December 2011
Volume 1 Issue 38

IPN IRISH PHARMACY NEWS

THE INDEPENDENT VOICE OF PHARMACY

Shortlisted BUSINESS TO BUSINESS MAGAZINE OF THE YEAR 2009
Magazines Ireland

In this issue:

IRISH PHARMACY AWARDS 2012

Recognising Excellence and Inspiring Change

IPN Communications Ltd is proud to launch The Irish Pharmacy Awards which will be held at the (hotel) on (date) May 2012.

Pharmacists and staff work hard to demonstrate on a daily basis their professional commitment to continuing professional development and to the growth of the industry as a whole

The Irish Pharmacy Awards will recognise those who demonstrate leadership in enhancing patient care and every other area of pharmacy practice.

At IPN our objective is to salute those who lead, inspire and empower, as well as celebrating innovation and those driving change.

We expect the standard and number of applications to be exceedingly high, displaying the breadth of excellence that is unique to Ireland.

The Irish Pharmacy Awards will be a unique platform with which to celebrate all the positive work being carried out within pharmacy from multidisciplinary working to excellent customer service while recognising those going above and beyond during their daily work.

At a time when the profession faces yet more hurdles; budget cuts and increased competition our categories highlight the immense undertaking professionals are displaying in keeping the country's health a top priority.

The awards will cover ten working categories with an industry leadership award for the person who has made an Outstanding Contribution to Pharmacy.

The Community Pharmacist of the Year Award will applaud a leader whose passion for, and effectiveness in, making a unique difference to their patient's lives is exemplary.

The Business Development of the Year Award creates a niche to recognise the person or pharmacy that best represents a model for other teams to emulate and best embodies the drive to face adversity with a positive outlook.

The others exciting categories are:

Young Community Pharmacist of the Year

Pharmacy Team of the Year

Counter Assistant of the Year

Hospital Pharmacist of the Year

Hospital Pharmacy of the Year

Pharmacy Team of the Year

Health Promotion

Locum of the Year

Outstanding Contribution to Pharmacy

The January Issue of Irish Pharmacy News will feature each Award category, containing application form details, criteria and our exclusive judging panel!

Award Categories

Health Promotion Award
Sponsored by Pfizer Healthcare Ireland

Hospital Pharmacist of the Year Award
Sponsored by Roche Products (Ireland) Limited

Hospital Pharmacy of the Year
Sponsored by Roche Products (Ireland) Limited

Locum of the Year Award
Sponsored by TTM Healthcare

Community Pharmacist of the Year Award
Sponsored by Pinewood Healthcare

Young Community Pharmacist of the Year Award
Sponsored by Teva Pharmaceuticals Ireland

Innovation in Service Development Award
(Chain 5 + pharmacies) Sponsored by Clonmel Healthcare Ltd.

Pharmacy Team of the Year Award
Sponsored by McNeil Healthcare (Ireland)

Counter Assistant of the Year Award
Sponsored by Sanofi Aventis & Avene

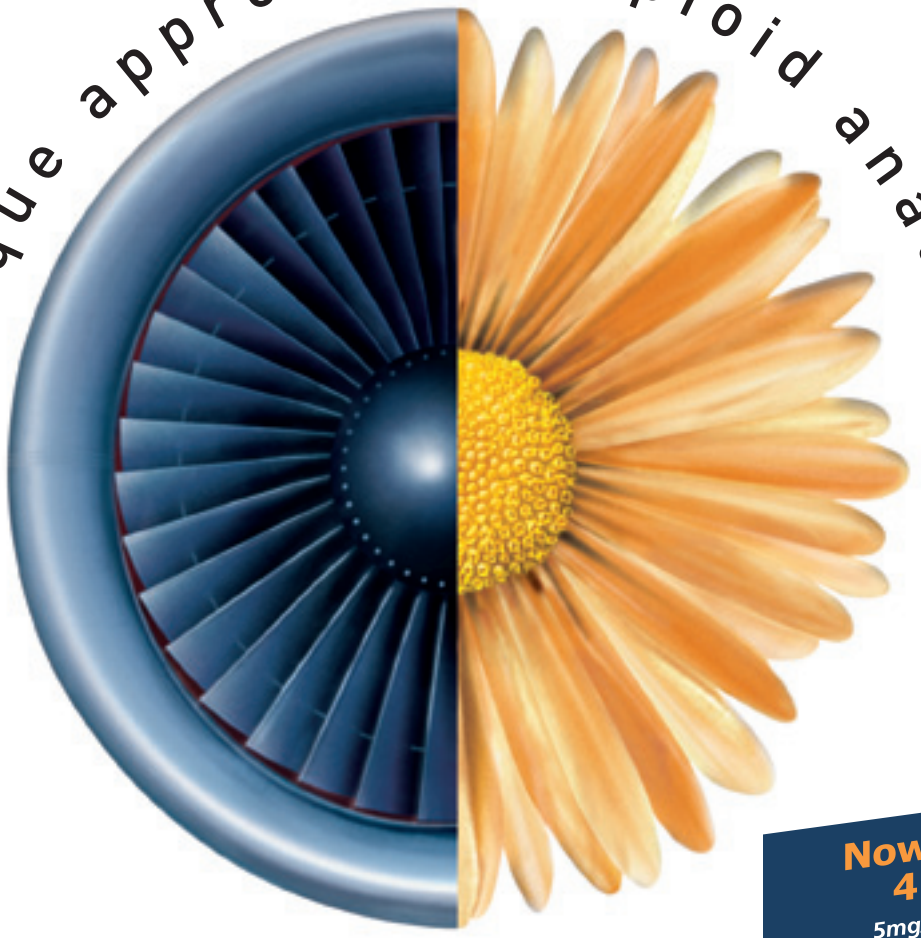
Actavis Academy Business Development of the Year Award - Independent Sponsored by Actavis

Business Development of the Year Award – Chain/Independent Sponsored by IPN Communications Ltd

The Power of Two

mundipharma

a unique approach to opioid analgesia



Now available in 4 strengths

5mg/2.5mg, 10mg/5mg, 20mg/10mg and 40mg/20mg oxycodone/naloxone prolonged release tablets

Powerful on Pain

Reduced risk of opioid-induced constipation

- ***TARGIN®*** provides pain relief that is as effective as oxycodone alone[1]
- ***TARGIN®*** reduces the risk of opioid-induced constipation when compared to oxycodone alone[1]
- ***TARGIN®*** is GMS re-imbursable

TARGIN® is indicated for severe pain, which can be adequately managed only with opioid analgesics. The opioid antagonist naloxone is added to counteract opioid-induced constipation by blocking the action of oxycodone at opioid receptors locally in the gut.

TARGIN®
OXYCODONE/NALOXONE

Targin® **tablets contain an opioid analgesic**

TARGIN® 5mg/2.5mg, 10mg/5mg, 20mg/10mg and 40mg/20mg prolonged release tablets

Prescribing Information Republic of Ireland

Presentation: Film-coated, oblong, prolonged release tablets containing oxycodone hydrochloride and naloxone hydrochloride, marked OXN on one side and the oxycodone strength on the other. Colours: Blue - 5mg (oxycodone hydrochloride)/2.5mg (naloxone hydrochloride), white - 10mg (oxycodone hydrochloride)/5mg (naloxone hydrochloride), pink - 20mg (oxycodone hydrochloride)/10mg (naloxone hydrochloride) and yellow - 40mg (oxycodone hydrochloride)/20mg (naloxone hydrochloride). **Indications:** Severe pain, which can be adequately managed only with opioid analgesics. The opioid antagonist naloxone is added to counteract opioid-induced constipation by blocking the action of oxycodone at opioid receptors locally in the gut. **Dosage and administration:** ***Adults over 18 years:*** Usual starting dose for opioid naïve patients is ***Targin®*** 10mg/5mg, taken orally at 12-hourly intervals. Patients requiring a higher dose are recommended ***Targin*** 20mg/10mg tablets. ***Targin*** 5mg/2.5mg is intended for dose titration when initiating opioid therapy and individual dose adjustment. The dosage is dependent on the severity of the pain and the patient's previous history of analgesic requirements. Patients already receiving opioids may be started on higher doses of ***Targin*** depending on their previous opioid experience. The maximum daily dose of ***Targin*** is 80mg oxycodone hydrochloride and 40mg naloxone hydrochloride. ***Targin*** tablets are not intended for the treatment of breakthrough pain. For the treatment of breakthrough pain, a single dose of "rescue medication" should amount to one sixth of the equivalent daily dose of oxycodone hydrochloride. Please refer to the SmPC for further details on dose titration. ***Targin*** tablets must be swallowed whole and not broken, chewed or crushed which leads to a rapid release and absorption of a potentially fatal dose of oxycodone. ***Children under 18 years:*** Not recommended. **Contra-indications:** Hypersensitivity to the active substances or excipients, any situation where opioids are contra-indicated, severe respiratory depression with hypoxia and/or hypercapnoea; severe chronic obstructive pulmonary disease, cor pulmonale, severe bronchial asthma, non-opioid induced paralytic ileus, moderate to severe hepatic impairment. **Precautions and warnings:** Respiratory depression, elderly or infirm, opioid-induced paralytic ileus, severely impaired pulmonary function, hypothyroidism, adrenocortical insufficiency, toxic psychosis, cholelithiasis, prostate hypertrophy, alcoholism, delirium tremens, history of alcohol and drug abuse, pancreatitis, hypotension, hypertension, galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption, pre-existing cardiovascular diseases, head injury (due to risk of raised intracranial pressure), epileptic disorder or predisposition to convulsions, patients taking MAO inhibitors, renal impairment, mild hepatic impairment, pre-operative use or within the first 12 – 24 hours post–operatively. Not suitable for the treatment of withdrawal symptoms. Not recommended in cancer associated with peritoneal carcinomatosis or sub-occlusive syndrome in advanced stages of digestive and pelvic cancers. **Interactions:** Substances having a CNS-depressant effect (e.g. alcohol, other opioids, sedatives, hypnotics, anti-depressants, sleeping aids, phenothiazines, neuroleptics, anti-histamines and anti-emetics) may enhance the CNS-depressant effect of ***Targin*** (e.g. respiratory depression). Interaction with coumarin anti-coagulants may increase or decrease INR. **Pregnancy and lactation:** Not recommended. **Side-effects:** Common adverse drug reactions are decreased/loss of appetite, restlessness, headache, vertigo, decrease in blood pressure, abdominal pain, diarrhoea, dry mouth, constipation, flatulence, vomiting, nausea, dyspepsia, increased hepatic enzymes, hiccups, altered mood, decreased activity, psychomotor hyperactivity, agitation, dysuria, pruritus, skin reactions, hyperhidrosis, dizziness, drug withdrawal syndrome, feeling hot and cold, chills, asthenic conditions. Some side-effects which are uncommon but could be serious are hypersensitivity, confusion, depression, halluc-inations, disturbance in attention, somnolence, speech disorder, convulsions, syncope, visual disturbances, palpitations, angina pectoris, tachycardia, increase in blood pressure, dyspnoea, respiratory depression, biliary colic, erectile dysfunction, urinary retention, peripheral oedema, abdominal distension and chest pain. Please refer to the SPC for further details of other uncommon side-effects and oxycodone class-effects. Tolerance and dependence may occur. It may be advisable to taper the dose when stopping treatment to prevent withdrawal symptoms. **Legal category:** CD (Sch2) POM. **Package quantities:** Blisters of 56 tablets. **Marketing Authorisation numbers:** PA913/025/001-4. **Marketing Authorisation holder:** Napp Pharmaceuticals Limited, Cambridge Science Park, Milton Road, Cambridge CB4 0GW, UK. Member of the Napp Pharmaceutical Group. **Further information is available from:** Mundipharma Pharmaceuticals Limited, Millbank House, Arkle Road, Sandyford, Dublin 18, Tel: +353 (0)1 2063800. **Date of preparation:** April 2011. (UK/UNA-11115).

References: 1. Simpson K, Leyendecker P, Hopp M, et al. Fixed-ratio combination oxycodone/naloxone compared with oxycodone alone for the relief of opioid-induced constipation in moderate-to-severe noncancer pain. Curr Med Res Opin 2008;24(12):3503-3512. 11144TRG

Adverse events should be reported to Mundipharma Pharmaceuticals Limited on 1800 991830

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Foreword

EDITOR
Bridget Casey

Talking Sense at Last

Of all the voices we have listened to in this last edition of *IPN* for 2011, it is the dignified voice of Fergal Murphy, which seemed to touch home. His is the quiet voice of wisdom, of reason, of concern, candidness, conciliation, practicality, the voice of mediation, of good judgement; in fact, good, all-round sense.

The Association of Pharmaceutical Manufacturers of Ireland (APMI) is quite obviously fortunate to have such a well-balanced and caring chairperson to represent them and it is to be fervently hoped that all the heads of all the other organisations involved in Pharmacy, including government departments will not try to pull rank if they do all decide to sit down with him to discuss the parlous finances and the state of play within Pharmacy, as he suggests, with the ultimate aim of defining a realistic and sensible generics' model that will work for everyone. We trust that no-one will try to belittle his fresh and understanding approach because they wish to take the credit, or think they know better, or continue to remain deaf. If they do, the health of the nation will be the worse for it and, rather than taking any credit they will, in the long run, be blamed instead.

A couple of the most striking points that Murphy makes is the result that price cutting has had on the supply of medicines and the fact that the Irish market within Europe is miniscule and, to put it into perspective, he compares it to the city of Manchester in the UK which, he points out has more hospital beds than there are in the whole of Ireland.

It would seem that Fergal Murphy is not seeking any limelight for himself, the (generics') company for which he works or the APMI, either. He just wants an equitable solution to some very sticky problems, which should be discussed calmly and, if necessary for days, until such time as every single person round the table is agreed on the best possible way forward for Ireland's health and the pockets of all those interested parties within the world of pharmacy. And, let us hope that the people representing their respective organisations have their heads screwed on as well as that of Fergal Murphy.

There will only be one opportunity to arrive at a sustainable Generic Strategy and Reference Pricing Policy and, getting it right is a virtually impossible task for most of those bureaucrats, who sit comfortably screened behind their desks, never going out into the field to see how the real world works. Here is someone who knows. Here is an opportunity, at least for the law makers and other heads of interested parties to sit down, listen and discuss with those who understand – and care – about Pharmacy so that everyone can profit from each other's knowledge and guidance and, subsequently come up with a definitive and workable plan, which is sensible and fair for all – and right first time around.

No-one will ever be entirely satisfied but, compromise is the name of the game, and of survival. Life is not a panacea.

Yes, times are hard – and they will probably get harder before the corner is turned. Things will not be easy but let us all hope that, in 2012, there will be more consensus and less acrimony within Pharmacy – and the DOH - than there has been in the last couple of years or so.

Murphy has thrown down the gauntlet – let's see who bothers to stoop to pick it up – or will there be a bogey man waiting in the wings to destroy what could be a pharmacy first? A harmonious 2012.

Annual Review

2011 Annual Review of Irish Pharmacy News

It has been a long and eventful year for pharmacists and for *Irish Pharmacy News*. The landing of the Troika, enforced austerity measures and crippling taxes have left the country in a somewhat precarious position. While the whole country has been affected by these harsh changes, a significant amount of change has had to be assimilated by the pharmacy sector in general and by independent pharmacists in particular.

From the introduction of pharmacy price cuts at the start of the year to the latest mishap over the pharmacy flu vaccination scheme, it has been a challenging and memorable year in pharmacy, to say the least.

Here, we look back on the highs and lows of 2011.

January

In January, *IPN* reported on the savage pharmacy price cuts that were introduced just before Christmas, which led to serious concerns about potential stock shortages and job losses in the industry. IPHA member companies, at the time gave a commitment to provide further savings of €200 million to the HSE in 2011 through a combination of price reductions and increased rebates.

In response to these cuts, the Irish Pharmacy Union made a submission to the Minister for Health and Children and highlighted that further cuts to pharmacists' income would have a dire impact on the viability of many pharmacies. The IPU said that, of the savings made by the IPHA reductions, pharmacists would be contributing €20 million on an on-going basis.

While the Emergency Hormonal Contraceptive pill became available in Boots Ireland, under a Patient Group Directive, Niall Behan, Chief Executive of the Irish Family Planning Association told *IPN* that he would like to see more pharmacies around the country dispensing the morning after pill.

John Corr, Pharmacy owner, spoke to IPN in the magazine's monthly profile. In it, he discussed how Irish pharmacy needs a strong and innovative internal advocate. He told IPN that he did not think that the government understood what community pharmacists could be doing for them, in terms of effective and efficient healthcare delivery.

IPN covered the Unicarepharmacy conference, when they announced that they would be rebranding all their pharmacies to DocMorris. Cormac Tobin, Managing Director of DocMorris said that the rebranding was not just a new game and a lick of paint but it was changing the rule book on how pharmacy does business in Ireland. He said, "The proposition is a pharmacy that is purely focused on health and beauty – no jewellery and no crystal candlesticks."

IPN talked to Jan O'Sullivan, Labour party spokesperson on the Labour party agenda for Health. She strongly advocated the introduction of a scheme of reference pricing and generic substitution and spoke of the Labour Party's mandate for the expansion of universal healthcare and of the role of the pharmacist in delivering primary care.

February

This month saw the Irish Medicines Board rule that Patient Group Directives are unlawful in Ireland. However, in a bolt from the blue, the IMB gave the sudden announcement that the NorLevo contraceptive pill had been licensed for sale, over the counter in pharmacies. This announcement was followed by the Pharmaceutical Society of Ireland issuing interim guidelines to pharmacists for the sale of NorLevo.

Profiled in this issue of *IPN* was Jane de Barra, pharmacist and barrister at Boots Ireland. She discussed how pharmacy services could be expanded in Ireland and talked about her role in providing legal, professional and clinical advice to all Boots' pharmacists.

The President of the IPU, Darragh O'Loughlin warned of there being no further scope for any 'unilateral and arbitrary' cuts in payments to IPU members. The IPU published a policy paper entitled, '*Time for a New Approach*'. In it, the IPU

Annual Review

acknowledged the need for the delivery of an efficient health service and argued that, despite the fact that over 420,000 people visit a pharmacy every week, pharmacists are largely ignored as being a valuable resource to community healthcare.

The Debate discussed the merits of generic substitution in order to keep pharmacy costs down.

The issue also covered the 5th Pharmaceutical Society of Ireland, All Ireland Conference, which took place in Dundalk. The possibilities for non-medical prescribing, the development of pharmacy anticoagulation clinics and antibiotic prescribing in primary care were discussed.

March

Cormac Tobin of DocMorris/Unicare Pharmacy publicly accused HRA Pharma of profiteering. The pharmaceutical company introduced a 40% price hike on its product, NorLevo, after gaining the IMB licence and, in effect a monopoly to sell the emergency hormonal contraceptive over-the-counter.

IPN profiled Damien Carolan, Managing Director of Pharbiz. As well as talking about his acquisition of the buying group, Pharbiz, he also discussed, among other things literature, the application of Michelangelo to commerce, the kick that brought the Grand Slam to Ireland for the first time in 61 years, the sigmoid curve and the relative merits of Leonardo da Vinci and Lionel Messi.

IPN debated whether or not Ireland could afford to train the next generation of pharmacists. The PEARs' Report clearly stated that change should begin as early as possible in the life of a pharmacist by introducing a new method of education/ training in order to develop a 'highly skilled and educated nucleus of healthcare professionals'. However, finance was highlighted as being the barrier to introducing such change. And to date, that question remains unanswered.

IPN covered the Irish Association of Community Pharmacy Technicians' Conference, which took place at the Athlone Institute of Technology when it played host to120 delegates from all over Ireland. The aim of the conference was to discuss the changing roles within community pharmacy and to, especially highlight the role of the pharmacy technician.

April

IPN reported anger amongst community pharmacists as the Minister for Health, Dr. James Reilly announced further cuts to wholesale mark-up prices.

IPN interviewed Dr. James Reilly, who discussed health reform and the expanding role of the pharmacy profession. He said, "The design of (the) Government's health reforms will fully consider international best practice and this will include learning from the achievements and experience of the Dutch healthcare system. However, any reforms implemented here will be designed to fit the Irish system and to obtain the best outcomes for Irish patients."

Concerns were raised this month on the issue of over-prescribing. A research study, funded by the Centre for Ageing Research and Development in Ireland (CARDI), found that, in nursing homes in the Republic of Ireland, 73% of residents were receiving at least one potentially inappropriate medicine. The cost of the inappropriate medicines per older person worked out at about €356 in the Republic of Ireland and €170 in Northern Ireland.

Following the reclassification of the emergency hormonal contraceptive in February, HRA Pharma held a training event for pharmacists. Speakers at the event included Dr Martin Henman from the School of Pharmacy and Pharmaceutical Sciences at Trinity College, Dublin, Dr Caitriona Henchion, Medical Director of the Irish Family Planning Association and Mr. John Stanley, School of Pharmacy, Hertfordshire.

May

As high quality information on medicines in Ireland was made available on Facebook for the first time, IPN received exclusive access to the first quarterly research results for 2011, which showed the site to be a huge success.

IPN profiled John Mulcahy, a pharmacist at the Mallow Clinic. He had recently expanded his pharmacy services by buying into the Mallow Clinic in Co. Cork. He said, "The decision to expand my business was an easy one for me. I'm young(ish), my future is here in Mallow and this type of Primary Healthcare Centre is the future."

Annual Review

IPN covered the Irish Pharmacy Union's Annual Conference. Speaking at its National Conference in Kilkenny, IPU President Darragh O'Loughlin highlighted to delegates the work carried out by the IPU to ensure that community pharmacy suffers no more and clearly stated the IPU's objectives in trying to find new approaches.

