Centre, BREAST-PREDICT. Ultimately, through this research, breast cancer patients in Ireland today are playing an important role in improving the lives of breast cancer patients in the future.”

The announcement of the roll-out of the clinical study comes as the Irish Cancer Society launches its new breast cancer campaign, ‘Paint it Pink’.
For over 200 years RCSI has played a major role in medical education and training in Ireland. Founded in 1784 to train surgeons, today the College provides extensive education and training in the healthcare professions at undergraduate and postgraduate level. The School of Pharmacy was established in 2002 and is now an integral part of the College. The School currently delivers a Bachelor of Science Pharmacy [BSc(Pharm)], a Master of Pharmacy (MPharm) and educates research students to MSc and PhD level. The School has now entered a period of significant growth and change, with expanding research activities across a number of areas and increasing international student numbers and activities.

To enable this growth the School has recently established a new management structure to support the Head of School in delivering the School strategy. Arising from this new management structure and our continued growth, a number of additional roles have been created within the School, for which we are now seeking applicants.

We are looking for highly motivated individuals who will thrive working in a dynamic and rapidly changing environment to join us in the next phase of our growth.

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**Closing Date: 24th October 2014**

RCSI is an equal opportunities employer
The Irish Pharmacist blog takes a look at the more unconventional niches in medical research and world news.

**In sickness and in health**

A new study by researchers at Rutgers University in the US has found that while wives become unhappy if their spouse is ill, the happiness level of husbands remains largely unchanged if their wives experience ill health.

“We know that when a partner is sick it is the wife that often does the care-giving, which can be a stressful experience, but often when a women gets sick it is not her husband she relies on, but her daughter,” according to Prof Deborah Carr of the Department of Sociology, School of Arts and Science at Rutgers.

The researchers also found that the happier a wife is in a marriage, the more content the husband will be: “It comes down to the fact that when a wife is satisfied with the marriage, she tends to do a lot more for her husband, which has a positive effect on his life. Men tend to be less vocal about their relationships and their level of marital unhappiness might not be translated to their wives,” explained Prof Carr.

The research was published in the Journal of Marriage and Family and assessed how the health of a marriage affects the psychological well-being of older adults.

The research involved 394 couples who were part of a national study of income, health and disability in 2009 and a minimum of one of the spouses was aged 60 or older and on average, the couples had been married for 39 years.

Study participants kept detailed diaries to record when their partner annoyed them most, including in activities such as performing household chores, shopping and watching TV. The overall results showed that husbands are generally happier in the marriage than their wives.

“For both spouses, being in a better-rated marriage was linked to greater life satisfaction and happiness,” commented Prof Carr. “The quality of a marriage is important because it provides a buffer against the health-depleting effects of later-life stressors and helps couples manage difficult decisions regarding health and medical decision-making.”

**The carrot and the stick**

For those who need an evidence-based reason not to spank their children, the issue has been put to bed once and for all by a new study.

Dr Murray Strauss, Co-Director of the Family Research Lab and Professor Emeritus of Sociology at the University of New Hampshire, US, has compiled four decades of data and shown that spanking a ‘naughty’ child increases the risk of criminal and antisocial behaviour and actually impairs cognitive development.

In his book The Primordial Violence, Dr Strauss collates the results from studies across 32 nations and 7,000 US families and presents compelling proof of the long-term societal damage caused by striking children, as well as evidence that spanking has a deleterious effect on children’s mental health.

“More than 20 nations now prohibit spanking by parents,” comments Dr Strauss.

“There is an emerging consensus that this is a fundamental human right for children. The United Nations is asking all nations to prohibit spanking. Never spanking will not only reduce the risk of delinquency and mental health problems, it also will bring to children the right to be free of physical attacks in the name of discipline, just as wives gained that human right a century and a quarter ago.”

While hard-line parents have claimed that spanking achieves the immediate result of altering a child’s behaviour, Dr Strauss found that this is achieved at a great cost: “Research shows that spanking corrects misbehaviour but it also shows that spanking does not work better than other modes of correction, such as time out, explaining and depriving a child of privileges,” he says.

“Moreover, the research clearly shows that the gains from spanking come at a big cost. These include weakening the tie between children and parents and increasing the probability that the child will hit other children and their parents and as adults, hit a dating or marital partner. Spanking also slows down mental development and lowers the probability of a child doing well in school.”