The Medicines Shortages continued to concern pharmacists in Ireland in May and this was the focus of the month's debate. According to the Irish Pharmacy Union, there were an average of over 40 medicines out of circulation and unavailable to patients in Ireland during the month of April.

IPN covered United Drug's 4th Annual Pharmacy Show where there were 54 exhibitors in attendance.

Retail Excellence Ireland (REI) reported that pharmacy sales had declined by 6% in the first quarter of 2011. REI said that the decline was as a result of weakened retail demand, dispensary price reductions and restrictions on the sale of Codeine.

June

IPN reported on the Irish Pharmacy Union having launched its five point plan to deliver a better and more cost-effective primary care system to patients.

Profiled in June was Mary Gallwey, pharmacist and owner of Gallwey's Pharmacy, Clonakilty, Co. Cork. She discussed running a business in rural Ireland and what it takes to be a good pharmacist and business woman.

In a report commissioned by the Pharmaceutical Society of Ireland, Pharmacy was perceived to be under-valued and under-appreciated in Ireland's current healthcare structure.

Details of the Pharmaceutical Society of Ireland's Annual Report were published. It reflected on the trials, tribulations and achievements of the year gone by and also offered an insight into what pharmacists may expect in the future.

The Irish Medicines' Board launched a public consultation on the legal supply classification of medicinal products. In the opinion piece that IPN ran, there was a general consensus amongst Irish pharmacists that there are many medicinal products that do not warrant being classified as Prescription Only Medicines.

July

The Council of the Pharmaceutical Society of Ireland elected Paul Fahey as its new President while Eoghan Hanly was elected Vice-President.

Following the first meeting between the Irish Pharmacy Union (IPU) and the new Minister for Health, Dr James Reilly, it was confirmed that, 'notwithstanding any legal issues' pharmacists would be allowed to administer the flu vaccine in the future.

Professor Paul Gallagher, Head of the School of Pharmacy at the RCSI was profiled. He discussed the impact that the Pharmacy Act (2007) has had on the pharmacy profession and what the future of pharmacy education will look like.

Following the Pharmaceutical Society of Ireland's seminar on nursing home care, some pharmacists took issue with the requirements of the PSI regulations and felt that the PSI did not understand the practical realities of dispensing to nursing home patients and that the regulations are quite unrealistic.

August

There was brighter news for the pharmacy sector in August when it was deemed to be one of the two best performing sectors within Irish retail sales, by Retail Excellence Ireland's Irish Retail Industry Performance Review.

In his address to the Select Committee on health costs for 2011, the Minister for Health, Dr. James Reilly announced that one of the areas where costs were increasing exponentially was in the area of drugs and medicines. He said, "In 1998, we spent just under €400 million. By 2010, our annual expenditure on drugs had increased to just under €2 billion."

IPN interviewed the newly elected President of the PSI, Paul Fahey. He discussed why he become involved in the politics of pharmacy and what he hopes to accomplish during his Presidency.

IPN debated the Minister for Health, Dr. James Reilly's announcement that pharmacists would be allowed to administer the flu vaccine, once the legal amendments were made. There was mixed opinion amongst healthcare professionals regarding this. Most pharmacists welcomed the announcement, whilst GPs were greatly concerned. However, all parties were sceptical because of the lack of information provided to them on the subject.

Supporting patients in the treatment of Chronic Hepatitis B or C[1,2]

Introducing the NEW
PEGASYS Prefilled Pen*

PEGASYS®
peginterferon alfa-2a (40KD)

* Both the Pegasys Prefilled Pen & Pegasys Prefilled Syringe will be available in the Irish market.

ABRIDGED PRESCRIBING INFORMATION (For full prescribing information refer to the Summary of Product Characteristics [SmPC]) Pegasys® (peginterferon alfa-2a) 180 micrograms (µg) and 135µg in 0.5ml solution for injection in a pre-filled syringe / pre-filled pen. Indications: Treatment of HBeAg-positive or HBeAg-negative chronic hepatitis B in adult patients with compensated liver disease and evidence of viral replication increased ALT and histologically verified liver inflammation and/or fibrosis. Treatment of chronic hepatitis C in adult patients positive for serum HCV-RNA, including patients with compensated cirrhosis and/or co-infected with clinically stable HIV. Optimal use of Pegasys in patients with chronic hepatitis C is in combination with ribavirin. This combination is indicated in naive patients and patients who have failed previous treatment with interferon alpha (pegylated or non-pegylated) alone or in combination therapy with ribavirin. Monotherapy is indicated mainly in case of intolerance or contraindication to ribavirin. **Dosage and Administration:** Physician must be experienced in the treatment of hepatitis B or C. Refer to the ribavirin SmPC when Pegasys is to be used in combination with ribavirin. Chronic Hepatitis B (HBeAg-positive and HBeAg-negative): 180µg once weekly for 48 weeks by s.c. administration in the abdomen or thigh. Chronic Hepatitis C treatment naive patients: 180µg once weekly by s.c administration in the abdomen or thigh given in combination with oral ribavirin or as monotherapy. Duration of combination therapy dependent on viral genotype. Refer to SmPC for details. Administer ribavirin with food. Chronic Hepatitis C treatment experienced patients: 180µg once weekly by s.c administration for 48 weeks. HIV-HCV Co-infection: Pegasys 180µg once weekly s.c. for 48 weeks, alone or in combination with ribavirin. Refer to the SmPC. Predictability of response and non-response-treatment naive patients: An early virological response by week 12 is predictive for sustained response. Predictability of response and non-response-treatment experienced patients: In non-responder patients re-treated for 48/72 weeks, viral suppression at week 12 (undetectable HCV RNA defined as <50 IU/mL) has been shown to be predictive for SVR. Refer to SmPC for dose adjustment due to adverse reactions. No dose adjustments required in elderly patients. Limited data in patients ≥6 - ≤18 years. Patients with end stage renal disease should be started on a dose of 135µg. Monitor all patients and reduce the dose in the event of adverse reactions. In patients with compensated cirrhosis (e.g. Child-Pugh A), Pegasys has been shown to be effective and safe. No data in patients with decompensated cirrhosis. Contraindications: Hypersensitivity to the active substance, to alpha interferons, or any of the excipients; autoimmune hepatitis; severe hepatic dysfunction or decompensated cirrhosis of the liver; neonates & young children up to 3 years; history of severe pre-existing cardiac disease (including unstable or uncontrolled cardiac disease in the previous six months); HIV-HCV patients with cirrhosis and a Child-Pugh score ≥6, except if only due to indirect hyperbilirubinaemia caused by drugs such as atazanavir and indinavir; combination of Pegasys with telbivudine. For contraindications to ribavirin refer to the ribavirin SmPC. Warnings and Precautions: Refer to the ribavirin SmPC when Pegasys is to be used in combination with ribavirin. Prior to beginning therapy, standard haematological and biochemical laboratory tests are recommended. Repeat haematological tests after 2 and 4 weeks and perform biochemical tests at 4 weeks. Perform additional testing periodically. A liver biopsy may be needed prior to commencing treatment in Hepatitis C patients – consult treatment guidelines. Caution when treating patients with low CD4 counts. Decreases in total WBC count, ANC and platelet count can occur. Anaemia seen in up to 15% of chronic hepatitis C patients undergoing combination therapy with risks higher in the female population. Caution when Pegasys is co-administered with other potentially myelosuppressive agents. Pancytopenia and bone marrow suppression reported 3-7 weeks after administration of peginterferon and ribavirin concomitantly with azathioprine - reversible within 4-6 weeks upon withdrawal of HCV antiviral therapy and concomitant azathioprine. Did not recur upon reintroduction of either treatment alone. No data in chronic Hepatitis C patients receiving combination therapy who have failed prior therapy due to discontinuation for hematological adverse reactions. Carefully consider the risks vs the benefits of re-treating this patient population. Thyroid function abnormalities or worsening of pre-existing thyroid disorders have been reported. Evaluate TSH and T4 levels prior to therapy and TSH levels during therapy if possible thyroid dysfunction is seen. Hypoglycaemia, hyperglycaemia and diabetes mellitus seen. Patients with uncontrolled hypoglycaemia, hyperglycaemia and diabetes mellitus should not begin Pegasys monotherapy or combination therapy. If patients develop these conditions and cannot be controlled, discontinue monotherapy or combination therapy. Severe CNS effects particularly depression, suicidal ideation and attempted suicide observed (including during the 6 month follow-up period after discontinuation of treatment). Other CNS effects also observed. Monitor patients closely and assess and manage any psychiatric disorders that appear. Discontinue treatment if symptoms persist or worsen (or if suicidal ideation is identified) and follow-up the patient, with psychiatric intervention as appropriate. Only initiate therapy in patients with existing or who have a history of severe psychiatric conditions following appropriate individualised diagnostic and therapeutic management of the psychiatric condition. Hypertension, supraventricular arrhythmias, congestive heart failure, chest pain and myocardial infarction have been seen. Perform ECG monitoring prior to therapy in patients with preexisting cardiac abnormalities. Suspend or discontinue Pegasys if deterioration of cardiovascular status is seen. In patients with cardiovascular disease, anaemia may necessitate dose reduction or discontinuation of ribavirin. Discontinue Pegasys in patients who develop evidence of hepatic decompensation during treatment or when the increase in ALT levels is progressive and clinically significant, despite dose reduction, or is accompanied by increased direct bilirubin. Discontinue Pegasys in the event of serious, acute hypersensitivity reaction and initiate appropriate medical therapy immediately. Disease exacerbations during therapy for chronic HBV are not uncommon and are characterised by transient and potentially significant increases in serum ALT. Autoimmune disease reported in patients receiving alpha IFNs. Patients predisposed to the development of autoimmune disorders may be at an increased risk. Patients presenting with signs or symptoms of autoimmune disorders should be evaluated and risk-benefit of continued interferon therapy assessed. Vogt-Koyanagi-Harada (VKH) syndrome observed in HCV patients treated with interferon – If suspected, withdraw antiviral treatment and discuss corticosteroid therapy. Flu-like syndrome is common, other causes of persistent fever must be ruled out, particularly in patients with neutropenia. Serious infections and sepsis have been reported during treatment with alpha IFNs including Pegasys. Appropriate anti-infective therapy should be started immediately - consider discontinuation of therapy. Ocular abnormalities which may result in loss of vision have been reported rarely. Discontinue therapy in patients who develop new or worsening ophthalmologic disorders. All patients should undergo a baseline ophthalmic examination with further periodic examinations in patients with preexisting ophthalmic disorders. A decrease or loss of vision requires a prompt and complete eye examination. Discontinue treatment in case of persistent or unexplained pulmonary infiltrates or pulmonary function impairment. Caution in patients with psoriasis. In case of onset or worsening of psoriatic lesions, consider discontinuation of therapy. Safety and efficacy of Pegasys and ribavirin therapy not established in patients with liver and other transplantations. Liver and renal graft rejections reported with monotherapy or in combination with ribavarin. Patients co-infected with HIV and receiving HAART may be at increased risk of developing lactic acidosis. Caution when adding Pegasys and ribavirin to HAART therapy. Co-infected patients with advanced cirrhosis receiving HAART may be at increased risk of hepatic decompensation and possibly death if treated with ribavirin in combination with Pegasys. Monitor co-infected patients closely for signs and symptoms of hepatic decompensation- e.g. a Child-Pugh score of ≥7. Child-Pugh scoring may be affected by factors related to treatment and not necessarily attributable to hepatic decompensation. Discontinue treatment in cases of hepatic compensation. Dental and periodontal disorders, which may lead to loss of teeth, have been reported in patients receiving pegasys and ribavirin combination therapy - refer to SmPC. Pegasys has a minor or moderate influence on the ability to drive and use machines. Refer to the Pegasys SmPC for further details. **Drug Interactions:** Interaction studies performed in adults. Pegasys inhibits cytochrome P450 1A2 activity. Monitor serum levels of theophylline and dose adjust theophylline during concomitant use with Pegasys. HCV patients on concomitant methadone maintenance therapy and Pegasys had higher mean methadone levels. Monitor patients for the signs and symptoms of methadone toxicity, especially patients on a high dose of methadone for the risk of QTc prolongation. Avoid use of peginterferon alfa-2a and Ribavirin concomitantly with azathioprin. Where benefit outweighs risk, close haematologic monitoring required to identify signs of myelotoxicity – if indicated stop treatment. Combination of telbivudine 600 mg daily with 180µg pegylated IFN alfa-2a once weekly by s.c. administration for treatment of HBV in a clinical trial was associated with increased risk for developing peripheral neuropathy. Combination of telbivudine and IFNs (pegylated or standard) may entail excess risk – benefit of combination unknown – therefore; combination of Pegasys with telbivudine is contraindicated. Co-administration of ribavirin and didanosine not recommended (fatal hepatic failure, peripheral neuropathy, pancreatitis, symptomatic hyperlactataemia/lactic acidosis reported). The concomitant use of ribavirin with zidovudine is not recommended due to an increased risk of anaemia. Consider replacing zidovudine in a combination ART regimen if this is already established and particularly when treating patients with a known history of zidovudine induced anaemia. **Fertility, Pregnancy and Lactation:** Use in pregnancy only if the potential benefit justifies the potential risk to the foetus. Discontinue nursing prior to starting treatment. Ribavirin is contraindicated in pregnancy. Extreme care must be taken to avoid pregnancy in female patients or in partners of male patients taking Pegasys in combination with ribavirin. Refer to the ribavirin and Pegasys SmPC for full details. **Side Effects and Adverse Reactions:** *Undesirable effects reported with Pegasys monotherapy for HBV or HCV or in combination with ribavirin for HCV patients: very common (≥1/10)* - anorexia, depression, anxiety, insomnia, headache, dizziness, concentration impaired, dyspnoea, cough, diarrhoea, nausea, abdominal pain, alopecia, dermatitis, pruritus, dry skin, myalgia, arthralgia, pyrexia, rigors, pain, asthenia, fatigue, injection site reaction, irritability; *Common (≥ 1/100 to < 1/10)* - upper respiratory infection, bronchitis, oral candidiasis, herpes simplex, fungal, viral and bacterial infections, thrombocytopenia, anaemia, lymphadenopathy, hypothyroidism, hyperthyroidism, emotional disorders, mood alteration, aggression, nervousness, libido decreased, memory impairment, syncope, weakness, migraine, hypoaesthesia, hyperaesthesia, paraesthesia, tremor, taste disturbance, nightmares, somnolence, vision blurred, eye pain, eye inflammation, xerophthalmia, vertigo, earache, tachycardia, palpitations, oedema peripheral, flushing, dyspnoea exertional, epistaxis, nasopharyngitis, sinus congestion, nasal congestion, rhinitis, sore throat, vomiting, dyspepsia, dysphagia, mouth ulceration, gingival bleeding, glossitis, stomatitis, flatulence, dry mouth, rash, sweating increased, psoriasis, urticaria, eczema, skin disorder, photosensitivity reaction, night sweats, back pain, arthritis, muscle weakness, bone pain, neck pain, musculoskeletal pain, muscle cramps, impotence, chest pain, influenza like illness, malaise, lethargy, hot flushes, thirst and weight decreased. For a full listing of adverse events including post- marketing experience, refer to the SmPC. **Legal Category:** Limited to sale and supply on prescription only. **Presentation and Marketing Authorisation Number(s):** Pegasys 180µg solution for injection in pre-filled syringe 0.5ml: pack of 4 (EU/1/02/221/008), Pegasys 135µg solution for injection in pre-filled syringe 0.5ml: pack of 1 (EU/1/02/221/005), Pegasys 180µg solution for injection in pre-filled pen 0.5ml: pack of 4 (EU/1/02/221/015), Pegasys 135µg solution for injection in pre-filled pen 0.5ml: pack of 1 (EU/1/02/221/011). **Marketing Authorisation Holder:** Roche Registration Limited, 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom. Further information is available from Roche Products (Ireland) Limited, 3004 Lake Drive, Citywest, Naas Road, Dublin 24. Telephone: (01) 4690700. Fax: (01) 4690791. **Date of Preparation:** October 2011.