Dr Strauss and his colleagues are lobbying for a governmental policy change to protect children from spanking, including warnings that would be included with birth certificates and ‘never spank’ public announcements.

“More than 100 studies have detailed these side effects of spanking, with more than 90 per cent agreement among them,” comments Dr Strauss.

“There is probably no other aspect of parenting and child behaviour where the results are so consistent.”

**Position paper**

As any healthcare professional knows, chronic back pain has a serious effect on quality of life, including the sex lives of couples less than a year old. Now Prof Stuart McGill of Waterloo’s Faculty of Applied Health Sciences and his team have established, for the first time ever, the specific movements of the spine during sex.

Using infrared and electromagnetic motion capture systems, the team found that medical advice traditionally given to back-pain sufferers seems to be erroneous.

Co-author Dr Natalie Sidorkewicz comments: “Before now, ‘spooning’ was often recommended by physicians as the one position that fits all. But as we’ve discovered, that is not the case. Sex positions that are suitable for one type of back pain aren’t appropriate for another kind of pain.”

The research, reported in Science Daily and published in the journal Spine, provides guidelines on ‘thrusting positions’ and offers evidence-based advice on correct sex positions based on what movements trigger the pain.

Dr Sidorkewicz adds: “For the first time ever, we now have very solid science to guide clinicians on their recommendations for patients who suffer debilitating back pain, but still want to be intimate. This has the potential to improve quality of life, and love-life, for many couples.”

The research focused on men with back pain but work is ongoing to produce similar guidelines for female back-pain sufferers, potentially changing the advice traditionally offered to such patients. Prof McGill explained: “Any family doctor will tell you that couples often ask them how to manage their back pain during and after sex. Many couples will remain celibate because one night of love-making can lead to months of back agony. Until now, doctors have never had any hard science to base their recommendations upon.”
Check your answer when you log on to PharmacistCPD. Complete our latest module on Allergic Rhinitis and earn CPD credits at the same time.

This module discusses the pathogenesis of, and risk factors for, allergic rhinitis. Possible complications and its impact on asthma are included. Treatment covers non-pharmacological interventions and both systemic and topical pharmacotherapy.
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Born from the happy re-phrasing of one of the bleakest foreign policies ever, these ‘War on Error’ erasers are rubbery reminders that everyone makes mistakes.

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These little soldiers are also a nice trip down memory lane for those of us deemed too old to play with the old-style toy soldiers. It’s a touch of nostalgia that will bring a smile to the face of the youngster in us all and a practical gift as the school year starts again.

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The world famous Leatherman Juice CS4 is the perfect tool for any occasion. Smaller hands will appreciate all the same power and features as other full-size multi-tools, with specially-sculpted handles. The colourful Juice CS4 is now available with textured aluminium handles in both Granite and Columbia.

The Juice is a fantastic tool that is ready and able for any emergency or quick-fix that may require some attention. It also includes a corkscrew for the more pleasurable after-hours requirements.

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A new web resource for people who have undergone an organ transplant, Transplant360.com, has been launched to provide long-term health advice and support. The initiative will be a focal point for the entire transplant community, including patients, carers and healthcare professionals, to promote long-term health after receiving an organ transplant.

“Currently in Ireland, out of 3,900 patients with failed kidneys 53 per cent, or 2,100, are transplanted and 47 per cent, or 1,800, are on dialysis. Including all other organ transplants, there are just under 3,000 people in Ireland enjoying extended life because of organ donation resulting in transplantation,” explained Mr Mark Murphy, CEO, Irish Kidney Association.

“Organ recipients face a number of challenges after a successful transplant and need to develop a particular approach to their wellbeing to keep themselves, and their new organ, as healthy as possible and Transplant360.com provides information and tips on how to deal with these issues,” he added.

The main adjustment for organ recipients is the strict regime of anti-rejection medication and regular check-ups, which go hand-in-hand with transplantation. Transplant360.com provides people living with a transplanted organ with in-depth information about how anti-rejection medications work and why it is vital to maintain a strict medication schedule, as well as attending follow-up checks.

According to Prof Jim Egan, respiratory physician specialising in heart and lung transplants: “Many organ recipients experience side-effects or find managing their medications challenging. After becoming accustomed to managing these, it is important to maintain a good diet and regular physical activity to keep cholesterol and blood pressure down.

“Organ recipients must also be aware of the risk of infection because medications dampen the immune system and Transplant360.com is a vital source of information for the transplant community in helping to manage this.”

New Novartis heart failure medicine LCZ696 cuts cardiovascular deaths by 20% vs ACE inhibitor

• Study showed significantly more HF-REF patients on LCZ696 regimen were alive and had fewer hospitalisations than those given enalapril regimen.
• On all-cause mortality, LCZ696 doubled the effect that enalapril, an ACE-inhibitor, previously showed vs placebo when added to current best treatment for HF-REF.
• 26 million people across US and Europe live with heart failure, facing high risk of death and poor quality of life.

Novartis has revealed that its investigational heart failure medicine, LCZ696, (presented at the European Society of Cardiology congress and published simultaneously in the New England Journal of Medicine), was superior to ACE-inhibitor enalapril on key endpoints in the largest heart failure study ever. In PARADIGM-HF, patients with heart failure with reduced ejection fraction (HF-REF) who were given LCZ696 were more likely to be alive and less likely to have been hospitalised for sudden deterioration of their heart failure than those given ACE-inhibitor enalapril. Patients received LCZ696 or enalapril on top of current best treatment.

The magnitude of benefit with LCZ696 against enalapril in HF-REF patients was highly statistically significant and clinically important. In the study, the benefit of LCZ696 was seen early, was sustained and was consistent across subgroups. LCZ696:

• Reduced the risk of death from cardiovascular causes by 20 per cent (p=0.00004). 
• Reduced heart failure hospitalisations by 21 per cent (p=0.00004).
• Reduced the risk of all-cause mortality by 16 per cent (p=0.00005).

Overall, there was a 20 per cent risk reduction on the primary endpoint, a composite measure of CV death or heart failure hospitalisation (p=0.0000002).

“By demonstrating a very significant reduction in cardiovascular deaths while improving quality of life, Novartis’s new heart failure medicine, LCZ696, represents one of the most important cardiology advances of the last decade,” said Mr David Epstein, Division Head, Novartis Pharmaceuticals.

LCZ696, a twice-a-day tablet being investigated for heart failure, has a unique mode of action which is thought to reduce the strain on the failing heart. It acts to enhance the protective neurohormonal systems of the heart (NP system), while simultaneously suppressing the harmful system (the RAAS). Currently-available medicines for HF-REF work only to block the detrimental effects. Despite existing therapies, the mortality rate remains very high, with up to 50 per cent of patients dying within five years of a diagnosis of heart failure. Approximately half of patients with heart failure have HF-REF12.

Analysis of the safety data from PARADIGM-HF showed side-effects were manageable in the study. Fewer patients on LCZ696 discontinued study medication for any adverse event compared to those on enalapril (10.7 per cent vs 12.3 per cent, respectively, p=0.03).

As part of the First 1,000 Days Awareness Week, which is running from 1-7 September, Danone Early Life Nutrition hosted a medical symposium in association with the INDI, which saw internationally renowned speakers discuss the long-term effects of good nutrition during the first 1,000 days of life. Attended by almost 100 Irish healthcare professionals, the event is part of a programme designed to deliver behavioural change in the approach taken to early life nutrition in Ireland.

The first 1,000 days of life, from conception right up to two years of age, has been identified by medical experts as a ‘window of opportunity’ where getting nutrition right can have a profound impact on the long-term health of an individual.

First 1,000 Days ambassador, dad and chef Neven Maguire; and Deputy Mary Mitchell O’Connor at the First 1,000 Days Awareness Week.

Speakers at the event included Prof Simon Langley-Evans, Deputy Head of School and Professor of Human Nutrition at the University of Nottingham’s School of Biosciences; Prof Marion M Hetherington, who holds a Chair in Biopsychology at the University of Leeds; and Dr Wendy Lawrence from the University of Southampton.

Speaking at the event, Prof Langley-Evans said: “Everyone knows the old ‘you are what you eat’ phrase but what people don’t understand is that really, we are what our mothers ate too. Our genes are programmed in early development and nutrition modifies the expression of such genes during critical developmental stages, this can have a permanent effect on our physiology and disease risk. Studies show that the greatest risk of diseases in adult life are driven by low birth weight followed by rapid weight gain in childhood.”