ABRIDGED PRESCRIBING INFORMATION (For full prescribing information refer to the Summary of Product Characteristics [SmPC]) COPEGUS® (Ribavirin) 200 mg and 400 mg film-coated tablets. Indication: Treatment of chronic hepatitis C as part of a combination regimen with interferon alfa-2a or with peginterferon alfa-2a. Copegus monotherapy must not be used. The combination of Copegus with peginterferon alfa-2a or interferon alfa-2a is indicated in adult patients who are positive for serum Hepatitis C Virus (HCV)-RNA, including patients with compensated cirrhosis. The combination with peginterferon alfa-2a is also indicated in patients co-infected with clinically stable HIV, including patients with compensated cirrhosis. Copegus, in combination with peginterferon alfa-2a, is indicated in naive patients and patients who have failed previous treatment with interferon alpha (pegylated or non-pegylated) alone or in combination therapy with ribavirin. Refer to the SmPC of peginterferon alfa-2a or interferon alfa-2a for prescribing information. **Dosage and Administration:** Only a physician experienced in the management of chronic hepatitis C should initiate and monitor therapy. *Adult Dose:* tablets are administered orally in two divided doses with food (morning and evening). Tablets should not be broken or crushed as ribavirin is considered a potential teratogen. In combination with peginterferon alfa-2a solution for injection: Dependent on viral genotype and body weight. *HCV patients:* Copegus treatment dependent on viral genotype and body weight. *HCV genotype 1 Low Viral Load (LVL) with Rapid Viral Response (RVR):* <75kg 1,000mg Copegus daily, ≥75kg 1,200mg daily. Treatment duration – 24 or 48 weeks. *HCV genotype 1 High Viral Load (HVL) with RVR:* <75kg 1,000mg Copegus daily, ≥75kg 1,200mg daily. Treatment duration – 48 weeks. *HCV genotype 2/3 LVL with RVR:* 800mg daily regardless of body weight for 16/24 weeks. *HCV genotype 2/3 HVL with RVR:* 800mg for 24 weeks. *HCV genotype 4 with RVR:* <75kg 1,000mg daily, ≥75kg 1,200mg daily. Treatment duration – 24 or 48 weeks. *HCV genotype 1/4 without RVR:* <75kg 1,000mg daily, ≥75kg 1,200mg daily. Treatment duration – 48 weeks. *HCV genotype 5 or 6:* Data limited. Recommend 1000/1200 mg for 48 weeks. Refer to SmPC for full details. *Treatment experience HCV patients:* Peginterferon alfa-2a 180mcg once weekly with 1,000mg Copegus (<75kg) or 1,200mg (≥75kg) regardless of genotype for a total of 48 weeks. At week 12, if virus detectable, stop treatment. HCV genotype 1 patients who are non responders to prior Peginterferon and Copegus treatment should be treated for 72 weeks. *HIV-HCV Co-infection patients:* Peginterferon alfa-2a 180mcg once weekly with 800mg Copegus daily for 48 weeks, regardless of genotype. No combination data with higher Copegus doses or reduced duration. Early virological response by week 12 is predictive for sustained response. In combination with interferon alfa-2a solution for injection: Dependent on body weight. <75kg requires 1,000mg Copegus daily, ≥75kg should receive 1,200mg daily. Minimum treatment duration of 6 months. HCV genotype 1 requires 48 weeks of treatment. The decision to extend treatment duration to 48 weeks for other genotypes should be based on other prognostic factors. Refer to the SmPC for dosage modifications/discontinuations in the event of severe adverse reactions or laboratory abnormalities. There are insufficient safety, efficacy and pharmacokinetics data to support specific recommendations for dose adjustment in patients with serum creatinine >2mg/dl or creatinine clearance <50ml/min - use Copegus only if essential and extreme caution in this patient population is advised. Not recommended in children and adolescents under the age of 18. **Contraindications:** Hypersensitivity to ribavirin or to any of the excipients; pregnancy and lactation; history of severe pre-existing cardiac disease, including unstable or uncontrolled cardiac disease, in the previous six months; severe hepatic dysfunction or decompensated cirrhosis of the liver; haemoglobinopathies. Peginterferon alfa-2a contraindicated in HIV-HCV patients with cirrhosis and a Child-Pugh score ≥6. **Warnings and Precautions:** Closely monitor patients for any signs or symptoms of psychiatric disorders. In some patients, severe CNS effects, particularly depression, suicidal ideation, attempted suicide have been observed both during and after discontinuation of Copegus combination therapy with peginterferon alfa-2a or interferon alfa-2a. Aggressive behaviour (sometimes directed against others such as homicidal ideation), bipolar disorders, mania, confusion and alterations of mental status have been observed with alpha interferons. If psychiatric symptoms persist or worsen, or suicidal ideation identified, discontinue therapy and obtain psychiatric intervention as appropriate. Treat patients with existence of, or history of severe psychiatric conditions only if judged necessary and after having ensured appropriate individualized diagnostic and therapeutic management of the psychiatric condition. Consult treatment guidelines to determine if a liver biopsy is required prior to commencing treatment. Copegus monotherapy is not effective and Copegus must not be used alone. Patients should be fully informed concerning the teratogenic risks. Ribavirin is mutagenic in some *in vivo* and *in vitro* genotoxicity assays - a potential carcinogenic effect cannot be excluded. Caution in patients with pre-existing cardiac disease – refer to SmPC for details. No adequate data in re-treating patients who have failed prior treatment due to haematological adverse events. Refer to SmPC for details of pancytopenia and bone marrow suppression occurring after the administration of Copegus and a peginterferon concomitantly with azothioprine. If an acute hypersensitivity reaction develops (not transient rashes), Copegus must be discontinued immediately and appropriate medical therapy instituted. Therapy should be discontinued in patients who develop evidence of hepatic decompensation. Discontinue therapy when ALT increase is progressive and clinically significant (despite dose reduction) or is accompanied by increased direct bilirubin. The pharmacokinetics of Copegus are altered in patients with renal dysfunction - haemoglobin levels should be monitored closely. Renal function should be evaluated in all patients prior to initiation of Copegus. All patients should have a baseline eye examination. Patients with preexisting ophthalmologic disorders should receive periodic ophthalmologic exams during therapy. Discontinue in patients who develop new or worsening ophthalmologic disorders. Monitor HIV-HCV patients for toxicities arising from antiretroviral and HCV therapies. Patients co-infected with HIV and receiving Highly Active Anti-Retroviral Therapy (HAART) may be at increased risk of serious adverse effects. Co-infected patients with advanced cirrhosis receiving HAART may also be at increased risk of hepatic decompensation and possibly death if treated with Copegus in combination with interferons. Caution when adding peginterferon alfa-2a and Copegus to HAART. Monitor co-infected patients closely – discontinue if a Child-Pugh score ≥7 is reached. Co-administration of Copegus with didanosine or stavudine is not recommended. Standard haematologic tests and blood chemistries must be conducted prior to initiating therapy and at weeks 2 and 4, and periodically thereafter as appropriate. Caution when treating co-infected patients with low CD4 counts. Uric acid concentrations may increase due to haemolysis, therefore the potential for development of gout must be carefully monitored in predisposed patients. Dental and periodontal disorders, which may lead to loss of teeth, have been reported in patients receiving Copegus and peginterferon alfa-2a combination therapy. Recommend patients to brush their teeth thoroughly twice daily and have regular dental examinations. If patients experience vomiting, they should be advised to rinse their mouth thoroughly afterwards. **Drug Interactions:** The potential for interactions may persist for up to two months after cessation of Copegus therapy (long half-life). There is a minimal potential for P450 enzyme-based interactions. Copegus inhibited phosphorylation of zidovudine and stavudine in *in vitro* studies. Concurrent use of Copegus with these products may lead to increased HIV plasma viraemia – monitor plasma HIV RNA levels closely and review the concomitant use of Copegus if RNA levels increase. Co-administration of Copegus and didanosine not recommended – reports of fatal hepatic failure, peripheral neuropathy, pancreatitis, symptomatic hyperlactataemia/lactic acidosis. Avoid concomitant use of Copegus and peginterferon alfa-2a with azothioprine – refer to SmPC for details. Concomitant use of Copegus with zidovudine not recommended due to increased risk of anaemia. Consider replacing zidovudine in a combination ART regimen if already established – important for patients with history of zidovudine induced anaemia. **Pregnancy and Lactation:** Teratogenic and/or embryocidal in animals at doses well below the recommended human dose. Do not use during pregnancy. Copegus treatment requires a negative pregnancy test immediately prior to initiation of therapy. *Female patients:* Women of child-bearing potential and their partners must use two forms of effective contraception simultaneously during treatment and for 4 months after treatment. Routine monthly pregnancy tests must be performed during this time. If pregnancy does occur during treatment or within 4 months from stopping treatment, the patient must be advised of the significant teratogenic risk of Copegus to the foetus. *Male Patients:* Animal studies have shown that Copegus produced changes in sperm at doses below the clinical dose. It is unknown whether the Copegus contained in sperm will exert its known teratogenic effects upon fertilisation of the ova. Male patients and their female partners of childbearing age must be counselled to use 2 forms of effective contraception simultaneously during treatment and for 7 months after treatment has been concluded. A pregnancy test must be performed before therapy is started. Men whose partners are pregnant must use a condom to minimise Copegus delivery to the partner. Nursing must be discontinued prior to initiation of treatment. **Side Effects and Adverse Reactions:** *Undesirable effects reported in patients who have received Copegus and peginterferon alfa-2a or interferon alfa-2a therapy: Very Common ≥1/10* - anaemia, anorexia, depression, insomnia, headache, dizziness, concentration impairment, dyspnoea, cough, nausea, diarrhoea, abdominal pain, alopecia, pruritus, dermatitis, dry skin, myalgia, arthralgia, pyrexia, rigors, pain, asthenia, fatigue, injection-site reaction, irritability. *Common ≥1/100 - <1/10* - upper respiratory infection, bronchitis, oral candidiasis, herpes simplex, thrombocytopenia, lymphadenopathy, hypothyroidism, hyperthyroidism, mood alteration, emotional disorders, anxiety, aggression, nervousness, libido decreased, memory impairment, syncope, weakness, migraine, hypoaesthesia, hyperaesthesia, paraesthesia, tremor, taste disturbance, nightmares, somnolence, vision blurred, eye pain, eye inflammation, xerophthalmia, vertigo, earache, tachycardia, palpitations, oedema peripheral, flushing, dyspnoea exertional, epistaxis, nasopharyngitis, sinus congestion, nasal congestion, rhinitis, sore throat, vomiting, dyspepsia, dysphagia, mouth ulceration, gingival bleeding, glossitis, stomatitis, flatulence, constipation, dry mouth, rash, sweating increased, psoriasis, urticaria, eczema, skin disorder, photosensitivity reaction, night sweats, back pain, arthritis, muscle weakness, bone pain, neck pain, musculoskeletal pain, muscle cramps, impotence, chest pain, influenza-like illness, malaise, lethargy, hot flushes, thirst and weight decreased. Additional events seen in ≥1% to ≤2% of co-infected patients receiving Copegus and peginterferon alfa-2a: hyperlactacidaemia/lactic acidosis, influenza, pneumonia, affect lability, apathy, tinnitus, pharyngolaryngeal pain, cheilitis, acquired lipodystrophy, chromaturia. For a full listing of adverse events including post marketing experience, please refer to the SmPC. **Legal Category:** Limited to sale and supply on prescription only. **Presentation and Marketing Authorisation Number:** 200mg (Pack size of 168 tablets, 112 tablets and 42 tablets) PA 50/153/1. 400mg (Pack size of 56 tablets) PA 50/153/2. **Marketing Authorisation Holder:** Roche Products Limited, 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom. Copegus is a registered trade mark. Further information is available from Roche Products (Ireland) Limited, 3004 Lake Drive, Citywest, Naas Road, Dublin 24. Telephone: (01) 4690700. Fax: (01) 4690791. **Date of Preparation:** May 2011.

References: 1. Pegasys Summary of Product Characteristics. **2.** CoPegus Summary of Product Characteristics. P29/10/11

Annual Review

September

IPN interviewed Marita Kinsella, Chief Pharmacist at the Department of Health, where she discussed aspects of her role and how the Pharmacy Act (2007) has affected the profession.

With the arrival of the online GP service, DrThom.ie on Irish shores, *IPN* asked whether the service would be of benefit to patients or whether it would be a potentially hazardous venture.

Since the introduction of the Pharmacy Act 2007, the landscape of pharmacy education and training in Ireland has changed dramatically. *IPN* debated the planned changes to pharmacy education with the Heads of the three Schools of Pharmacy in Ireland.

Profiled this month was Aidan Nolan, Managing Director of Blue Sky Products. He told *IPN* that, while the beauty industry has found itself struggling in Ireland's troubled economy, the recession has presented some surprising benefits for Blue Sky Products.

October

Pharmacists were given the go-ahead to provide flu vaccinations. Under the new regulations, the vaccine would be given free of charge to patients over the age of 65 and to those in 'at- risk' groups. Pharmacists were told that they would receive remuneration from the HSE of €15 per person for carrying out vaccinations on patients in possession of medical cards.

Counterfeit drugs were on the rise in Ireland when the Irish Medicines Board released details of the role it played in the latest global operation to target the sale of online drugs. In Ireland, 51,621 tablets, capsules and creams, with an estimated value of more than €150,000, were recovered after 492 packages were seized in one week.

Generic substitution and reference pricing was the subject under debate this month. Key stakeholders within the industry offered their opinion to *IPN* on the country's position regarding generic substitution and reference pricing.

The Pharmaceutical Society of Ireland and the Irish Medical Council signed a Memorandum of Understanding agreeing to improve the mutual cooperation between the two regulators.

Kate Mulvenna, Chief Pharmacist at the HSE was profiled. She discussed her motivation for entering into the administrative side of pharmacy and talked about the numerous developments taking place in community pharmacy.

November

IPN reported teething problems with the pharmacy flu vaccination programme. A significant number of pharmacists reported difficulties with the HSE PCRS website.

November also saw Tesco embark on a threatened medicines' price war as it entered into the pharmacy sector.

Emer Cooke, EMA International Liaison Officer discussed the EMA's relevance to Ireland and its position in a globalised market.

It was reported that reimbursement of the drug, Pradaxa was slashed by the HSE. In a letter circulated by the HSE, it was stated that pharmacists will now only be reimbursed for one month's supply of the drug, where it is prescribed to patients who have undergone elective hip or knee replacement surgery.

The Irish Pharmacy Union (IPU) published its submission to the FEMPI review committee. The IPU made itself clear in its submission that 'there is absolutely no scope for any further cuts.'

The focus of the debate was on the Irish Medical Organisation's disapproval of pharmacists administering the flu vaccine to patients. The IMO said that the legislation amounted to 'inconsistent fumbling' because it required some details to be recorded and that these should be forwarded to patients' doctors unless the details were unavailable. The doctors felt this created confusion and they also believed this to be a breach of the Data Protection Act.

IPN profiled pharmacist, Tony Mitchell, owner of Cogaslann Agatha in Carna, Co. Galway. He discussed setting up and opening a pharmacy in rural Connemara. He also told how he managed to raise over €100,000 for Cancer Care West.

IRISH PHARMACY NEWS PRESENTS

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Dr Ambrose McLoughlin

Significant role for pharmacy in a re-engineered health system

Dr Ambrose McLoughlin, Registrar and CEO of the Pharmaceutical Society of Ireland

We are, indeed living in exceptional times and there are significant challenges ahead for the wider health sector and the pharmacy profession, more specifically.

The pharmacy profession and sector provide essential services to their patients and communities, and the expansion of pharmacy services and roles, in line with the international best practice evidence base, is important in the context of providing more value to patients and the wider health service. In 2011, we saw some of these developments beginning to happen, the most significant being the inclusion of community pharmacy into this winter's seasonal influenza vaccination campaign and the switching of emergency hormonal contraception to pharmacist-supply.

From 2012 onwards, the establishment of the Institute of Pharmacy and the necessary framework for continuing professional development (CPD) to maintain the competencies of pharmacists will facilitate future developments in pharmacy practice. It is vitally important that all in the pharmacy profession and the wider sector support this initiative. It will not only put in place a quality assurance system around pharmacy CPD but it will also be a platform for the future development of the profession. This will happen by ensuring that developments and expansions in practice and services are underpinned by appropriate CPD and the international evidence base. This should then result in high quality services for patients and patient safety, with the evolving needs of patients and the wider health system the primary focus.

Pharmacists can play a greater role in integrated patient care delivery. For example, when it comes to managing chronic disease patients, pharmacists could provide screening and monitoring services, for blood pressure, cholesterol levels and blood sugars or for warfarin patients or asthma patients. The potential for pharmacy to provide 'more for less' is considerable. The scope for pharmacists within primary care to manage more patients in their community and, at the lowest level of complexity within the system is substantial. This can be done by facilitating shared care of patients already within primary care or referring people to a GP, when issues are detected during screening or consultations.

In addition, pharmacists could also play a more significant primary preventive role, participating in more national immunisation campaigns such as pneumococcal disease or cervical cancer prevention, and in contributing to tackling the national issues of obesity and smoking. The underpinning of all of these activities by appropriate training and CPD is essential.

Within hospital pharmacy too, pharmacists can contribute significantly to improving the cost-effectiveness of therapeutic care, as well as improving patient safety, for example by overseeing medication reconciliation and review at the points of admission and discharge.

The PSI and its National Pharmacy Reference Group have been and will continue to support and facilitate the work of Dr Barry White, and the various clinical care programmes, to improve the quality, access and cost of care to patients.

One of the other significant developments in 2011 was the establishment of the National Forum to oversee the implementation of the PEARs report recommendations and the move to an integrated 5-year Masters for pharmacy. This is essential to ensure the future sustainability of the employment and career development of pharmacy graduates. While the interim Internship Programme is a significant improvement on the old system, the re-configuration of pharmacy undergraduate education and training, in line with best international practice, is vital for the future of the profession.

The PSI will continue to support Minister Reilly's reform programme and the ongoing work of Dr Barry White, and I see a significant role for pharmacy in a re-engineered health system, with greater collaboration and integration with other healthcare professions being a key part of that future.

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Prescribing Information- Celebrex®
Celebrex 100 mg Capsules containing celecoxib 100 mg Celebrex 200 mg Capsules containing celecoxib 200 mg Refer to Summary of Product Characteristics before prescribing.

Indications: Symptomatic relief in the treatment of osteoarthritis, rheumatoid arthritis or ankylosing spondylitis. The decision to prescribe a selective COX-2 inhibitor should be based on an assessment of the individual patient's overall risks.**Dosage**: Celebrex should be introduced at the lowest effective dose and for the shortest duration possible. In the absence of therapeutic benefits with the maximum daily dose, other therapeutic options should be considered. Patient's need for continued therapy should be re-evaluated periodically.
Osteoarthritis: Usual recommended daily dose is 200 mg taken once daily or in two divided doses. The maximum daily dose is 400 mg taken as two divided doses of 200 mg if needed.Rheumatoid arthritis: Initial recommended daily dose is 200 mg taken in two divided doses; maximum daily dose 400 mg taken in two divided doses. Ankylosing spondylitis: Usual recommended daily dose is 200 mg taken once daily or in two divided doses. The maximum daily dose is 400 mg taken once daily or in two divided doses.Elderly: Initial recommended dose is 200 mg per day; maximum daily dose 400 mg in two divided doses. Take particular caution with elderly patients who have a body weight less than 50kg. Hepatic impairment: Initiate treatment at half the recommended dose in established moderate impairment (serum albumin 25-35 g/l). Renal impairment: Experience is limited in mild-moderate impairment. Patients should be treated with caution. Children: Not indicated.**Contraindications**: Hypersensitivity to celecoxib or excipients, known sulphonamide hypersensitivity. Active peptic ulceration or gastrointestinal (GI) bleeding. Patients who have experienced allergic-type reactions after taking aspirin or NSAIDs including COX-2 inhibitors. Pregnancy, women of childbearing potential unless using effective contraception, breast feeding. Severe hepatic dysfunction (serum albumin <25 g/l or Child-Pugh score ≥10). Inflammatory bowel disease. Patients with creatinine clearance <30 ml/min. Congestive heart failure (NYHA II-IV). Established ischaemic heart disease, peripheral arterial disease and / or cerebrovascular disease. **Warnings/Precautions**: Upper gastrointestinal complications, some of them resulting in fatal outcome, have occurred in patients treated with celecoxib. Therefore caution is advised in patients most at risk of developing a gastrointestinal (GI) complication with NSAIDs (e.g. elderly, patients using any other NSAID or aspirin concomitantly, patients with history of GI disease such as ulceration and GI bleeding). There is further increase in the risk of GI adverse effects for celecoxib (GI ulceration or other GI complications) when celecoxib is taken concomitantly with aspirin, even at low doses (see Interactions). Avoid concomitant use with non-aspirin NSAIDs. Increased risk of serious cardiovascular events, mainly myocardial infarction, observed in a long term study at dose of 200mg BID and 400mg BID. Cardiovascular risks of celecoxib may increase with dose and duration of exposure so the lowest effective dose should be used for the shortest possible duration. The need for symptomatic relief and response to therapy should be re-evaluated periodically, especially in patients with osteoarthritis. Patients with significant risk factors for CV events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking) should only be treated after careful consideration. Celecoxib is not a substitute for aspirin for cardiovascular prophylaxis. Celecoxib should be used with caution in patients with history of cardiac failure, left ventricular dysfunction, hypertension or pre-existing oedema for any other reason. Caution is also required in patients taking diuretic treatment or at risk of hypovolaemia. Like all NSAIDs, celecoxib can lead to onset or worsening of hypertension, which may contribute to increased incidence of cardiovascular events. Monitor blood pressure closely during initiation and throughout treatment. The elderly are more likely to develop compromised renal, hepatic function and especially cardiac dysfunction and therefore treatment should be monitored with appropriate medical supervision. NSAIDs, including Celecoxib may cause renal toxicity. Clinical trials with celecoxib have shown renal effects similar to those seen with comparator NSAIDs. Carefully monitor patients at greatest risk for renal toxicity, including those with impaired renal function, heart failure, liver dysfunction, and the elderly. Some cases of severe hepatic reactions (some with fatal outcome or requiring liver transplant) including fulminant hepatitis, liver necrosis and hepatic failure have been reported with celecoxib. Most of the severe adverse hepatic events developed within one month after initiation of celecoxib treatment. Appropriate measures should be taken and discontinuation of celecoxib therapy should be considered if there is a deterioration of organ system functions. Serious skin reactions, some of them fatal, have been reported very rarely in patients receiving celecoxib. The highest risk for onset of these reactions in the majority of cases is within the first month of treatment. Serious hypersensitivity reactions (anaphylaxis and angioedema) have been reported in patients receiving celecoxib. Patients with any other drug allergy may be at greater risk of serious skin reactions or hypersensitivity reactions. Discontinue at the first sign of skin rash, mucosal lesion or other sign of hypersensitivity. Celecoxib may mask fever and other signs of inflammation. In patients on concurrent warfarin therapy, serious bleeding events have occurred (see Interactions). Exercise caution when combining celecoxib with warfarin and other oral anticoagulants. Patients with hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take celecoxib. Celecoxib inhibits CYP2D6. Caution should be exercised in patients known to be poor metabolisers of CYP2C9 and with medicines known to affect CYP2D6.
Interactions: Monitor anticoagulant activity in patients taking warfarin or other anticoagulants, particularly when starting or changing the dose of celecoxib. NSAIDs may reduce the effect of diuretics and antihypertensive drugs. The risk of acute renal insufficiency, usually reversible, may be increased in some patients with compromised renal function when ACE inhibitors or angiotensin II receptor antagonists are combined with NSAIDs, including celecoxib. Monitor renal function when celecoxib is given in combination with these medicines especially in the elderly or when given with ciclosporin or tacrolimus. Celecoxib can be used with low dose aspirin but is not a substitute for aspirin for cardiovascular prophylaxis. Concomitant administration of celecoxib with low dose aspirin increases the risk of GI ulceration or GI complications compared with celecoxib alone. Dose reduction may be necessary for individually dose-titrated drugs metabolised by CYP2D6 (e.g. antidepressants (tricyclics and SSRIs), neuroleptics, anti-arrhythmic drugs). Celecoxib had no clinically relevant effects on the pharmacokinetics of oral contraceptives (norethisterone/ ethinylestradiol). Celecoxib had no significant effect on the pharmacokinetics of methotrexate but consider adequate monitoring when combining these two drugs. Closely monitor patients on lithium when celecoxib is introduced or withdrawn. In known CYP2C9 poor metabolisers avoid combination of celecoxib and CYP2C9 inhibitors. Use half the recommended dose of celecoxib in patients on fluconazole, a CYP2C9 inhibitor. Concomitant use of inducers of CYP2C9 such as rifampicin, carbamazepine and barbiturates may reduce plasma concentrations of celecoxib. **Adverse effects**: Very common (≥1/10): hypertension. Common (≥1/100, <1/10): sinusitis, upper respiratory tract infection, urinary tract infection, allergy aggravated, insomnia, dizziness, hypertonia, myocardial infarction, pharyngitis, rhinitis, cough, dyspnoea, abdominal pain, diarrhoea, dyspepsia, flatulence, vomiting, dysphagia, rash, pruritis, flu-like symptoms and peripheral oedema/fluid retention. Uncommon (≥1/1000, <1/100): anaemia, hyperkaelemia, anxiety, depression, tiredness, blurred vision, paraesthesia, somnolence, cerebral infarction, tinnitus, hypoacusis, heart failure, palpitations, tachycardia, hypertension aggravated, constipation, eructation, gastritis, stomatitis, aggravation of gastrointestinal inflammation, abnormal hepatic function, increased SGOT and SGPT, urticaria, leg cramps, increased creatinine and BUN increased. Rare (≥1/10,000, <1/1000): leucopenia, thrombocytopenia, confusion, ataxia, taste alteration, duodenal, gastric, oesophageal, intestinal and colonic ulceration, intestinal perforation, oesophagitis, melaena, pancreatitis, eleveation of hepatic enzymes, alopecia and photosensitivity, Postmarketing experience (frequency not known): pancytopenia, serious allergic reactions, anaphylactic shock, anaphylaxis, hallucinations, headache aggravated epilepsy, meningitis aseptic, ageusia, anosmia, fatal intracranial haemorrhage, conjunctivitis, ocular haemorrhage, retinal artery or vein occlusion, arrhythmia, flushing, vasculitis, pulmonary embolism, bronchospasm, nausea, gastrointestinal haemorrhage, colitis/colitis aggravated, hepatic failure (sometimes fatal or requiring liver transplant), fulminant hepatitis (some with fatal outcome), liver necrosis, hepatitis, jaundice, ecchymosis, bullous eruption, exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, angioedema, acute generalized exanthematous pustulosis, arthralgia, myositis, acute renal failure, interstitial nephritis,hyponatraemia, menstrual disorder NOS, chest pain. Please refer to the SmPC for details of previously unknown adverse reactions occurring in polyp prevention trials. **Packaging quantity and price:** Pack of 30 capsules: €26.85 (Celebrex 200 mg). Pack of 60 capsules: €26.85 (Celebrex 100 mg). **Marketing authorisation numbers and holder**: PA 936/20/1 (100 mg) and PA 936/20/2 (200 mg); Pharmacia Ireland, 9 Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24, Ireland. **Legal category**: POM. **Further information** is available on request from: Medical Information at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS, UK. Tel: +44 (0) 1304 616161 **Date of Preparation of P.I.**: October 2011. CB 4_1

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Pfizer

Richard Collis

Will we be Dinosaurs?