Prof Hetherington spoke about the importance of early, varied and repeated exposure to healthy foods. She said: “The fact of the matter is that a diet rich in fresh vegetables, and fruit to a lesser extent, can protect an individual against certain cancers, heart disease, type 2 diabetes and cognitive decline. You often hear parents saying their child won’t eat vegetables but it is actually relatively easy to learn to like vegetables. Studies show that early, varied and repeated exposure to healthy foods promotes their intake.”

Dr Lawrence spoke about the importance of support in order to aid behaviour change. She said: “Simply providing pregnant women and parents with information about healthy eating is unlikely to be effective. A far better strategy is to support them to identify the problems they face in eating well, and empower them to generate their own solutions and plans for change.”

For more information visit www.first1000days.ie.
Pfizer Consumer Healthcare has announced the launch of a new OTC treatment for Heartburn, Nexium Control.

Available now, Nexium Control is indicated for the short-term treatment of reflux symptoms in adults. Presented in pack sizes of seven and 14 tablets, each gastro-resistant tablet contains 20mg esomeprazole, the world’s leading PPI. Full product information is available on www.medicines.ie.

The launch will be supported by marketing investment to include in-store point of sale, window material and merchandising, and online and TV advertising. Product training and educational resources are also available.

For more information, please contact your local Pfizer Consumer Healthcare representative or call 01 467 6500.

**National Diabetes Cup**

Bayer Diabetes Care in Ireland and Medtronic have sponsored The National Diabetes Cup for the second year running. The football tournament is a fun day out for 7-14 year-old children who suffer from diabetes and is held in association with the national patient group, Diabetes Ireland.

The day was a great success, with fun-packed events and prizes, games and a family barbecue, plus a few well-known football stars paid a visit to search for next generation of talent. Type 1 diabetes is an autoimmune condition that can occur at any stage in life, but is predominantly seen in children. There are approximately 2,500 children with type 1 diabetes in Ireland. Pictured is Ms Michelle Condell, Diabetes Care, Bayer Ireland; Ms Aoife McFadden, Gweedore, Co Donegal with her daughter Laura and son Cronin; and Ms Donna McCormick, Medtronic Diabetes

**Lundbeck receives European marketing authorisation for Abilify Maintena indicated for maintenance treatment of schizophrenia in adults**

Lundbeck (Ireland) Ltd has announced it has received notification from the HSE that Abilify Maintena (aripipra-zole) is to be added to the list of medicines available to patients under the GMS and DPS schemes. Abilify Maintena is available in Ireland from 1 October, 2014.

Abilify Maintena is indicated for maintenance treatment of schizophrenia in adult patients stabilised with oral aripiprazole.

Abilify Maintena (aripiprazole) reduces the risk of relapse for patients. Recurring relapse in schizophrenia can lead to clinical deterioration and decreased functioning. In a 38-week study with dosing under controlled trial conditions, the relapse rate with Abilify Maintena was comparable to that of oral aripiprazole (7.1 per cent vs 7.8 per cent, respectively). Abilify Maintena can significantly reduce the risk of relapse during long-term treatment. In a 52-week study, Abilify Maintena significantly delayed the time to relapse vs placebo (P<0.0001). Abilify Maintena can maintain personal and social functioning. In a 52-week study, Abilify Maintena achieved improvements in personal and social functioning vs placebo, as measured by the Personal and Social Performance Scale during stabilisation treatment, and maintained these over the course of the double-blind treatment phase.

For patients who have never taken aripiprazole, tolerability with oral aripiprazole must occur prior to initiating treatment with Abilify Maintena. The recommend- ed starting and maintenance dose of Abilify Maintena is 400mg. Titration of the dose is not required. It should be administered once monthly as a single injection (no sooner than 26 days after the previous injection). After the first injection, treatment with 10mg to 20mg oral aripiprazole should be continued for 14 consecutive days to maintain therapeutic aripiprazole concentra-tions during initiation of therapy.

The most frequently observed adverse drug reactions (ADRs) reported in ≥5% of patients in two double-blind controlled clinical trials of Abilify Maintena were weight increased (9.0 per cent), akathisia (7.9 per cent), insomnia (5.8 per cent), and injection site pain (5.1 per cent).
First locum vaccination service launched

This autumn, Clarity Locums is offering a locum vaccination service, the first of its kind in the country, allowing pharmacy owners greater flexibility around the provision of this relatively new pharmacy service.