Richard Collis, Former President of the Irish Pharmacy Union and pharmacy owner in Phibsborough, Dublin 7.

A decade and a half on from the new contract of '96, can it be said that the profession of pharmacy has progressed? And, will whatever progress there has been condemn single operator pharmacists to near extinction?

On the professional issue, clause 9 has crystallised, for many, the role we play in Primary care, the need to listen and to advise is seminal. Indeed, it could be said that the innovation of the consulting room was a logical extension of this clause in our contract. Many pharmacies are now active in the provision of Methadone; this scheme has never got the kudos it deserves. It has successfully brought the marginalised into the mainstream and has provided a positive environment for those wishing to change their lifestyle. Another innovation from the contract was that pharmacies would now source and dispense High Tech medicines, a function that Health Boards had previously carried out. There is also the reality that medicine usage is not a straight forward situation and requires dealing with issues, such as compliance and suitability. There is, thus a strong sense among the population that pharmacists are significant players when it comes to the health of the community. As our base of service provision broadens slowly, there will be ample opportunity to exploit this goodwill and further enhance the reputation of the profession.

Pharmacists, in common with all the professions were very cosseted and prospered significantly during the boom. Central to that prosperity was the role of the Pharmacy Union at the negotiating table. While there was always a trade-off involved, it cannot be denied that, individually and collectively pharmacy never had it so good. To listen, however to some of my colleagues, mainly of the corporate/multiple mindset, these benefits appeared out of the ether, or were a function of their own creation. The reality is that, over the last twenty years the Union has been at the heart of the benefits that have accrued to our profession.

Probably it is inevitable, as the cutbacks begin to bite that revisionism would take root. The ancient and very prevalent trend in Irish culture, 'The Split' seems to be getting traction. It may be seen by some as being inevitable, given the growth of pharmacy multiples over the last decade or so, a growth that shows no sign of faltering. What is worrying is that there is a drive to split at representative level. The failure of our strike action two years ago was, in no small way due to the fact that certain multiple chains did not go out in sympathy with a democratically reached decision, whatever its right and wrongs. The opportunity to ameliorate the negotiating approach of the HSE was lost, and the reason why will be etched in the minds of officialdom for generations to come. This, taken in tandem with the emergence of another body purporting to represent pharmacy interests, will further weaken our position in negotiation.

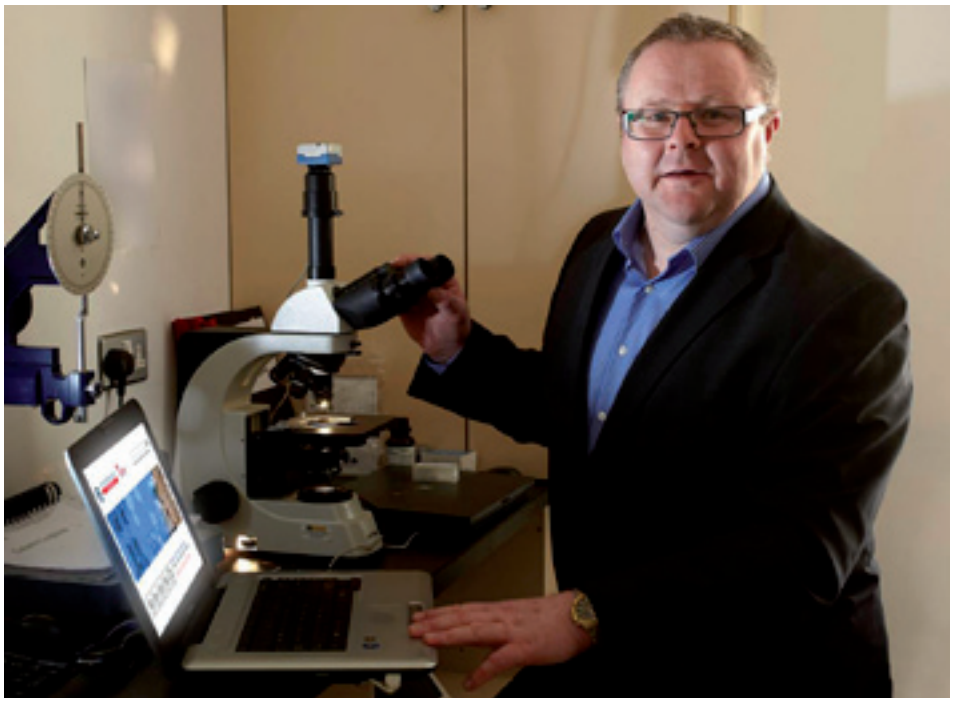
Difference of opinion about policy is as common as rain in an Irish summer. As long as there is a forum for those differences to be aired, a democratic outcome is guaranteed. In our society it is the best we can hope for, because, to paraphrase Churchill, the alternative is infinitely worse. Unfortunately, people become so convinced of the correctness of their position, they seek ways and means to impose it. It is how splinter groups emerge. Their benefit to the welfare of the many is doubtful as their aims and aspirations usually have the self-interest of the few at their core.

But, what about the supposed inhabitants of the pharmaceutical Jurassic Park, the single pharmacy operators? The onward march of Boots and good old Dr Morris is inevitable, thus will there be room at the inn for our humble selves? The answer is a resounding yes. The only people immune to spin are those that are unwell. While they are susceptible to quack cures, a front of shop presentation, with its dynamic and 'in your face' approach appears somewhat a distraction from their most pressing issues. That not so subtle commercial approach is the calling card of the Multiples; that retail tension in the air is undeniable. The last thing our loyal cohort of customers need is tension, they get it in the hospital, the surgery, and it is even within, often for very good reason.

It is the relaxed and laid back atmosphere of the less commercially driven pharmacies that are key to the phenomenal customer loyalty that we enjoy. The customer knows they will be listened to and advised, where necessary, that is the key to our future and the reason we won't be going the way of the Raptor and the Dinosaur any time soon.

Fergal Murphy

Finding a sensible solution to generic substitution and reference pricing



Fergal Murphy, Company Director, Pinewood and Chairperson of the APMI

Looking back on the year, the pharmaceutical industry has been hit hard by austerity measures, price cuts and a downsized economy. While all industries have been negatively impacted by the receding Irish economy, the pharmaceutical sector, which relies heavily on state spending, has been severely affected. To date, the market is showing a negative growth of 5%.

At the beginning of 2011, the Department of Health agreed price cuts with the Irish Pharmaceutical Healthcare Association (IPHA) and this was followed by further price cuts to medicines in August, to which the Association of Pharmaceutical Manufacturers of Ireland (APMI) had to deliver upon.

From a generic industry point of view the price, cuts in August of this year lead to serious pressure being placed on generic companies to continue to supply various products here in Ireland. Continuity of supply is an issue right now for the Department of Health and I feel that this needs to be seriously addressed in 2012. Price reductions have had a hugely negative effect on the entire pharmacy sector and already, one generic manufacturer, HelsinnBirex, has ceased operation in the Irish market this year. The pharmaceutical manufacturers are hurting, as well as the pharmacists, who are struggling to run their businesses at a profit.

The challenges for the New Year will be the introduction of generic substitution and reference pricing and getting it right. It will be difficult to introduce in Ireland in its purest form because the market is so small. Just to offer some perspective on how small the Irish market is, there are more hospital beds in the greater Manchester area than there are in all of Ireland. In sum, the volume and capacity for generic substitution and reference pricing is minute and any introduction of Generic Substitution needs to be well planned with continuity of supply in mind.

We need a tiered approach to reference pricing and generic substitution and, as the Chairperson of the APMI, I have a number of different proposals ready for the Department of Health to consider. How the legislation is progressed is out of our hands and the ball is firmly in the Departments of Health's Court but the APMI is willing to engage with the Department of Health, IPHA, the Irish Medical Organisation and the Irish Pharmacy Union to help in defining a model that will work for everyone.

Overall, 2011 has seen significant consolidation in Ireland with all aspects of the sector being impacted: Retail Pharmacy margins have taken a hit, the industry has downsized and patients have less money to spend on medications.

I look forward to 2012 and working with the DOH in an effort to design and implement a sustainable Generic Strategy here in Ireland, which will benefit the patient and the ever dwindling health budget.

Anne Nolan

Bad laws should be avoided at all costs

Anne Nolan, Chief Executive, IPHA

Although it was used somewhat prematurely in the recent past to describe the state of the economy, the phrase, 'Ireland has turned a corner', seems to sit a lot more comfortably now as 2011 draws to a close. Sadly, the last couple of years have been the toughest experienced by our country since the 1950s, and maybe even since independence.

Though the austerity measures currently being implemented must be sustained until at least 2015, there is a resilience in the Irish economy - and the Irish people - which is quite remarkable. This is reflected in the thousands of men and women who, despite drops in their disposable income, continue to work and pay tax in this economy. The industrial base, a lot of it based around foreign direct investment, remains largely intact, and at its very heart is the pharmaceutical industry.

Not only has the pharmaceutical industry continued as a major hub of enterprise and innovation, 2011 has seen it at the very forefront of a quite remarkable performance by our exports. Still employing 25,000 people directly, over half of which are third level graduates and as many more indirectly, the pharmaceutical industry, along with chemicals and medical devices now accounts for over 50% of Irish exports. Such exports were worth over €50.8 billion in 2010 and, on current figures are expected to surpass this in 2011. A thriving export market alone will not return Ireland to full economic prosperity, however, there is an increasing consensus that without our exports, such recovery would be far slower in coming, and without the role of pharmaceuticals, even slower still.

An absolutely crucial dynamic in maintaining the underlying strength of the industry has been the robust defence by the Government of our 12.5% corporation tax. In doing so, a clear demonstration has been given, that the State values innovation and the contribution of dynamic sectors such as the international research-based pharmaceutical industry. As well as protecting a vital revenue stream worth €3 billion, this enhances Ireland's reputation as a good place to do business and increases the likelihood of further investment here in terms of manufacturing plants, shared service centres or clinical trials.

Whereas 2011 has been a relatively stable year for the pharmaceutical industry, in terms of output and employment, significant pressure has been - and continues to be - experienced on the pricing front. IPHA, whose member companies supply 85% of the medicines to the Irish health services, has for many years operated a supply agreement with the State to ensure that innovative medicines and therapies are available to all Irish people, regardless of income. This has always worked well and been conducted in a spirit of cooperation and partnership. The current agreement, which was begun in 2006, lapses in March 2012 and it is estimated that, by then, it will have delivered savings to the State of over €300 million.

On top of these savings, IPHA companies responded positively in 2010 to two separate requests from the Government to make further savings in the State medicines' bill. In February 2010, additional measures were taken that yielded savings of approximately €94 million in a full year and further concessions agreed in December, will yield €140 million in savings during 2011.

In responding to the realities of the economic situation, IPHA members realise that the Government must continue to implement austerity measures in order to get our deficit down to 3% of GDP by 2015. However, the value of the pharma market has contracted considerably and there are very real fears that any further reductions in prices paid by the State to IPHA member companies could negatively impact on existing jobs and threaten future investment.

IPHA is anxious to proceed towards a new partnership with the State post March 2012 that is, at least as constructive as the present arrangements. However, there must be no further erosion of a market that is in serious decline.

Separate to the supply agreement, but of perhaps even more fundamental importance to the pharmaceutical industry and IPHA companies in particular, is the plan by the Government to legislate for a reference pricing system, possibly accompanied by some form of generic substitution. As things stand, the Government is saying that it hopes to bring this into law in 2012. Unfortunately, a degree of lazy analysis has accompanied much of the debate to date around the legislation and the potential of such pricing arrangements to bring further savings to the State medicines bill.

There is no compelling evidence to show that savings will accrue to the State and, indeed it must be said that if any such legislation led to further significant price erosion, then it could threaten the supply of certain medicines to Irish patients.

IPHA and its member companies accept that some legislative change is on the way, however, it urges the Government to think carefully about the bill it produces and, at the very least a comprehensive cost benefit analysis should be conducted before any commencement order is signed. In a rush to rationalise resources, bad law should be avoided at all costs.

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**Generics Bulletin, June 2011*

KRKA

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Living a healthy life.

Patrick McCormack

The chill of recession continues to bite....

Patrick McCormack Managing Director, Sam McCauley Chemists Group

Last December, the country was gripped by heavy snowfall and freezing conditions, which had a very detrimental impact to the normally busy Christmas period for many pharmacies. Just when we thought things could only improve, the Irish Pharmacy sector was hit with the IPHA price reductions days before Christmas. The communication of this message, from the relevant authorities implementing the cuts as agreed with the Department of Health was very poor to say the least. The nature and extent of the cuts were far worse than anyone had anticipated.

There is no doubt that these cuts, in addition to the FEMPI cuts have threatened the very survival of many pharmacies. In the past twelve months, we have seen several pharmacies before the commercial courts in receivership and examinership. There is also no doubt that this trend will continue - and probably get worse in 2012.

As if this wasn't bad enough we have also seen the implementation of restrictions on the sale of medicines containing codeine and the removal of many cough medicines from pharmacy shelves. It would be very interesting to see what beneficial effects these restrictions will have on the public health.

Ironically, this all happened at a time when pharmacists were forced to invest heavily in consultation rooms. I assume that this was done with a view to expanding the role of the pharmacist, as well as providing better facilities so that the pharmacists could use their expertise to provide more extensive patient consultations? There appears to be a contradiction here somewhere?

There are many challenges facing pharmacists in 2012 and there is no doubt that there is 'nothing certain but change.'

The government policy of development of primary care centres will no doubt gather pace in the next 12 months. It is also very interesting to note that we will all be the beneficiaries of free GP care by 2015/ 2016 and that it is intended to start this 'roll out' in the next 12 months with free GP care for all patients on the long term illness scheme.

It will be very interesting to see how this will be funded and where the Department will find all the extra GPs that will be required to provide this service . Based on experiences in other jurisdictions, it is safe to assume that the number of patients visiting GPs will increase significantly with the advent of free consultations. There is no doubt that this, in conjunction with our increasing age profile will contribute to increased volumes of medicine consumption over the coming years.

It is estimated that we currently have 11% of our population in the over 65 age group now and that this will increase to 15% by 2021. In addition, it is estimated that a capital investment of over €1 billion is required to put the physical infrastructure in place to provide primary care centres across the country .The number of primary care centres required to service the country is currently put at over 200, with less than 30 in place at present. Significant funding will be required to make this a reality.

The advent of generic substitution needs to happen as a matter of urgency, in order to save money. Reference pricing, which has been in the pipeline for some time now looks like it will happen in mid-2012. This will save the government significant money and put further financial pressure on many pharmacists.

There is no doubt that 2012 will see a further erosion in pharmacists' incomes and pharmacy valuations and it is highly likely that there will be further job losses in the sector and further downward pressure on wage and other costs.

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References 1. European patent office. http://ep.espacenet.com/, May 2011.

07/2011, Ireland, 5066-2011, RB.

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Mark Ryan

Pharmacy Legislation - Much Change; A Lot More To Come

*Mark Ryan, Whitney Moore Solicitors**

From talking to pharmacist clients and reading the pharmacy press, it is very obvious just how much change the sector has undergone, starting with the enactment of the Pharmacy Act in 2007. A common complaint is that pharmacists have come under increased pressure as a result of regulatory changes and greater administrative burdens, for example in processing their claims under the various community drugs schemes operated by the State. With reductions in staff forced on them as a result of cuts in their remuneration, many pharmacists are finding it difficult to find the time to devote to their patients and to the development of new services.

The noticeable increase in regulation is partly due to the fact that, as a profession, pharmacy had been grossly under-regulated for so long and is now in catch-up. However, it would appear that what some pharmacists perceive as a "regulatory overload" may just be the groundwork for the Government's plan to expand the role of primary care in this country.

Pharmacists have for many years called for greater recognition and utilisation of their knowledge and skills in the delivery of an accessible, efficient and cost-effective healthcare system for this country. The Pharmacy Ireland 2020 Working Group, in its interim report published in April 2008, identified several ways in which community pharmacists could enhance the services they provide to patients and deliver cost-effective solutions to problems within the health system. Among the measures envisaged are –

- The involvement of pharmacists in the carrying out of regular medication reviews for all patients.
- A greater role for pharmacists – including the power to prescribe – in the management and treatment of minor ailments.
- The provision of health screening.
- The administration of vaccination programmes.

In October 2011 the Medicinal Products (Prescription and Control of Supply) Regulations 2011 were introduced, permitting suitably trained pharmacists to supply and administer the flu vaccine for the first time in Ireland. Other jurisdictions where pharmacists are involved in the delivery of immunisation programmes have seen increased uptake rates due to the greater accessibility of the service and it will be interesting to see whether this trend is replicated here.

Pharmacist-prescribing and the introduction of a Minor Ailments Scheme are other proposals on the agenda with a view to achieving a more rational use of healthcare resources, by keeping minor ailments away from busy GP surgeries, thereby allowing them to treat more serious conditions requiring medical intervention. Central to these proposals is the proposal to provide wider access to medicines which have a proven safety record by switching them from prescription-only status (POM) to medicines which can be sold without prescription in pharmacies (P). The Pharmacy Ireland 2020 Report, already referred to, identifies several medicines as being suitable for switching in this way, including –

- Analgesics for migraine;
- Malaria prophylaxis;
- Antifungal treatments;
- Inhaled bronchodilators.

The Report notes that in the UK these and many other medicines are available in pharmacies without prescription, including emergency contraception, and recommends the development of a national policy in this country with regard to POM to P switching.

Earlier this year one of the country's larger pharmacy chains took matters into its own hands by rolling out a service providing the emergency contraceptive pill and the flu vaccine without the need for a doctor's prescription. It did so on the basis of what it described as a "Patient Group Directive" or PGD issued by the pharmacy's own medical director which, it was claimed, allowed it to supply prescription-only medicines without a prescription. PGD's are a feature of the English system but do not exist under Irish law. The service was discontinued after intervention from the IMB. Whether this was the catalyst for change, or whether change would have happened in any event, is not entirely clear but, not long after, the status of Norlevo was changed from POM to P.

It is interesting to note that the 2020 Report

Mark Ryan

calls for a new category of "pharmacist prescribed" medicines – OTC medicines which could be supplied only after the pharmacist had carried out a number of clinical checks, with the pharmacist having to record details of the consultation. The Report identifies Codeine as one such medicine that should come within this new category. This would appear to explain the rationale behind the PSI's Guidance issued to pharmacists in August 2010 requiring codeine-based OTC medicines to be stored in the dispensary or in a location where they would not be visible to the public. And just last month pharmacists will have received further guidance from the PSI advising that, due to new safety issues concerning non-prescription domperidone medicines (Motillium and Domerid Relief 10mg), these should be stored in the dispensary. If indeed new information has come to light which casts doubt as to the safety of a medicinal product that is available without prescription, one wonders whether it would not be more appropriate that its OTC status be changed to prescription-only rather than create a new class of product which is not recognised in Irish law. As regards the particular safety issue relating to domperidone, one pharmacist client of mine commented that, short of hooking patients up for a quick ECG at the counter, it is anyone's guess as to whether there is a risk in supplying it! In short, if there is a safety issue with this medicine, then its sales status may need to be reviewed (or the product withdrawn) rather than issuing a guidance which requires pharmacists to verify whether it is safe to supply.

Moreover, it would appear that the Pharmacy Regulator is – not for the first time – acting beyond its powers as the classification of medicinal products is a function of the Irish Medicines Board and not the Pharmacy Regulator. In addition, the legal status of this Guidance is, at best, uncertain. By all means, if it is considered appropriate that a class of "pharmacy prescribed" medicine be introduced, then this should done on a proper statutory basis with clear rules surrounding such matters as storage, supply and advertising. The Guidance just issued in relation to domperidone states that, as regards the promotion of such products, "any material which is not consistent with the new safety situation should be removed." Because "pharmacist prescribed" medicines are not yet a legally recognised classification, the law permits the advertisement of OTC medicines, subject to compliance with the requirements of the Medicinal Products (Advertising) Regulations 2007. No Guidance issued by the PSI can alter that or introduce restrictions, as the Pharmacy Regulator does not have power to legislate.

Whilst on the subject of medicines advertising and promotion, in October 2011 the PSI issued new Guidance relating to the advertising, promotion and sale of medicinal products, and related matters. In an email to all pharmacists the PSI explains that this new Guidance is intended to replace Practice Notice 5 on the Advertising and Promotion of Medicinal Products on the basis of price or quantity discounts issued in 2009. However, the PSI did not give any explanation as to the reasons for revising its guidance, which was issued without any consultation. Without an explanation, the significance of the new guidance is likely to be lost on pharmacists.

Practice Notice 5 stated that the promotion of OTC medicinal products on the basis of price or quantity discounts was both unlawful and in breach of the Statutory Code of Conduct for Pharmacists. The truth is that it was neither! In fact there is no mention whatsoever of price promotions or quantity discounts either in pharmacy legislation or in the Code. Whilst the new Guidance does not make a similar claim, it does not inform pharmacists that the law permits the advertising and promotion of medicinal products on the basis of price or quantity discounts and the tenor of it is such that pharmacists will continue to be under the misapprehension that price promotions are unlawful. Contrast this with the equivalent Guidance of the UK's Medicines and Healthcare products Regulatory Agency in its Blue Guide. This makes clear that such promotions are lawful but encourages good practice and responsible behaviour, whilst discouraging volume-based price promotions of analgesics which could result in unnecessary purchases and put consumer safety at risk.

Once again, there is an issue with regard to the legal status of the PSI's Guidance on price promotions which is questionable. It is claimed that it is issued pursuant to section 7(2)(b)(vii) of the Pharmacy Act 2007, however that particular section empowers the Society to "make public statements about any aspect of pharmacy to which its functions relate." The Guidance (non-compliance with which would presumably result in a disciplinary process under Part 6 of the Act) would not amount to a public statement. Whether or not that view is correct, it is unsatisfactory for such an important issue to be dealt with by way of Guidance.

If the role of pharmacists is to be developed in the manner envisaged by the Pharmaceutical Society in the 2020 Report, it is critical that a rigorous regulatory framework and fitness to practise regime is put in place. The Pharmacy Act 2007 was just the start of the process. Unfortunately, the "regulatory overload" that has followed appears to be the price pharmacists will have to pay for the expansion of their role in the delivery of primary care services. But it is important that this is done on a proper statutory basis – and not by means of the issue of one "guidance" after another.

There is one practical issue causing difficulty for pharmacists in their every-day practise in relation to which they would welcome a change in the legislation. Under the Medicinal Products (Prescription and Control of Supply) Regulations one of the requirements for a valid prescription is that it be in ink. This presupposes that there is always someone to walk into the pharmacy and present an original prescription.

Very often, the reality is quite different. Take, for example, the supply of medicines to patients in residential homes (which includes prisons). Significant numbers of patients in these settings are seen by their doctor on any given day resulting in substantial numbers of prescriptions being issued at all times of the day. In many of these cases fax is the only means of transmitting the prescription to the pharmacist if the medication is to be dispensed and delivered to the patient in a timely manner. However, the Pharmacy Regulator insists that these patients be treated in the same way as patients who attend personally at the pharmacy and has stated that faxed prescriptions will not be tolerated. Surely, in this digital age some practical solution can be found to deal with what is a daily problem, so that pharmacists can practise within the law?

*Mark Ryan is a partner in Whitney Moore, Solicitors specialising in pharmaceutical regulation

John Corr

Doing more in community pharmacy

John Corr, Pharmacist and PSI Council Member

The year 2011 has been a challenging year for pharmacists around the country. Pharmacists have had to face increased regulatory burdens, HSE PCRS cuts and additional costs at the same time and we are all just working through it and hoping to come out intact at the other end.

In light of these challenging times, my friends and colleagues encouraged me to stand for the PSI Council elections, suggesting that more independent community pharmacists were needed to contribute at the regulatory level.

As a member of the PSI Council, I want particularly to contribute to ensuring that we operate as a regulatory body with a philosophy of financial prudence. There has been a history of financial wastage within public bodies in Ireland and in the current climate it is important that we make the best use of our resources and look at ways of reducing costs where possible, for example our legal costs are becoming more significant now that we have fitness to practise.

The availability of the morning after pill through pharmacy and the launch of the flu vaccination programme through pharmacy, both of which have happened in 2011, have been interesting and novel breakthroughs for the profession in Ireland. I have already vaccinated between 30 and 40 patients with the flu vaccine to date, with great success. Through providing this service in pharmacy, pharmacists can vaccinate those patients that the GPs would never get. I find that many older male patients would resist having to make an appointment with the GP for a flu vaccination but, because it is now available in pharmacy on a walk-in basis, the service has become more accessible and less intimidating to them.

Only now are we finally catching up with the more progressive countries around the world that have been carrying out these kind of services, through pharmacy, for years and this is the aim of the PSI's *Pharmacy Ireland 2020* initiative. The Department of Health needs to maintain a receptive ear and listen to pharmacists when we say that we can deliver extra, professional services.

One of the major issues looming for the Irish healthcare system is the GP manpower issue, and already we are seeing a reduction in GP manpower. Whilst the country learns to deal with the GP shortages, there will be a transition period whereby community pharmacists can step in and work with their colleagues in primary care to look at task-shifting and better utilising the pharmacy and pharmacist resources we have. However, in doing so, I should emphasise that in my view, the provision of many of these extra services by pharmacists will require examination of how pharmacists are remunerated for their professional services.

In terms of the other developments coming from the introduction of the Pharmacy Act 2007, I think pharmacy is moving into the next phase of that and the introduction of the framework around continuing professional development (CPD) and the establishment of an Institute of Pharmacy are the next important developments.

CPD is now mandatory for pharmacists and we will be putting the infrastructure in place to support pharmacists in adapting to the new system.

While such a change may sound intimidating, it is nothing to be fearful of. I think that every pharmacist would agree that the profession should be made up of suitably qualified pharmacists who maintain their competency and develop professionally throughout their careers.

The model of CPD that will be brought into Ireland is based on the system that is in place in Ontario, Canada. It will involve keeping a portfolio of self-learning, attending lectures and courses and from 2014 there will be a quality assurance and assessment system in place.

Pharmacists already do independent learning every time they read up on a new drug or discuss with their colleagues aspects of a particular treatment, so it's about developing this aspect of their practice, of pharmacists reflecting on their learning needs and documenting their learning.

Another key feature of the CPD system will be the regional and local peer networks that will be developed. This could be as simple as pharmacists meeting up once a month for an hour long discussion of a pharmacy related topic, followed by a social game of bridge or football or whatever the members of the group find most attractive. I think that a peer network will be critical because there can be a sense of professional isolation in pharmacy, and it is hoped that this type of approach can facilitate active group learning by pharmacists.

The most important thing for us as the PSI is to ensure that the system is supportive of pharmacists and that we communicate what the system will entail.

Communication has played a central role to the PSI in carrying out its regulatory functions. I think that the PSI has gotten much better at reaching out and communicating with pharmacists on the changing regulatory environment that the profession now practises within.

The profession needs pharmacists to get actively involved in developing their knowledge and skills. And, in turn, society will value the work carried out by pharmacists and their contribution to the health service, and I think it will also facilitate better and closer working relationships with our colleagues from the other professions. And ultimately our patients will benefit from that.

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References. 1. Conbriza Summary of Product Characteristics.

Date of preparation: October 2011. CON/2011/017.

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Mary Rose Burke

Tidying up community pharmacy

Mary Rose Burke, Superintendent Pharmacist at Boots Ireland

A good gardener, while they may not be outside in December weather tending plants, will spend many productive hours reviewing the last year. How the planting went, did they select the right plants, seeds and bulbs for the soil type and weather conditions, how did the garden flourish over the summer, what grew well and what failed, what plants need to be removed or replaced and which would benefit from robust pruning?

This is the time of year to tidy up the garden and review the brochures that promise colour and pleasure next spring and summer. No matter the success and failures of the past year the gardeners reviews and learns and continues to plan and plant for the future.

When I look back on 2011 and the world of pharmacy I see many parallels.

Last year we had introduced for the first time in Ireland, a Winter Flu Vaccination Service through pharmacy which was very successful and particularly we saw in January when the incidence of flu increased rapidly that very many people chose to access vaccination by a pharmacist. I think our experience very clearly demonstrated that while various stakeholders see merit in the development of pharmacy, no-one will do it for us and we within the profession of pharmacy must take ownership and leadership of future development.

Some initiatives did not find fertile soil and still remain dormant, but I believe there is merit in further exploring how the concept of a patient group direction could be provided for within government health policy, and there are many areas that lend themselves to pharmacist-delivered care within an agreed protocol. This is an area that may yet bloom!

With regard to pruning, I think pharmacy has probably had to face into cost reduction with more focus than ever before and most of the more easily achievable savings and efficiencies have been accessed. We now need to look at how we bring a spirit of transformation in healthcare to life in pharmacy and re-examine how the pharmacy team is led and developed to ensure that pharmacists time is freed up to focus on delivering expert pharmaceutical care.

When I look into my crystal ball, I see many reasons to be optimistic about the future of pharmacy and think the silver lining of the financial and economic crisis the country faces will be that it will force us to re-engineer how healthcare is delivered in Ireland. I believe there is a bigger role for pharmacy to play in management of healthcare in the community and would like to see real political buy- in to seeing pharmacy as an integral part of primary care. We need grown up debate and discussion about patient care pathways and how the various professionals will work together for the best patient outcome. The healthcare challenges facing the country have no one solution and we know things have to be done differently. My hope for the pharmacy sector in 2012 is that, having had years of cuts to reimbursement and remuneration by the HSE, that now is the time for consultation and progress about value and where pharmacy can truly deliver value in health promotion and screening, in harm prevention, in health maintenance and health management. The new economic reality needs a new way of doing things in pharmacy and healthcare in general. Pharmacy has demonstrated how it can deliver services previously confined to doctor's surgeries to the benefit of patients and it is now time to build on this and to respond to people's demand for convenient accessible and affordable healthcare through pharmacy. So, over all it has been a productive year in 2011 with new ideas taking root and thriving, and every reason to believe that green shoots will thrive.

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Lactation Paracetamol and caffeine are excreted in breast milk. Paracetamol Human studies with paracetamol at the recommended doses have not identified any risk to lactation or the breast-fed offspring. Caffeine Caffeine in breast milk may potentially have a stimulating effect on breast fed infants but significant toxicity has not been observed. **Side Effects of paracetamol:** All very rare: Thrombocytopaenia, Anaphylaxis, Cutaneous hypersensitivity reactions including skin rashes, angiodema, and Stevens Johnson syndrome, Bronchospasm in patients sensitive to aspirin and other NSAIDs, Hepatic dysfunction. **Side Effects of caffeine:** Nervousness, Dizziness. When the recommended paracetamol-caffeine dosing regimen is combined with dietary caffeine intake, the resulting higher dose of caffeine may increase the potential for caffeine-related adverse effects such as insomnia, restlessness, anxiety, irritability, headaches, gastrointestinal disturbances and palpitations. **Overdose Paracetamol** Immediate medical attention (in-hospital, if possible) is required in the event of overdose, even if there are no significant early symptoms. **Caffeine** Symptoms and Signs Overdose of caffeine may result in epigastric pain, vomiting, diuresis, tachycardia or cardiac arrhythmia, CNS stimulation (insomnia, restlessness, excitement, agitation, jitteriness, tremors and convulsions). **MARKETING AUTHORISATION HOLDER** GlaxoSmithKline Consumer Healthcare (Ireland) Ltd, Stonemasons Way, Rathfarnham, Dublin 16. Further information is available on request from: GlaxoSmithKline, Consumer Healthcare, Stonemason's Way, Rathfarnham, Dublin 16. Tel: 01 495 5000 | Fax: 01 495 5525. **Marketing Authorisation Number** PA 678/39/10. **Date of (Partial) Revision of the Text** December 2010. **Legal Category:** Pharmacy Only.

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Marek W. Radomski & Anne Marie Healy

Five-year Integrated M.Pharm: The Trinity View

Marek W. Radomski School of Pharmacy & Pharmaceutical Sciences Trinity College Dublin.

About authors: Prof. M.W. Radomski MD, FTCD, DHC is Chair of Pharmacology (1979) and Head of School of Pharmacy & Pharmaceutical Sciences;

Prof. A.M. Healy BSc (Pharm.) PhD, FTCD is Director of Undergraduate Teaching and Learning School of Pharmacy & Pharmaceutical Sciences.

The current debate on the future shape of the undergraduate curriculum in Pharmacy stemmed from the report by the Aston University academics, Keith Wilson and Christopher Langley Pharmacy Education and Accreditation Reviews (PEARs) Project. The report, commissioned by the Pharmaceutical Society of Ireland (PSI) in 2008 and published in June 2010 was structured around six major recommendations, including replacement of the current 4 + 1 model of pharmacy education (4 years of academic learning and 1 year of pharmacy practice) with a 5-year-long, fully integrated curriculum (the pharmacy practice year to be divided and integrated into the curriculum), development of national practice-based learning, professional standards for patient care and safety and new accreditation

Marek W. Radomski & Anne Marie Healy

processes. The enabling recommendations were the provision of adequate funding (the existing streams, Government, employers and student fees) and the establishment of a National Pharmacy Forum (NPF) to assist in the transition process. The PSI Council approved the PEARs report and recommended the implementation of an integrated curriculum for Pharmacy as early as September 2012.

For a number of reasons that cannot be discussed here, the 2012 deadline is no longer realistic. We also wish to point out that significant challenges face the introduction of an integrated curriculum. Although the integrated curriculum appears to be appealing, no evidence is available showing that the 4 + 1 curriculum produces less able pharmacists than a 5-year-integrated system. It is worth noting that, to date, the UK schools of pharmacy have not moved to take up the fully integrated programme.

The elephant in the room is the financial resource required for such a programme. Firstly, the PEARs report was assembled at times of national prosperity, running up to 2008. Funding for public universities, including Trinity College, has been halved over the last 3 years.

Furthermore, the Irish pharmacy programmes for historical reasons have been deemed to be “not clinical” and attract much lower weighting than medicine or dentistry, compounding the substantial underfunding of the existing pharmacy programmes.

Secondly, academia cannot responsibly propose new teaching initiatives that do not break even and are undertaken at the taxpayers’ expense. The realistic cost of one year of undergraduate pharmacy studies at Trinity greatly exceeds the current registration fee paid to the PSI for the current (+1 year) M.Pharm. programme, which amounts to €2000.

Thirdly, given the extremely difficult state of the public finances, the only sustainable way to finance the new curriculum would be to dip into students’ and/or their families’ pockets. The Irish Universities Association has already urged the government to consider the reintroduction of student fees. It is clear that pharmacy student fees cannot be discussed in isolation from the issue of third-level education fees as a whole.

Anne Marie Healy School of Pharmacy & Pharmaceutical Sciences Trinity College Dublin.

The Trinity College integrated M.Pharm. proposal, which has been presented to the National Pharmacy Forum, represents a significant improvement over the current 4 + 1 programme. Our students will have at their fingertips the state-of-the-art Boots Practice of Pharmacy facility that will facilitate practice training throughout their course of studies. Early summer placements and one-year-long practice experience (potentially split into two six month periods) between years four and five combines practice-based learning with teaching-through research, which is unique to the Trinity College student experience.

We feel that we can deliver this exciting curriculum in an economically viable way that would be acceptable for the current and future pharmacy students.

Dr Zeibun Ramtoola

Pharmaceutical Industry in Ireland Set for Change

According to a recent publication in the Irish Times, Ireland's multinational pharmaceutical sector is well prepared for the changes that will beset the industry when a number of branded drugs come off patent next year. A number of large companies here have been moving into biologics, in anticipation of the change, and Ireland now has one of the strongest clusters of biologics in the world.

Speaking at the recent launch of IBEC's PharmaChemical Ireland's recent report on Ireland as location of choice for scientific investment, the Minister for Research and Innovation Sean Sherlock said, "Ireland is globally recognised as a major centre of excellence in the pharmaceutical industry and is now emerging as a leading location for biopharmaceuticals".

With this rapidly expanding biopharmaceutical sector, enormous challenges face the industry as the scientific and regulatory issues are complex and it is critical for Ireland to maintain a highly skilled workforce and its strong and excellent compliance record with statutory and quality regulations and FDA inspections.

In response to this need, the School of Pharmacy at RCSI in collaboration with the School of Science, IT Sligo has launched the Postgraduate Diploma in Science in Pharmaceutical Regulatory Affairs, for those who would like to enter this field or who are working in the area but want to develop their knowledge and skills. This course encompasses 6 modules, delivered by distance learning over two years. The course will see its first intake of students in January 2012.

In addition to this course, the School of Pharmacy, RCSI and the School of Science, IT Sligo also offers the MSc in Industrial Pharmaceutical Science course. This MSc course fulfils the educational requirements contained in Article 49 of Directive 2001/83/EC and Article 53 of Directive 2001/82/EC for Qualified Person acceptability. This course consists of 12 modules delivered by distance learning over a 2-year period, with a research project at the end of year 2. This MSc course, set up in 2003, has conferred approximately 200 graduates to-date and graduates are currently employed in a variety of roles in the pharmaceutical, biopharmaceutical and medical device industries, as well as the Irish Medicines' Board. Graduates from this course have also gone on to be registered as QP in the UK.

Both courses are modularised and, therefore can be studied for continuing professional development across the Industry. In addition, with the recent Continuous Professional Development initiative by the PSI, relevant modules from either course are also suitable as CPDs to those in clinical practice.

> "Ireland now has one of the strongest clusters of biologics in the world"

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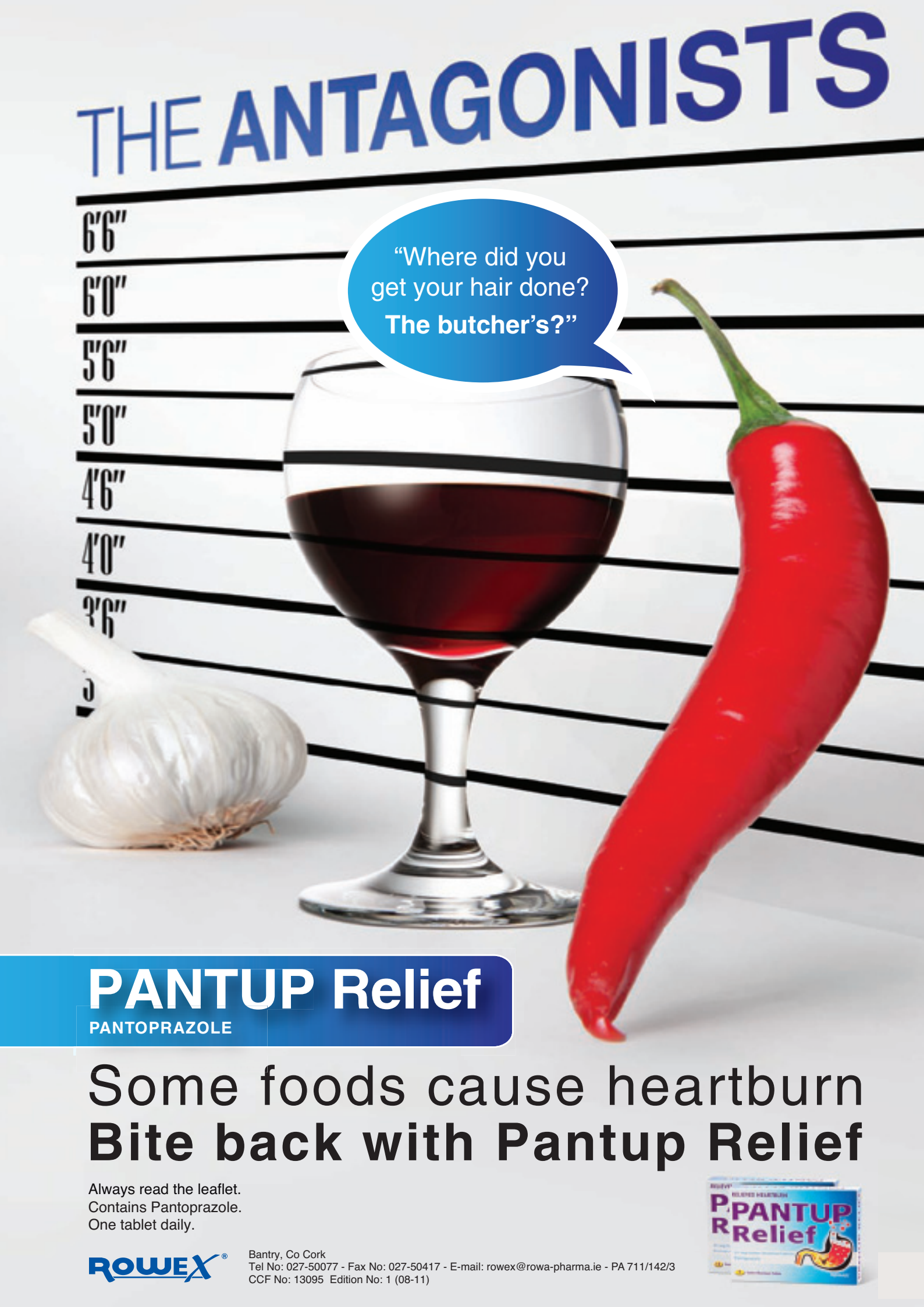

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CPD

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1. REFLECT
Before reading this module, consider the following: Will this clinical area be relevant to my practice

2. IDENTIFY
If the answer is no, I may still be interested in the area but the article may not contribute towards my continuing professional development (CPD). If the answer is yes, I should identify any knowledge gaps in the clinical area.

3. PLAN
If I have identified a knowledge gap - will this article satisfy those needs - or will more reading be required?

4. EVALUATE
Did this article meet my learning needs - and how has my practise changed as a result? Have I identified further learning needs?

5. WHAT NEXT
At this time you may like to record your learning for future use or assessment. Follow the 4 previous steps, log and record your findings.

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CPD 12: COPD

Biography
Mark Beddis MPSI is Superintendent Pharmacist with Tesco Pharmacy Ireland. He graduated from the University of Brighton in 1997, qualifying as a pharmacist in 1998. Mark moved over to Ireland to progress his career and has been involved in several committees over the course of the last eight years including serving on the Council of the Pharmaceutical Society of Ireland from 2005 to 2007, as well as being a founding member of the Employee Pharmacist Committee of the Irish Pharmacy Union.

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CPD 12: COPD

Introduction

Chronic Obstructive Pulmonary Disease (COPD) is the co-occurrence of chronic bronchitis and emphysema, a pair of commonly co-existing diseases of the lungs in which the airways become narrowed. This leads to a limitation of the flow of air to and from the lungs, causing shortness of breath (dyspnea). People with either chronic bronchitis or emphysema can also be diagnosed as suffering with COPD, however the majority of people suffering with COPD have both.

Chronic bronchitis: bronchitis means 'inflammation of the bronchi'. These are the tubes or airways that carry oxygen from the air through the lungs. This inflammation increases mucus production in the airways, producing phlegm that makes you cough.

Emphysema: this is where the alveoli (air sacs) in the lungs lose their elasticity. This reduces the support of the airways, causing them to narrow. It also means the lungs are not as good at getting oxygen into the body, so you may have to breathe harder. This can result in shortness of breath.