Discussing the new initiative, Mr Anthony O’Neill, Managing Director, said: “It’s a service we’ve been thinking about for some time. From my own experience locuming, I have worked in pharmacies for some time. From my own experience I have worked in pharmacies that have really engaged in the vaccination service and others that have taken a more circumspect view.

“Our service will allow owners who have doubts to run a pilot service in their own pharmacy and then perhaps go on to engage with it more fully in years to come. It also allows locums to get involved in the provision of vaccination service.

“It is a win-win for the community pharmacy sector.”

Clarity Locums has enjoyed a strong 2014 thus far, expanding its locum and full-time recruitment service across the county. It has recently opened a new office on Dame Street in Dublin City centre, with further plans for expansion in 2015.
Signs of Tiger madness

I came across an interesting article in the Sunday Independent a few weeks ago, in which a journalist had asked various business people about the end of the Celtic Tiger and their specific memories of the moment they realised that the country had lost the run of itself. For instance, David Walsh, the CEO of Netwatch, recollected that he knew it was all going wrong when he went to a terraced house in Clondalkin to survey it for a top-of-the-range security system, and found the owner and a few friends in a giant hot-tub that took up the entire back garden — the hot-tub had been lifted into place by a crane reaching over the house.

The ‘celebrity solicitor’ Gerald Kean thought things were getting barmy when he was travelling by helicopter to the Punchestown Races and they had to wait in a queue of choppers being organised by a copter to the Punchestown Races and they had to wait.

There was also a comparable period of madness in the pharmacy sector during the Celtic Tiger period. Pharmacies were changing hands with a sale price equivalent to multiples of their turnover, whereas for many years previously they had sold for less than the turnover. Some of the deals that went through were for the pharmacist selling, but the financial advice received by the buyers must have been questionable.

One pharmacy in a provincial town sold at a premium price of three times its turnover, even though it was located on a street, not protected by exclusivity in a shopping centre. Inevitably, another pharmacist simply opened a competing pharmacy a few doors away, destroying the buyer’s financial projections. There were other similar tales around the country, but for slow-motion train-crash effect, that one stands out in my head.

The days of crazy sale prices may be over, and probably forever, but there could be a problem of a different kind afoot, given the number of new openings that we see. I know that the turnover of existing pharmacies, including mine, has been dropping year-on-year. Nobody knows when that drop is going to stop, given that reference pricing, cut-throat competition, probable HSE cuts and depressed consumer spending are all in play.

Opening a new pharmacy in this market is a brave move indeed, given the uncertain future we all face. From what I hear, the viability of some new openings is doubtful, but that remains to be seen. I just hope that a new chapter in the stories of madness has not started to be written.

Doctoring the figures

I was chatting to a pharmacist recently and he recounted a tale of a dodgy Dalmane prescription. The scenario is common enough — a junkie went to a GP and got a prescription for 30 Dalmane capsules. However, he regarded 30 as an opening bid, so he got a pen and changed the quantity to 60. The change was not a subtle one, so the pharmacist discreetly rang the doctor, who confirmed that 30 was correct.

At this point, the pharmacist could have treated the prescription as no longer valid and sent the junkie away empty-handed, but that had the potential to get unpleasant or even dangerous. Given that altering a prescription is a criminal offence, he could have called the gardaí and had the guy arrested. However, the pharmacist reckoned that even if the gardaí arrested him, they would probably not bother to charge him. If they did charge him, there was the chance of the pharmacist having to waste a day attending the trial, after which the judge would probably give a suspended sentence.

Plus, there was the possibility of the junkie returning with a grudge. So

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Stock crock

There are some words and phrases that inspire instant loathing, such as ‘your call is important to us’ and ‘Progressive Democrat’, but in recent weeks there is a new contender which has slithered into existence. There is an ever-growing list of medications which are ‘on allocation’.

When I hear those words from some blameless lady in tele- sales denying me the stock I need to fill a script, I need to remind myself not to shoot the messenger. I snapped one day and ranted ‘listen, I don’t order more of this drug than I need, I don’t screw around with parallel selling or exporting and I have a patient calling back for this, so you can do this the easy way and send me the stock I need, or you can talk to your supervisor to get them to authorise you to send it, or I can ring my rep and get him to ring your supervisor, but I need the stock’. It worked that time (and I did apologise to the nice lady after) but the stock shortage situation is getting worse every month. I think we all know what the problem is — so whose job is it to fix it?