In clinical practice, COPD is defined by its characteristically low airflow on lung function tests. In contrast to asthma, this limitation is poorly reversible and usually gets progressively worse over time.

COPD is caused by noxious particles or gas, most commonly from tobacco smoking, which triggers an abnormal inflammatory response in the lung. The diagnosis of COPD requires lung function tests. Important management strategies are smoking cessation, vaccinations, rehabilitation, and drug therapy (often using inhalers). Some patients go on to require long-term oxygen therapy or lung transplantation.

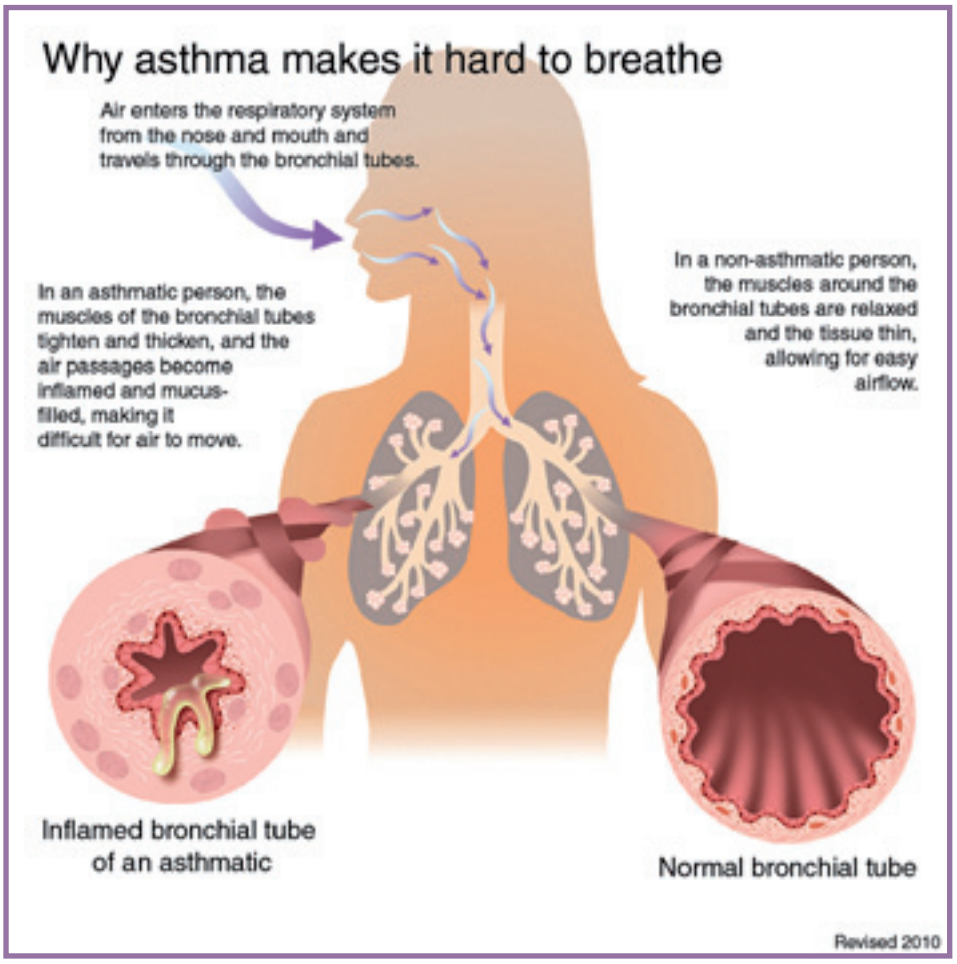
Worldwide, COPD ranked as the sixth leading cause of death in 1990. It is projected to be the fourth leading cause of death worldwide by 2030 due to an increase in smoking rates and demographic changes in many countries. Up to 300,000 people in Ireland suffer with the disease. 110,000 people are currently diagnosed with it, however it is widely believed that an additional 200,000 people suffer but are currently undiagnosed.

Around 12,000 people are admitted to Irish hospitals annually with the condition, remaining as inpatients for on average 10 days. The group of people with the most severe form of the disease requires frequent readmissions.

Chronic bronchitis

Where there is lung damage and inflammation in the large airways, this results in chronic bronchitis. Chronic bronchitis is defined in clinical terms as a cough with sputum production on most days for 3 months of a year, for 2 consecutive years.

In the airways of the lung, the hallmark of chronic bronchitis is an increased number (hyperplasia) and increased size



(hypertrophy) of the goblet cells and mucous glands of the airway. As a result, there is more mucus than usual in the airways, contributing to narrowing of the airways and causing a cough with sputum.

Microscopically there is infiltration of the airway walls with inflammatory cells. Inflammation is then followed by scarring and remodeling that thickens the walls, and also results in narrowing of the airways. As chronic bronchitis progresses, there is squamous metaplasia (an abnormal change in the tissue lining the inside of the airway) and fibrosis (further thickening and scarring of the airway wall). The consequence of these changes is a limitation of airflow.

Patients with advanced COPD that have primarily chronic bronchitis rather than emphysema were commonly referred to as "Blue Bloaters" because of the bluish color of the skin and lips (cyanosis) seen in them. The hypoxia and fluid retention leads to them being called "Blue Bloaters".

Emphysema

Where there is lung damage and inflammation of the air sacs (alveoli), this results in emphysema. Emphysema is defined as enlargement of the air spaces distal to the terminal bronchioles, with destruction of their walls. The destruction of air space walls reduces the surface area available for the exchange of oxygen and carbon dioxide during breathing.

It also reduces the elasticity of the lung itself, which results in a loss of support for the airways that are embedded in the lung. These airways are more likely to collapse causing further limitation to airflow.

There are 4 types of emphysema:

Centriacinar/centrilobular: proximal to central parts of acini (air spaces closer to bronchioles) are affected

Panacinar/panlobular: enlargement of all air spaces (from bronchioles to terminal blind alveoli). This type is associated with alpha-1-antitrypsin deficiency

Distal acinar/paraseptal: proximal acinus normal, distal acinus affected

Irregular: various parts of acinus involved. Associated with fibrosis.

Symptoms and Signs

The essentials of diagnosis include:

1. History of cigarette smoking.

2. Chronic cough and sputum production (in chronic bronchitis)

3. Dyspnoea (Shortness of breath or SOB)

4. Rhonchi (decreased intensity of breath sounds, and prolonged expiration on physical examination)

5. Airflow limitation on pulmonary function testing that is not fully reversible and most

often progressive.

One of the most common symptoms of COPD is shortness of breath. People suffering with COPD typically first notice becoming short of breath during vigorous exercise, when the demands on the lungs are greatest.

Over the years, dyspnea tends to get gradually worse so that it can occur during milder, everyday activities such as housework. In the advanced stages of COPD, dyspnea can become so bad that it occurs during rest and is constantly present.

Other symptoms of COPD are a persistent cough, sputum or mucus production, wheezing, chest tightness, and tiredness.

People with advanced (very severe) COPD sometimes develop respiratory failure. When this happens, cyanosis, a bluish discoloration of the lips caused by a lack of oxygen in the blood, can occur. An excess of carbon dioxide in the blood can cause headaches, drowsiness or twitching (asterixis). A complication of advanced COPD is cor pulmonale, a strain on the heart due to the extra work required by the heart to pump blood through the affected lungs. Symptoms of cor pulmonale are peripheral edema, seen as swelling of the ankles, and dyspnea.

There are a few signs of COPD that a healthcare worker may detect although they can be seen in other diseases. Some people have COPD and have none of these signs. Common signs are:

- Tachypnea, a rapid breathing rate
- Wheezing sounds or crackles in the lungs which can be heard through a stethoscope
- The time breathing out taking a longer time than the time breathing in
- Enlargement of the chest, particularly the front-to-back distance (hyperaeration)
- Active use of muscles in the neck to help with breathing
- Breathing through pursed lips
- Increased anteroposterior to lateral ratio of the chest (i.e. barrel chest)

Causes of COPD

Smoking
The primary risk factor for COPD is chronic tobacco smoking. Approximately 80 to 90% of cases of COPD are due to smoking. Exposure to cigarette smoke is measured in pack-years, the average number of packages of cigarettes smoked daily multiplied by the number of years of smoking. The likelihood of developing COPD increases with age and cumulative smoke exposure, and almost all life-long smokers will develop COPD, provided that smoking-related, extra-pulmonary diseases (cardiovascular, diabetes, cancer) do not claim their lives beforehand.

Occupational exposures
Intense and prolonged exposure to workplace dusts found in coal mining, gold mining, and the cotton textile industry and chemicals such as cadmium, isocyanates, and fumes from welding have been implicated in the development of airflow obstruction, even in nonsmokers. Workers who smoke and are exposed to these particles and gases are even more likely to develop COPD. Intense silica dust exposure causes silicosis, a restrictive lung disease distinct from COPD; however, less intense silica dust exposures have been linked to a COPD-like condition. The effect of occupational pollutants on the lungs though appears to be substantially less important than the effect of cigarette smoking.

Air pollution
Studies in many countries have found people who live in large cities have a higher rate of COPD compared to people who live in rural areas. Urban air pollution may be a contributing factor for COPD, as it is thought to slow the normal growth of the lungs, although the long-term research needed to confirm the link has not been done. Studies of the industrial waste gas and COPD/asthma-aggravating compound, sulfur dioxide, and the inverse relation to the presence of the blue lichen Xanthoria (usually found abundantly in the countryside, but never in towns or cities) have been seen to suggest combustive industrial processes do not aid COPD sufferers. In many developing countries, indoor air pollution from cooking fire smoke (often using biomass fuels such as wood and animal dung) is a common cause of COPD, especially in women.

Genetics
Some factor in addition to heavy smoke exposure is required for a person to develop COPD. This factor is probably a genetic susceptibility. COPD is more common among relatives of COPD patients who smoke than unrelated smokers. The genetic differences that make some peoples' lungs susceptible to the effects of tobacco smoke are mostly unknown. Alpha 1-antitrypsin deficiency is a genetic condition that is responsible for about 2% of cases of COPD. In this condition, the body does not make enough of a protein, alpha 1-antitrypsin. Alpha 1-antitrypsin protects the lungs from damage caused by protease enzymes, such as elastase and trypsin that can be released as a result of an inflammatory response to tobacco smoke.

Autoimmune disease
There is mounting evidence that there may be an autoimmune component to COPD, triggered by lifelong smoking. Many individuals with COPD who have stopped smoking have active inflammation in the lungs. The disease may continue to get worse for many years after stopping smoking due to this ongoing inflammation. This sustained inflammation is thought to be mediated by auto-antibodies and auto-reactive T-cells.

Other risk factors
A tendency to sudden airway constriction in response to inhaled irritants, bronchial hyper-responsiveness, is a characteristic of asthma. Many people with COPD also have this tendency. In COPD, the presence of bronchial hyper-responsiveness predicts a worse course of the disease. It is not known if bronchial hyper-responsiveness is a cause or a consequence of COPD. Other risk factors such as repeated lung infection and possibly a diet high in cured meats (possibly due to the preservative sodium nitrite) may be related to the development of COPD.

Pathophysiology

It is not fully understood how tobacco smoke and other inhaled particles damage the lungs to cause COPD. The most important processes causing lung damage are:

- Oxidative stress produced by the high concentrations of free radicals in tobacco smoke
- Cytokine release due to inflammation as the body responds to irritant particles such as tobacco smoke in the airway
- Tobacco smoke and free radicals impair the activity of anti-protease enzymes such as alpha 1-antitrypsin, allowing protease enzymes to damage the lung

Narrowing of the airways reduces the rate at which air can flow to and from the air sacs (alveoli) and limits the effectiveness of the lungs. In COPD, the greatest reduction in airflow occurs when breathing out (during expiration) because the pressure in the chest tends to compress rather than expand the airways. In theory, airflow could be increased by breathing more forcefully, increasing the pressure in the chest during expiration. In COPD, there is often a limit to how much this can actually increase airflow, a situation known as expiratory flow limitation.

If the rate of airflow is too low, a person with COPD may not be able to completely finish breathing out (expiration) before he or she needs to take another breath. This is particularly common during exercise, when breathing has to be faster. A little of the air of the previous breath remains within the lungs when the next breath is started, resulting in an increase in the volume of air in the lungs, a process called dynamic hyperinflation.

Dynamic hyperinflation is closely linked to dyspnea in COPD. It is less comfortable to breathe with hyperinflation because it takes more effort to move the lungs and chest wall when they are already stretched by hyperinflation.

Another factor contributing to shortness of breath in COPD is the loss of the surface area available for the exchange of oxygen and carbon dioxide with emphysema. This reduces the rate of transfer of these gases between the body and the atmosphere and can lead to low oxygen and high carbon dioxide levels in the body. A person with emphysema may have to breathe faster or more deeply to compensate, which can be difficult to do if there is also flow limitation or

hyperinflation.

Some people with advanced COPD do manage to breathe fast to compensate, but usually have dyspnea as a result. Others, who may be less short of breath, tolerate low oxygen and high carbon dioxide levels in their bodies, but this can eventually lead to headaches, drowsiness and heart failure.

Advanced COPD can lead to complications beyond the lungs, such as weight loss (cachexia), pulmonary hypertension and right-sided heart failure (cor pulmonale). Osteoporosis, heart disease, muscle wasting and depression are all more common in people with COPD.

Diagnosis of COPD

The diagnosis of COPD should be considered in anyone who has dyspnea, chronic cough or sputum production, and/or a history of exposure to risk factors for the disease such as regular tobacco smoking. No single symptom or sign can adequately confirm or exclude the diagnosis of COPD, although COPD is uncommon under the age of 40 years.

The main diagnosis of COPD is confirmed by spirometry, a test that measures the forced expiratory volume in one second (FEV1), which is the greatest volume of air that can be breathed out in the first second of a large breath. Spirometry also measures the forced vital capacity (FVC), which is the greatest volume of air that can be breathed out in a whole large breath. Normally, at least 70% of the FVC comes out in the first second (i.e. the FEV1/FVC ratio is >70%). A ratio less than normal defines the patient as having COPD. More specifically, the diagnosis of COPD is made when the FEV1/FVC ratio (FEV1%) is <70%.

Spirometry can also help to determine the severity of COPD. The FEV1 (measured after bronchodilator medication) is expressed as a percentage of a predicted "normal" value based on a person's age, gender, height and weight. The severity of COPD ranges from mild (≥80) through to very severe (<30 or chronic respiratory failure symptoms).

Other methods to help diagnosis include chest x-rays, where the lungs can appear over-expanded. This can also be useful to help exclude other lung diseases and other conditions such as heart disease that may be causing the symptoms.

Blood samples taken from an artery, (Arterial Blood Gas) can be tested for blood gas levels which may show low oxygen (hypoxaemia) and/or high carbon dioxide (respiratory acidosis of pH is also decreased). A blood sample taken from a vein may show a high blood count (reactive polycythemia), a reaction to long-term hypoxemia.

Treatment

Following diagnosis, it is important to reduce the patient's exposure to the risk factor(s) that have caused the COPD. Usually this entails the patient stopping smoking. It is important that the patient is aware that continuing to smoke will only result in their condition worsening and will most probably lead to premature death. The pharmacist is a key part of helping the patient to stop smoking by adding encouragement and building a trusting and supportive relationship.

It is likely though that the patient, having been diagnosed with COPD will require medication as well:

Bronchodilators

Bronchodilators relax smooth muscle around the airways, increasing the calibre of the airways and improving airflow. They can reduce the symptoms of shortness of breath, wheeze and exercise limitation, resulting in an improved quality of life for people with COPD. They do not slow down the rate of progression of the underlying disease. Bronchodilators are usually administered with an inhaler or via a nebuliser.

There are two major types of bronchodilator, β2 agonists and anticholinergics.

Each type may be either long acting (with an effect lasting 12 hours or more) or short acting (with a rapid onset of effect that does not last as long).

β2 agonists stimulate β2 receptors on airway smooth muscles, causing them to relax. There are several β2 agonists available. Salbutamol and terbutaline are the most widely used short acting β2 agonists and provide rapid relief of COPD symptoms. Long acting β2 agonists (LABAs) such as salmeterol are used as maintenance therapy and lead to improved airflow, exercise capacity, and quality of life.

Anticholinergic drugs cause airway smooth muscles to relax by blocking stimulation from cholinergic nerves. Ipratropium provides short-acting rapid relief of COPD symptoms. Tiotropium is a long-acting anticholinergic used as maintenance therapy whose regular use is associated with improvements in airflow, exercise capacity, and quality of life.

Corticosteroids

Corticosteroids are used in tablet or inhaled form to treat and prevent acute exacerbations of COPD. Well-inhaled corticosteroids (ICS) have not been shown to be of benefit for people with mild COPD, however, they have been shown to decrease acute exacerbations in those with either moderate or severe COPD. They however have no effect on overall one-year mortality and are associated with increased rates of pneumonia.

Other medication

Theophylline is a bronchodilator and phosphodiesterase inhibitor that in high doses can reduce symptoms for some people who have COPD. More often, side effects such as nausea and stimulation of the heart limit its use. In lower doses, it may slightly reduce the number of COPD exacerbations.

Oxygen Therapy

When a patient reaches a point where their medication is not giving them enough oxygen, oxygen therapy becomes a necessity. Generally this is reserved for the more severe forms of COPD. Using oxygen for more than 15 hours a day can help patients do tasks or activities with less shortness of breath, protect the heart and other organs from damage, sleep more during the night and improve alertness during the day and also live longer.

Surgery

Surgery is sometimes helpful for COPD in selected cases. A bullectomy is the surgical removal of a bulla, a large air-filled space that can squash the surrounding, more normal lung. Lung volume reduction surgery is similar; parts of the lung that are particularly damaged by emphysema are removed allowing the remaining, relatively good lung to expand and work better. Finally lung transplantation is sometimes performed for severe COPD, particularly in younger patients.

Dermott Jewell

Greater transparency needed in medicine pricing

Dermott Jewell, Chief Executive, Consumer's Association of Ireland

It has long been acknowledged by consumers that healthcare and all costs associated with it are increasing with staggering increments and frequency, which seriously affect their affordability of drugs and medical services.

A not unsurprising or unnatural consequence is that the consumers' focus, therefore becomes very determinedly and forensically concerned with the elements making up the cost that they are being charged.

This is because cost is now measured, more than ever, in terms of affordability but, more importantly, also in comparison to other prices in other jurisdictions. Add to this, frequent nationwide media price comparative articles, which show examples of how an Irish consumer pays significantly more for many products essential to their wellbeing than their European counterpart in most Member States and, unsurprisingly, the focus turns to profits and margins. This presents the not unreasonable demand for price transparency, tinged with a slow burning, but growing mistrust of pharmacy profit margins, which has the potential to dilute the positive and personal relationship that exists between patient/customer and provider.

When the Irish Independent released the results of their survey on October 17, last comparing prices and indicating how, 'Pharmacists impose mark-ups of between 73pc and 354pc on the wholesale price of prescription drugs for private customers' this was not denied. Rather, the Irish Pharmacy Union (IPU) advised that, 'Prices are high because manufacturers set higher factory prices for drugs than in other countries'. Yet, when pointed out, the research showed how, for example and just one of many, Lipitor, with a wholesale price in Ireland of €36.06, cost customers €65.77, a mark-up of 82%, the response from the IPU was that 'It is an accepted feature of the Irish healthcare system that private patients pay more to cross-subsidise lower state prices'.

I would respectfully suggest that, if you asked for a show of hands from private patient consumers in any room in support of or acknowledgement of this there would be, at best, a very low number of accepting hands raised. The more likely response would be clenched fists being raised in anger. Who is it that accepts this 'feature'? I can advise that it is not the paying private consumer of pharmaceutical products.

It was also interesting to note how the HSE disagreed with any suggestion of cross-subsidisation and advised all consumers to seek refunds of any sums charged for prescription drugs in excess of the prices listed on the HSE website. Clearly, the HSE were equally frustrated at the lack of clarification and transparency from the IPU that pharmacists are paid a 20% retail mark-up, plus a €5 dispensing fee under the Drug Payment Scheme (DPS).

A major concern here for the Consumers' Association of Ireland (CAI) and its members is that, as a result of these frustrations and their inability to take personal action, consumers are increasingly taking personal control and moving to the World Wide Web to source their medications. The difficulty here is that a great number of products available online are fake, counterfeit and dangerous and international fraudsters are easily targeting pro-active but gullible consumers. Alternatively, of course, it needs to be borne in mind that not all providers are rogues and many are delivering quality medicines at hugely reduced and affordable prices.

This is the goal of the EU single-market and is not to be mistaken or confused with self-diagnosis, which is an entirely different matter.

The point is always made by the CAI that consumers have choice. Here, we are presented with a dilemma. Who is responsible for moving the consumer in the direction of searching for their branded medicine or a cheaper substitute online? Is it the Government, who have dragged their heels in introducing ease of access to generic alternatives of medicines, regardless of the prescribed 'brand-name'? Is it the Government who are failing in determining realistic pricing policies for drugs? Is it the European Commission, which is placing extraordinary demands upon wholesale margins? Is it pharmacists, who are demanding excessive margins and support from customers who, despite their calls for value for money, are seen simply as subsidisers who will pay more?

Regardless of how many are to blame, the fact that many consumers have turned away from the traditional outlets is a signal that all is not well and that it is time for change. Pharmacy closures are in no one's interest but it must be noted that these are not simply due to reduced business in drug sales. The market has changed and discount stores and supermarket chains have stepped in and stepped up the price war on all toiletries, perfumes and associated products.

What is also different is that consumers have now a choice to compare prices and either support their local pharmacy or buy online. As we engage with the provisions of budget 2011 and prepare for, undoubtedly more harsh ones in Budget 2012, one thing is clear – cross-subsidisation cannot continue.

Mark Beddis

CPD, an opportunity to grow

I am full of enthusiasm for pharmacy in 2012. Compulsory Continual Professional Development will open up a multitude of new avenues for our profession and exemplify to the public and policy makers that we have a profession that is willing to change and adapt to the new health system that we work under.

For pharmacists, continual learning has been the norm ever since leaving university and embarking on our varied careers. Whether this involves researching a particular condition or disease for one of our patients or keeping abreast of various pharmacy issues through the reading of various journals, none of us have been able to avoid CPD, it is a part of our everyday professional life.

I would imagine there is a large amount of scepticism and fear across the industry. Nobody really likes change and certainly not change that is compulsory and part of our continued registration. However, we should not be worried in any way; this will formalise the work we all already carry out.

The Pharmaceutical Society of Ireland will ensure that the portfolio of evidence for CPD will be used to enhance our role. The addition of new services such as Emergency Hormonal Contraception, have shown clearly that pharmacists can work within strict protocols and deliver extra services of the highest professional standards.

Love them or hate them, the codeine guidelines introduced by the PSI have been another wholly positive example of our profession, delivering proper and safe sales protocols and giving an increased level of trust to our customers, as well as providing proof that as pharmacists we can deliver when given the opportunity.

I imagine that a number of medicines will undergo 'POM to P' switches in 2012. The most obvious candidates for me, especially having trained and qualified in the UK, would be Fluconazole 150mg capsules, Sumatriptan 25mg tablets for migraine (this would attach itself nicely to the codeine guidelines and give pharmacists a real alternative to offer their patients) and Aspirin 75mg tablets.

Mark Beddis, Superintendent Pharmacist, Tesco Pharmacy

We all know the medicines that should be OTC, we now need to give the IMB the confidence to deliver a safe and robust protocol-led supply without the need for a prescription. The evidence we have put together already stands us in great stead. I expect more of our CPD to be utilised to help change the way in which we work.

We are on the cusp of some very exciting and highly fulfilling times for our industry. We have the Pharmacy Act providing the legal backbone in everything we do. We are also lucky to have a progressive regulator in the PSI that is trusted by the Department of Health and is able to work with the IMB to ensure that our profession is always on minds whenever changes are afoot. We also have the IPU, working tirelessly to ensure that we do not stand still and rest on our laurels, by giving us opportunities to enhance and grow.

So I ask all pharmacists to grasp the opportunity that compulsory CPD provides and prepare for the new challenges that undoubtedly await us. The public has only seen the tip of the proverbial iceberg as to what we can do.

Let us demonstrate how great we are - and make 2012 a year to remember.

David Fitsimons

Hard times lie ahead

David Fitsimons, Chief Executive Officer Retail Excellence Ireland

The latter part of 2011 experienced acceleration in the deterioration of domestic retail activity, following a period of modified declines earlier in the year. While the market has witnessed a number of positive developments in recent months, including improvements in exports and inward tourism, increased volatility and concern in the wider Euro Zone has smothered Irish consumer sentiment and delivered a very fragile domestic situation.

In simple terms, the Irish consumer is frozen with fear, resulting in increasing bank deposits and reduced spending. While the wider Euro Zone situation has contributed significantly to current Irish economic weakness, domestic interventions have also played their part, no more so than Budget 2012, the timing and content of which has been very damaging to current consumer spending.

A grave concern is that the wider issues afflicting all of the retail industry still prevail and, indeed get worse. Issues including penal commercial rents, significant local authority rates levels, a 2% VAT increase, the transfer of four weeks mandatory sick pay to the private sector and the further extension of the planning cap in urban areas, which will directly undermine the high street have all contributed to a bleak situation.

As we look towards 2012, continued Euro Zone financial instability, mixed with an austere domestic budget and weakened domestic market demand will contribute to the continuation of aggressive market declines and certain retail operator failure.

Concentrating on the pharmacy market specifically highlights the dire situation faced by operators within this sector. Trading sales volumes and values remain in a downward spiral, with each primary category, including dispensary, OTC and retail coming under significant pressure. The non-discretionary nature of some proportion of pharmacy spending has offered the sector some respite, albeit the sector continues to suffer significant like-for-like declines, as a result of reduced domestic market spending, regulatory intervention and Government reimbursement contract modification.

The pharmacy sector has borne its fair share of challenges in recent months and years. The implementation of reduced levels of Government reimbursement added to other regulatory intervention, including the Irish Medicines Board restriction on cough bottle availability and codeine restrictions, which have contributed to a very challenging situation. Other interventions, including the 50 cent prescription charge have gradually eroded demand. The legal obligation to increase capex investment through the mandatory provision of patient consultation rooms has further weakened many operators liquidity. Furthermore, Budget 2012 interventions, pertaining to prescription charges will only make matters worse.

Of greatest concern is the fact that a market, which has contracted significantly over the last four years simply cannot continue to bear an increasing number of pharmacy stores. The recent entrance of Tesco into the Irish pharmacy market will add to the strain and, all told, significant market failure is no longer possible, it is probable.

When compared to other retail sectors, pharmacy operates a current labour cost model, which is out of kilter with market demand and standard retail ratios. A current labour investment rate of circa 15.5% of business sales is simply untenable. Pharmacy operators agree and, in a recent REI Pharmacy Salary analysis the predicted new hire rates across all grades are expected to fall by 15.27% in 2012.

With further Department of Health/HSE budget erosion anticipated, it is likely that pharmacy reimbursement levels will be negatively impacted by on-going and future commercial challenges, margin erosion and other fiscal interventions.

It looks like 2012 will be the most challenging year for pharmacy to date.

Nexazole

20 mg & 40 mg gastro-resistant capsules, hard

Esomeprazole

Nexazole: for the treatment of erosive reflux oesophagitis

Prescribing Information for Nexazole 20 mg & 40 mg gastro – resistant capsules, hard. Qualitative and Quantitative Composition: Each capsule contains 20 mg or 40 mg of esomeprazole (as esomeprazole magnesium dihydrate). **Pharmaceutical Form**: Hard, gastro-resistant capsule: Slightly pink body and cap, containing white to almost white pellets. **Therapeutic Indications:** Treatment of erosive reflux oesophagitis. Prevention of relapse of healed oesophagitis in long-term management of patients. Symptomatic treatment of gastroesophageal reflux disease (GERD). Eradication of *H. pylori* concurrently given with appropriate antibiotic therapy for treatment of *H.pylori*-associated ulcers. Treatment of NSAID-associated gastric and duodenal ulcers in patients requiring continued NSAID-treatment. Prophylaxis of NSAID-associated gastric ulcers and duodenal ulcers in patients at risk requiring continued therapy. Prolonged treatment after i.v. induced prevention of rebleeding of peptic ulcers. Treatment of Zollinger Ellison Syndrome. **Dosage and Method of Administration:** Capsules should be swallowed whole with liquid. The capsules can be opened and the pellets mixed in half a glass of non-carbonated water or if desired this solution administered through a gastric – tube in patients with swallowing difficulties. The capsules and / or contents should not be chewed or crushed. Treatment of erosive reflux oesophagitis: 40 mg once daily for 4 weeks. Long-term management of patients with healed oesophagitis to prevent relapse: 20 mg once daily. Symptomatic treatment of gastroesophageal reflux disease: 20 mg once daily. Eradication of *H. pylori* for treatment of *H.pylori*-associated ulcers: 20 mg with 1 g amoxicillin + 500 mg clarithromycin, all twice daily for 7 days. NSAID associated gastric & duodenal ulcers: 20 mg once daily for 4 – 8 weeks. Prophylaxis treatment: 20 mg once daily. Prolonged treatment after i.v induced prevention of rebleeding of peptic ulcers: 40 mg once daily for 4 weeks. Zollinger Ellison Syndrome: Initial dose is 40 mg once daily. Dosage should be individually adjusted. Daily doses up to 160 mg have been used. If the required daily dose exceeds 80 mg, it should be divided and given twice daily. Severe liver impairment: Patients should not exceed a max. dose of 20 mg. **Contraindications:** Hypersensitivity to esomeprazole or to any of the excipients. Esomeprazole should not be administered with atazanavir. Pregnancy and breast-feeding due to insufficient data. Children under 12 years. **Special warnings and precautions for use:** The possibility of a malignant gastric tumour should be excluded as Nexazole may alleviate symptoms and delay diagnosis. Regularly monitor patients on long-term treatment. Patients on on-demand treatment should contact their physician if symptoms change in character. If esomeprazole is used in combination with antibiotics, then the instructions for the use of these antibiotics should also be followed. Treatment with esomeprazole may lead to slightly increased risk of gastrointestinal infections such as *Salmonella* and *Campylobacter*. Contains sucrose – Patients with rare hereditary problems of fructose intolerance, glucose – galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. **Drug Interactions:** Esomeprazole can affect the absorption of ketoconazole and itracanazole. Dose reduction may be required when administered with drugs metabolised by CYP2C19 as esomeprazole may increase their plasma concentration. Monitor patients when given in combination with warfarin or other coumarine derivatives. **Undesirable effects:** Common: Headache, abdominal pain, constipation, diarrhoea, flatulence, nausea/vomiting. **Shelf Life:** 2 years. **Marketing Authorisation Holder:** Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary. **Marketing Authorisation Holder Number(s):** PA 281/146/1-2. This medicine is a prescription only product. Further prescribing information is available on request. **Date of revision of text:** July 2010.

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New Developments in Pharmacy

Cormac Tobin

The highlight of 2011, as far as DocMorris/Unicare is concerned has been the successful transformation of Unicare Pharmacy to DocMorris. Already we have exceeded our targets for 2011, having rebranded 25 pharmacies this year.

Despite the difficult consumer market, I am very pleased with all that has been achieved. Earlier in the year, we launched our loyalty programme with great success, offering our patients and customers excellent discounts. To date, we have signed up 40,000 patients and customers to the scheme.

People still want to buy new and innovative products. DocMorris/Unicare successfully tapped into this by developing 'MyMed', a weekly dosage system, designed in conjunction with Age Action Ireland, Comfort Keepers and The Carers Association.

Another product that DocMorris/Unicare Pharmacy launched this year was the 'Mother's Touch' thermometer, which can be worn on the finger like a ring. This has, literally been flying out of our pharmacies.

We have been successful in making our category management much clearer and have also become much more innovative in our marketing techniques. Before, we were not much good at solution selling for feet, lips and ear-problems and so on but we took this head on and have become much better.

More recently, DocMorris/Unicare won the titles: 'Company of the Year' and 'Employer of the Year' at the Retail Excellence Ireland Awards. We are all extremely proud of our success and winning those awards has served to motivate the entire DocMorris/Unicare team.

Another exciting development for us at DocMorris/Unicare has been the launch of the DocMorris franchise. Already, we have received a lot of interest from independent pharmacists for 2012. The commercial environment has become much more strained for community pharmacists. It has become much more difficult for independent pharmacists to offer competitive prices because, more often than not, they do not have the buying force of a group behind them. The DocMorris franchise may be the solution to their problems as it will provide solutions for marketing, margin enhancements, innovation and professionalism.

The pharmacy sector has witnessed some interesting and welcome developments over the past year. For instance, the Emergency Hormonal Contraceptive pill being reclassified from POM to P was one positive development for the sector, but I think that many more medicines should be reclassified to the same level.

The introduction of the flu vaccination programme to pharmacy was another welcome development. We have been inundated by hundreds of patients walking in to get their winter flu vaccination. These have been hugely significant developments that have greatly benefitted patients and pharmacists alike.

There is so much talent and information available within pharmacy that the HSE should make more use of the profession by introducing more such changes in the future.

Medicine pricing has become very topical within the industry, particularly with the arrival of Tesco pharmacy on the scene. I think that Tesco Pharmacies have injected some healthy competition into the market. One thing that its arrival has done is to create a public discussion on the cost of medicines in Ireland. Patients here do not understand the price of medicines and I think that they are deserving of greater transparency in this respect. I am not saying that every medicine should have its price advertised but I see no reason why patients should not be made aware of the price of certain categorised medicines.

Good care also means value for money and DocMorris/Unicare will continue to offer both to our patients as we move into 2012.

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Akram Hanna

Special by name and special by nature

Akram Hanna - Managing Director QM Specials

There is no doubt that the whole Pharmacy sector in Ireland has been facing regular, disproportionate and unprecedented challenges. In QM Specials, we have been fully aware of the situation but, nevertheless, we have invested substantially in the company, in order to offer unique facilities and drive Irish Specials' Manufacturing into the international arena.

Over the past year, we have expanded our Manufacturing Licences to include the manufacturing of Cold Chain and Controlled Drug Products. This was a complex and expensive process but, nonetheless we are very pleased that we are now able to offer such outstanding, additional services in the Irish Pharmacy Market.

Our founding concept was to provide an exceptional service to pharmacies, both in the community and in hospitals. This enables professional pharmacists to grant their patients access to products, which were previously unavailable to them, thus enhancing patient care.

This concept has paid off. Our commitment and reputation have developed above and beyond what is needed in Ireland, to the extent that we have now been approached to supply other countries.

The cost of operating our high standard operation is not cheap; nevertheless, we are extremely conscious of the economic challenges that are facing us all. In QM Specials, we keep our prices as low as possible, by constant review and by auditing operating costs and, yet we always focus on the best interests of the patients, which, of course is our primary concern.

Specials' manufacturing is a complicated area which, by its very nature, requires substantial investment in personnel, training and research, in addition to the expansion and diversification of the technical areas, which are necessary to keep our processes up to date.

Establishing a valid method of manufacturing requires a chain of relevant and comprehensive procedures. These are required not only to ensure compliance with our licences but also to take account of the nature of the products and the purposes for which they are used.

Being a pharmacist myself, I do understand the urgency in supplying pharmacies and hospitals with specific orders in a very timely manner. We have experienced a number of situations where we have delivered medicines out of hours to various locations in some extreme cases, driving them there at all hours of the night.

I believe we have achieved most of our goals in the past year, considering the national and global financial situations. We have advanced our facility, not only to be able to continue providing our high standard of service but also to endeavour to further improve them, in a cost effective way to all parties involved. In addition, we have established valuable global contacts.

We believe that manufacturing specials products in our facility in Ireland will be beneficial to the country and to the economy. And, moreover, it will reduce the dependence on imported products, which frequently have to be purchased in foreign currency.

The appreciation of our tireless efforts is reflected in the constant requests we receive on a daily basis to open new accounts, which is something we are proud of and find most rewarding.

We can truly say that we have an Irish manufacturing facility that is unique in its concept in manufacturing Specials and supplying Unlicensed Medicines, combined with a unique service that is making QM Specials, very special indeed.

When we said on Day One, “QM Specials … Special Manufacturing … Special Service… Well, we meant it!

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The new TriXéra+ line is formulated to repair the skin barrier through its balanced and specific lipid complex and decrease feelings of discomfort. The addition of Sélectiose, a patented innovation, reinforces the effectiveness of TriXéra+ by decreasing the reactivity of irritated skin.

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Jane de Barra

Law and Ethics in Community Pharmacy

Ethical challenges within a legal framework form part of the daily professional life of a pharmacist. It is exactly this that the Pharmacy Law and Ethics Association (PLEA) endeavours to capture during meetings, in writing responses to public consultations and sharing experiences with other members. During its second year of existence, PLEA Ireland's membership expanded to include members of the medical profession and philosophers who have an interest in the area of law & ethics, in addition to pharmacists with an interest in law, ethics or both.

The association met formally twice this year, and lively debate was central to both meetings. Following on from the introduction of emergency contraception as a medicine for sale through pharmacy, a discussion was held at one meeting on the topic of conscientious objection and the healthcare professional, and whether this right is actually enshrined in each profession's code of conduct, and if so, whether that then impinges on the right of the patient to treatment. It is interesting to note that in September 2011, the General Pharmaceutical Council in the UK committed to reviewing the policies of other health regulators in relation to this matter, acknowledging at that meeting that "judgment on this subject involves balancing a number of competing legitimate, but ultimately incompatible, imperatives, including ethics values and individuals' human and legal rights".

When PLEA met again in June, the topic centred on the ever-present conflict between the professional and commercial aspects of running a pharmacy business, in light of regulatory changes and economic challenges.

PLEA welcomed the Irish Medicines Board's public consultation on the legal classification of medicinal products during the summer, and made a considered group submission to this important topic, both looking at medicines that the group considered could more highly regulated, in addition to those that could be made more widely available. This submission was contributed to from members who represent many areas of the profession of pharmacy.

Regulatory developments affecting the pharmacy profession during 2011 have brought Emergency Contraception and Flu Vaccination into the realm of the pharmacist, both of which represent welcome advances in the role of the pharmacist in primary care, and the accessibility and affordability of clinical services. The Regulations enabling pharmacists to supply and administer flu vaccines have been left open to the possible further addition of other vaccines into the Schedule. This would signal an open mindedness in the eyes of the Department of Health to the roll out of further vaccination services through pharmacy.

Inherent in offering such clinical services is the obtaining of "informed consent" by the pharmacist from the patient for invasive treatments. The importance of this cannot be over-emphasised, and pharmacists require appropriate guidance on guiding the patient through a consultation effectively. Informed consent, or the lack thereof, forms a significant part of litigation against medical practitioners, and pharmacists must be mindful of this as we keep pace with regulatory changes enabling development of the profession.

2011 saw the first "fitness to practice" and "fitness to operate" hearings run by the Pharmacy Regulator under Section 6 of the Pharmacy Act 2007, against pharmacists and pharmacies respectively. These hearings present challenges for all involved, but are a reminder of the importance of working within the remit of the 2007 Act and its associated regulations, and in particular within the pharmacist's Code of Conduct, in the best interests of the patient.

Jane de Barra, Secretary at PLEA Ireland

PLEA plans to kickstart 2012 with an essay competition open to all pharmacy students in Ireland, details of which will be circulated to all universities shortly. There will be a prize for the best two entrants, which will be judged by members of the association. The first PLEA meeting of 2012 will focus on pharmacy practice research ethics, and will be held in late January 2012 in the School of Pharmacy in Trinity.

For more information about PLEA (Ireland), please contact Cicely Roche (Chairman) at cicelyroche@eircom.net or Jane de Barra (Secretary) at janedebarra@gmail.com

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PREMIER HEALTH

Joanne Kissane

Grasping Opportunity during Challenging Times

Joanne Kissane, Superintendent Pharmacist, DocMorris/Unicarepharmacy

The year 2011 has been both rewarding and challenging for Community Pharmacy in Ireland. It has been a year where significant expansion of the role of the pharmacist has occurred. However reduced reimbursement and a raft of cuts by the HSE have resulted in continued difficult times for the industry.

The legislation change, allowing the pharmacist to supply emergency hormonal contraception without a prescription in February, along with the recent launch of pharmacist administration of the seasonal influenza vaccine service in October, represent innovative and significant developments in the profession. There can be no doubt that allowing patients access to these services in the local community pharmacy is more cost effective and promotes best use of resources at a time when we all have a role to play in returning the country to prosperity and growth.

The year 2011 has also seen the transformation of 27 Unicarepharmacy branches to the DocMorris brand. Significantly, this rebranding is consistent with the message of reform that the current government is bringing to the health service. DocMorris stands for:

- Value for money
- Innovation
- Proximity to the customer.

Minister Reilly's vision is that quality care will be provided for all at an affordable cost. He is an advocate for the provision of services at a local level through primary care. DocMorris is in a unique position to provide accessible and affordable healthcare while adopting a customer-centric approach.

In 2012, we should see the continuation of the broadening scope of pharmacists in Ireland. To date, pharmacists have successfully demonstrated that they have the expertise and competence to embrace new roles and to enable the delivery of healthcare to be more effective and efficient, along with being more accessible for patients. Hopefully, 2012 will also see generic substitution becoming a reality. At a time when healthcare costs are rising, the rationale for use of generic medicines is compelling. Both the State and patients would reap immediate and significant savings.

Further savings could be made through the expansion of the role of the pharmacist in providing regular Medicine Use Reviews (MURs) for all patients. Drugs wastage is running at unacceptably high levels, with an estimated 20% of all medicines prescribed not taken at all and 45% of all medicines not taken correctly. A national policy for medicines management and medicine use review urgently needs to be developed in Ireland and the benefits to the patient, health service, GP and pharmacist would be hugely valuable. An increase in the numbers of medicines reclassified from POM to P would be a welcome advancement by the government and IMB in 2012. The current uncoordinated approach, which is done by and when the pharmaceutical industry decides, is frustrating for many community pharmacists, especially when so many POMs are available as OTC products in Northern Ireland. Wider access to medicines that have a long established safety profile allows greater patient choice. Patients subsequently take greater control of their own healthcare and reduce the burden of cost on the State. Community pharmacists have the skills and competence to safely provide these medicines.

I believe that the profession is at a turning point and the future role of the pharmacist within the Health Service lies within our own hands. We need to move away from an over reliance on the current reimbursement model to a model that incorporates the professional input of the pharmacist in the provision of services and reimburses them accordingly. The profession needs to embrace new technologies such as apps, mobile and internet technology to provide innovative solutions to customers' needs.

Undoubtedly the year ahead will be challenging in many ways but, as healthcare professionals, DocMorris and Unicarepharmacy colleagues will have an important role in supporting public health and safety in difficult times. The current challenging times will continue to present opportunities to the pharmacy profession to contribute to the reforms of the health service in the best interests of the patient.

Paul K Gorecki & Anne Nolan

Challenges and Opportunities for the Irish Pharmacy Sector 2012

Paul K Gorecki, Economic and Social Research Institute, Dublin

Anne Nolan, Economic and Social Research Institute, Dublin

Introduction

Increased competition, greater patient information and opportunities for pharmacists to provide a greater range of professional services are likely to characterise pharmacy in 2012 and beyond. These developments are driven by a desire for greater value for money as a result of the current economic and budgetary crisis and a new openness to competition that has characterised other professions, such as dentistry.

Increasing Competition

Retail pharmacy will experience greater competition due to the entry of Tesco in November 2011, with its commitment to follow the Health Service Executive model of pricing for the cash-paying customer - a 20 per cent mark-up and a dispensing fee of €3.50. This will put pressure on those pharmacies that continue to charge the traditional 50 per cent mark-up for the cash-paying patient. If other supermarkets or retail outlets follow the lead of Tesco, then competitive pressures will increase still further.

Informing Consumers

Traditionally, professions provided little information to the patient concerning prices and services. This is beginning to change. The Dental Council of Ireland, for example, has mandated that dental surgeries display information concerning their services, together with the corresponding price for a standard set of common procedures. Patients can shop around and compare. In the case of pharmacy, the mark-up and dispensing fee, together with the associated pharmacy services, could be posted by pharmacies, both in-store and at the discretion of the pharmacy, in the print media or on the internet. Such a system of in-store disclosure has long been in place in Ontario, the largest Canadian province.

Expanding the Role of the Pharmacist

Regulatory change offers considerable opportunities for pharmacists to diversify and expand their roles. The recent extensions in the role of pharmacy to include the administration of the seasonal influenza vaccine and the dispensing of emergency hormonal contraception illustrate the types of areas in which there is further scope for enhanced involvement by the pharmacy profession in the provision of health-care services, subject, of course, to appropriate training.

Under the government's reference pricing and generic substitution proposals (the legislation for which is currently being drafted), the pharmacist will play a central role in selecting the interchangeable pharmaceutical product that is dispensed to the patient. As such, pharmacists will play a leading part in educating patients concerning the safety and efficacy of generic products, in collaboration with physicians, the Health Service Executive and regulatory bodies, such as the Irish Medicines Board and Pharmaceutical Society of Ireland.

The Future: Half-Full or Half-Empty?

2012 will see a continuation of the current recession. This, allied with the large fiscal consolidation that is ongoing, will impact on all levels of economic activity and create a difficult trading environment for all businesses in Ireland. Press reports refer to the financial difficulties of some pharmacy chains. The use of the FEMPI powers is seen as leading to a decline in profitability and a reduction in the number of pharmacies. However, the number of pharmacies continues to increase year on year, even in 2011. While the rate of increase has slowed, it is still positive.

On the other hand, increased retail competition in pharmacy, the provision of information concerning the range of pharmacy services available to patients and the greater use of the expertise of pharmacists offer the prospect of a better informed patient and the delivery of more value added services by the pharmacist. A win-win situation for both patients and pharmacists.

Keith Harford

Beware the wolf in sheep's clothing!

Based on the UK experience, what can we expect from Tesco in the near future?

Keith Harford, Commercial Director, Pharbiz

Tesco Ireland has just opened its first two pharmacies at Naas, Co. Kildare and at Balbriggan, Co. Dublin. We shouldn't be in any way surprised, other than to ask "what took them so long?" This is a well-trodden path by Tesco in the UK, where the giant retailer has opened 354 pharmacies and has plans for many more.

The Tesco business model is very hungry for sales. Their share price and market capitalisation (overall market value of the company) is driven by the constant need to grow sales and market share in as many categories as possible. Anyone who thinks of Tesco as a grocery store is severely out of date. Today, Tesco is closer to a department store selling clothing, electrical, toys, books and stationery, DVDs and other home entertainment and, indeed anything else that can sit on a shelf. And, it doesn't stop there. Tesco also provide banking services, insurances, petrol, mobile phones and **now**, pharmacy. It will be interesting to see how soon it attempts to deliver pharmacy through its internet service.

So, what can we expect in the future?

Tesco are known in the retail trade as 'category killers'. They conduct advance research on any category they plan to attack, apply their massive buying power and launch. Considerable advance planning is involved and it is unknown for them to withdraw from a category once they start.

For example:

- Tesco have 194 Phone Shops in the UK (2011 Annual Report)
- They sold almost €1.2 Billion of clothing in the UK alone last year
- Tesco's 'Finest' brand outsold Coca Cola in the UK last year
- Tesco's 'Clubcard' has over 15 million **active** members

Tesco have announced plans to open eight more pharmacies over the next two years but this is likely to be very conservative.

Based on the UK experience, we can expect a lot more pharmacies to be opened a lot more quickly. Tesco's larger stores are

Keith Harford

Let's be clear, Tesco are here to stay and you need to be prepared for the threat

built to be flexible, with areas earmarked for new developments, seasonal promotions and other uses. It is relatively easy to construct an in-store pharmacy and get it going once the concept has been tested and the wrinkles ironed out, which is now underway.

Tesco are also superb at PR and often make sweeping statements that put competitors on the defensive. The media reported verbatim from the advance media releases issued by Tesco as follows: *The new Tesco pharmacies are expected to significantly undercut other pharmacies by charging a lower-than-average mark-up of 20 per cent on prescription drugs – as recommended by the HSE but ignored by many pharmacists. They will also charge a dispensing fee of €3.50 per item which is €1.50 less than the fee suggested by the HSE*.

Therefore, Tesco has already started to convince the public that they can deliver huge savings. The journalists took the bait as usual. It's all free publicity. And the National Consumer Agency said it "…will lead to lower prices for the consumer".

Darragh O'Loughlin, President of the Irish Pharmacy Union, was quoted as saying he is "frightened to speculate" about how many independent pharmacists might lose their jobs following Tesco's decision to enter the market. While this may well be true, this type of statement reaffirms, in the customers' mind that Tesco will offer better value.

If we look back at the PWC report from February 2007, the net profit coming from Community Pharmacy was stated as 6%. We are all well aware of the massive negative changes to that figure since that time. However, Tesco's 2011 Annual Report shows trading margin at 6.1%, and that includes the very low margin Petrol business.

But, let's be clear, Tesco and its pharmacies are here to stay and you need to be prepared for that threat. There will be a significant roll-out of new Tesco pharmacies in the coming months and years. It is just a question of how many and how quickly?

Roisin Shortall

Minister of State with responsibility for Primary Care, Roisin Shortall

The Pharmacist's role in the delivery of Primary Care

As pharmacists are aware, the development of Primary Care is central to our Programme for Government in the area of health. My appointment as Minister of State with responsibility for Primary Care is evidence of the Government's commitment to improving the delivery of fairer and more affordable health services in our society. I am committed to ensuring that, in primary

Roisin Shortall

care health services, we deliver better, more effective care for every patient in a cost-effective way.

The Programme for Government commits to the introduction of Universal Primary Care for our entire society. Universal Primary Care will involve the removal of fees for GP care. Our Programme also recognises the contribution that primary care health professionals can make in improving the management of chronic diseases, particularly in primary care. Primary care can facilitate patients receiving services at local level close to their homes and can reduce the significant pressure and demands on our hospital system.

We have made considerable progress in 2011 in the development of primary care services towards our Programme for Government commitments. The Health (Provision of General Practitioner Services) Bill 2011, which is currently at committee stage in the Dail, has been a key step towards our goal of Universal Primary Care. When enacted, this legislation will eliminate the restrictions on GPs wishing to obtain contracts to treat public patients under the GMS Scheme and will open up access to GP services.

During 2011, the HSE also made significant progress in its work, developing integrated chronic disease programmes to improve patient access and manage patient care in an integrated manner across primary and secondary care settings. Guidelines are being developed for the following priority programmes relevant to primary care: Stroke; Heart Failure; Asthma; Diabetes and COPD. The Diabetes' programme is due to start in 2012. The purpose of these programmes is to ensure best health outcomes, enhanced clinical decision-making and the most effective use of resources. Pharmacists have been actively involved in these initiatives through the work of the National Pharmacy Reference Group, liaison pharmacists and a number of stakeholder meetings held during 2011.

Two significant primary care developments in community pharmacy in 2011 have been the roll-out of the seasonal influenza vaccination programme and the community pharmacy needle-exchange programme. The Pharmacy Needle-Exchange Programme, which is a collaborative initiative between the Elton John Aids Foundation, the HSE and the Irish Pharmacy Union, has been implemented in 65 community pharmacies. It provides a valuable harm-reduction service to drug users outside of Dublin.

In addition, Regulation was put in place in Oct 2011 to allow pharmacists to administer seasonal influenza vaccination to patients, as part of the national vaccination programme. This is a major development, both in pharmacy practice and primary care, as Ireland is one of only a small number of countries, which have developed such a service.

Other important primary care initiatives have been progressing during 2011, such as the Medicines Usage Reviews' project, Falls Prevention initiatives, a smoking cessation project, development of an implementation plan for IV therapy within the primary care setting and a project on the management of Asthma. I await with interest the outcomes of these projects as they are key initiatives in the future development of primary care services.

Pharmacists have a key role to play in the development and delivery of our health services going forward. Pharmacists are well placed to work with patients, GPs, nurses and other health professionals to manage medicines and promote the effective, appropriate and rational use of medicines. It is imperative that we use medicines more effectively and cost-effectively now so that our health system will be sustainable and will have the capacity to allow patients to access new and innovative treatments in the future.

2012 will see the publication of draft legislation to allow for generic substitution by community pharmacists. This measure, in combination with a reference pricing system will provide a more efficient use of both the skills of community pharmacists and the financial resources of the HSE in continuing to meet the needs of patients.

In 2012, I also hope to see pharmacists coming forward with, and implementing, solutions to address key medication issues, such as medicines wastage and inappropriate usage of medicines, and solutions to support and improve chronic disease management and patient adherence to their medication.

Rosemary McGrath

New Challenges and Opportunities for 2012

Rosemary McGrath, Managing Director, United Drug

At the time of going to press, we are still waiting to hear the final outcome of the Budget 2011 and the impact that this will have, not just on the Pharmacy sector but on the Irish economy as a whole. 2011 has not been an easy year for most retail sectors – margins are down, consumer spending is at an all time low, and there is an element of gloom across the board.

But without sounding too glibe, the saying "no rain, no rainbows" has to come to mind. We have to face our challenges head on and decide what is best for business. What products are perfect for Pharmacy? What services can you offer that will give your business a point of difference? How can you market your business to make sure all your customers know just how great you are? In a nutshell, what can you do differently?

Pharmacy is a unique sector within retail. Pharmacists are not marketeers, not promoters – pharmacists are much more important than that. Pharmacists are a vital part of the community, that customers rely on and look to in times of need. We have heard so much negative press about how the pharmacy sector having enjoyed such excellent times, very little was ever said about the invaluable patient counselling offered freely by all pharmacies, the walk-in health screening offered nationwide, the drugs advice offered – and sometimes more invaluably questioned by pharmacies.

In a lot of cases, pharmacists may be the only Medical Practitioner who realises exactly what customers have been prescribed and can act on this information. These are services that are invaluable to Ireland, and these points of differences are what pharmacists need to promote themselves to get through the coming months and years.

United Drug, whilst their core business is wholesale, realise the need to assess points of difference. We are constantly looking to see where we can help our loyal customer base to promote themselves. In recent years, we have launched Pharma Le Cheile, the largest and most transparent buying group within Pharmacy. We are launching the Pharmacy Channel this month, and next year will see us give our biggest hand yet to the Pharmacy Sector as our Retail Initiatives project comes to market. Our Pharmacy Show in May will showcase all of these new ideas, indeed this is our fifth Pharmacy Show and with some excellent ideas already in the mix, it's going to be one not to miss!!!

We, like any other business today, cannot sit still and need to be constantly looking at new markets, new products, new services, new ideas, and yes - new challenges to overcome – but we wouldn't be in business if we were doing anything less!

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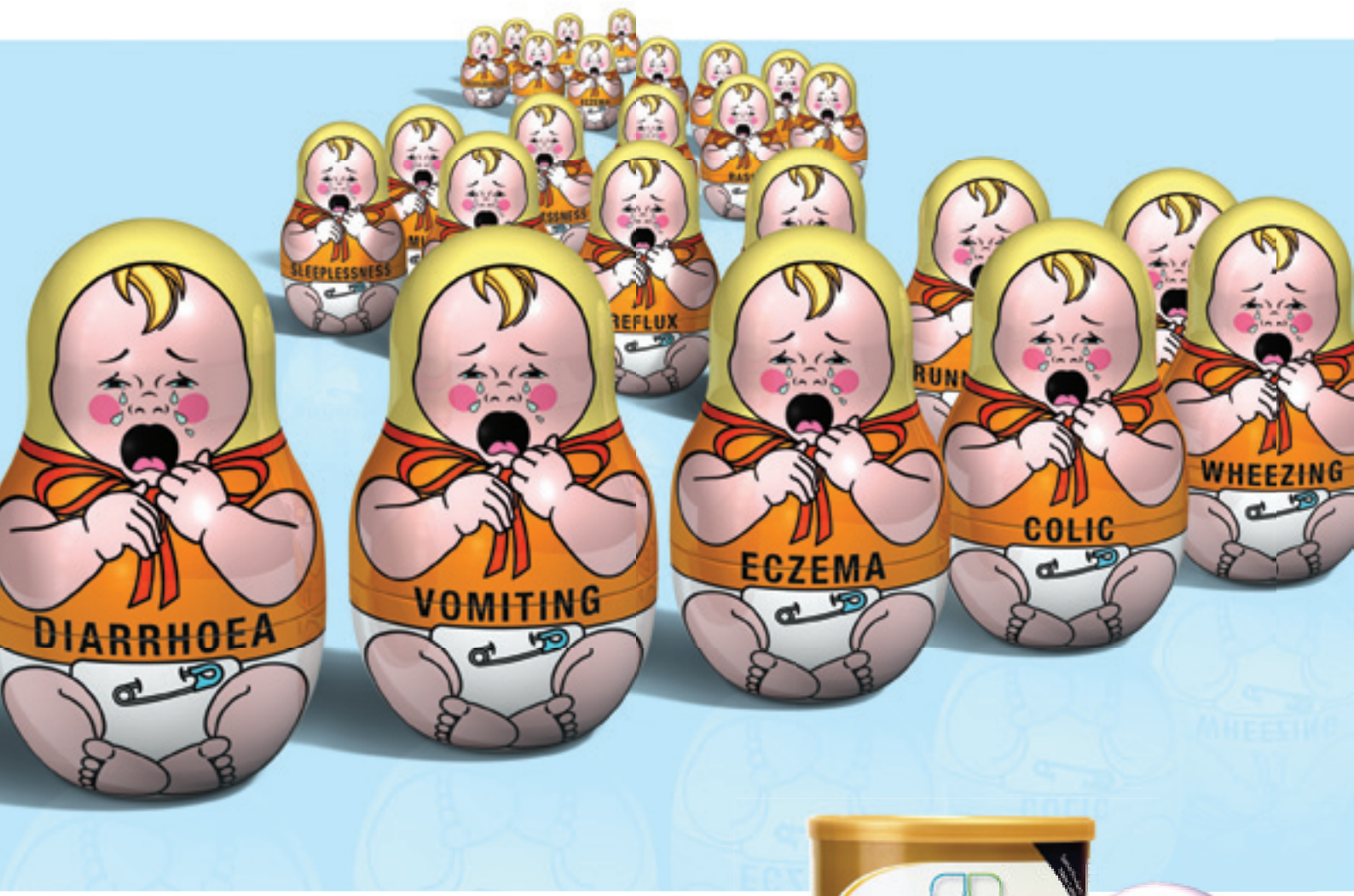

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Gary Collins

Cahill May Roberts Ltd, Supporting Pharmacists since 1902

Gary Collins, Managing Director, CMR

Our industry has seen tremendous change over the past number of years, particularly in the past 12 months. It has been a difficult year for the industry as a whole, mainly due to the Economic crisis our country faces and also due to the deep level cuts implemented by the Department of Health and the HSE through price reductions, margin reductions and FEMPI legislation.

Nevertheless, Cahill May Roberts Ltd (CMR) has continued to work with its customers in 2011 and will continue to do so to face the challenges of 2012. As CMR is part of the Celesio Group, which operates in 15 different countries, we have good knowledge and experience of the change that is taking place in all of these markets and, through our Group synergies can develop the required services to assist our customers, some of which include:

The Connect Buying Group, with over 280 members, continues to be the leading Buying Group on offer in the market place. Working with our retail customers and with over 65 manufacturers, we ensure that we can continue to grow volumes and improve the margin capability for our customers. Members also avail of additional support through our enhanced services across areas such as Category Management, Monthly Promotions and our Health Watch therapeutic educational and training programmes.

Alchemy, our Exempt Medicines business, has grown substantially in both hospital and retail sectors. It now allows customers to order on-line via CMR's IMB approved website. Alchemy customers have access to an extensive database of more than 700,000 medicines. The new website (www.cmrg.ie/alchemy) allows customers to manage all aspects of the exempt medicines part of their business. We have a dedicated technical team, headed up by Brian Collins MPSI, to help source products if they are not available in the market place.

Our dedicated Sales team is available to assist customers to ensure they have access to our 'Just in Time' twice-a-day service. We work with customers to meet the challenges imposed and faced by them in the current market place. We continue to develop our range of products and offer financial support when customers expand or develop their businesses. If you require further information about our business and how we can assist you please contact Derek Clarke, Sales Manager or one of our Business Development Executives in Cahill May Roberts.

Movianto is our logistics and distribution service provider whose broad service portfolio offers our clients warehousing and transport solutions, as well as repackaging and re-labelling services, controlled drugs, clinical trials and samples management.

Movianto has the expertise to act as a reliable outsourcing partner across the entire supply chain. It is continually developing individual logistics solutions, thus allowing clients to benefit from the greatest possible level of expert knowledge, along with the highest service standards.

The consistency and transparency of validated processes is one of Movianto's top priorities, always driven by the highest quality standards in all areas of its business. Flexibility and efficiency is what the team works for at Movianto. In addition, Movianto offers an unparalleled platform for designing supply chain solutions to meet the needs of the industry, today and in the future. For any further information please contact James Quinn, Commercial Director Movianto.

We believe that 2012 will bring additional challenges. Due to the economic crisis, we expect further impacts on the industry's profitability through Government intervention. We expect to see the introduction of reference pricing and await the specifics as to how this will be introduced in the market place. We firmly believe that the Department of Health \ HSE should do a complete review of the industry, working with the key stakeholders -Manufacturers, Wholesalers, Community and Hospital Pharmacists - to develop a new model for the industry going forward.

Our customers and clients are managing their own businesses in this time of uncertainty. Cahill May Roberts Ltd has been supporting its customers since 1902 and, with its International reach we believe we are firmly in the best position to support the needs of customers and future customers going forward.

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Company information

Alchemy is the **exempt medicines division** of Cahill May Roberts.

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Alchemy is an **Irish company** and employs pharmacists, technicians and tele-sales personnel to guide you through the complete process of ordering/sourcing exempt medicinal products for your customers & patients needs.

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Cahill May Roberts

E: alchemy@cmrg.ie
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Infant Awards

The 2011 SMA Nutrition Maternity and Infant Awards

Almost 300 people attended the 2011 SMA Nutrition Maternity and infant Awards, which were televised from the Shelbourne Hotel, Dublin by TV3 in early December.

The Awards recognise the best in products and services, which are available for mothers and babies in Ireland. The Irish public was asked to vote on the various categories and over 58,000 votes were counted.

The Awards also honoured the 'background heroes', when some parents and children were given due recognition in the special People Awards.

SMA Nutrition was the winner of the Baby/Infant Food of the Year category. AVENT breast pump won the title of Breast Feeding Product of the Year. Winner of Baby Skincare Product of the Year was Sudocrem, with Calpol winning the Health/Medicinal Product of the Year category. Organix won Environmentally Friendly Product of the Year while Pampers were the winners in the Nappy of the Year category.

Conor, Oisin, Baby Alice May, Niall & Marie Black, Kevin Lillis Forest Labs, Baby Store of the Year

Emma Burke, Jill Sommerville, Aine Waldron, Alan Downey, Philip McCabe, SMA Pfizer

Aoife Byrne, Aileen Regan, Aptamil

Martin Gallagher, Sam Doundoulakis, Amy Farrell, Kelley Treanor, Clonmel Healthcare

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Clinical Profile

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Roche Products (Ireland) Limited are pleased to announce the launch of the PEGASYS Prefilled Pen

Roche Products (Ireland) Limited are pleased to announce the launch of the PEGASYS Prefilled Pen in both135mcg and 180mcg presentations. Both the PEGASYS Prefilled Pen and Prefilled Syringe are available in the Irish Market.

PEGASYS® is indicated for the treatment of HBeAg-positive or HBeAg-negative chronic hepatitis B in adult patients with compensated liver disease and evidence of viral replication, increased ALT and histologically verified liver inflammation and/or fibrosis.

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Reference: Pegasys Summary of Product Characteristics; CoPegus Summary of Product Characteristics.

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Keith O'Hourihane - *Cork*

Appointments

Deepak Khanna, UK Managing Director of Merck Sharpe & Dohme and Senior Vice President of its US-based parent company Merck & Co, has been elected President of the Association of the British Pharmaceutical Industry (ABPI). Khanna will take over the role from Simon Jose of GSK after the ABPI's next AGM in April 2012. He will serve initially for one year, with a possible re-election for a further 12 months.

The PSI has appointed a Risk Review Group to advise on the issues around the recently reported error in patient underdosing with the seasonal influenza vaccine in some pharmacies. The Group will look at what the learnings might be from this issue.

The Review Group will comprise:

Professor Peter Weedle

Professor Peter Weedle, adjunct Professor of Pharmacy Practice at the School of Pharmacy in University College Cork, community pharmacist, former member of the PSI Council (Chair)

Ms Mary Culliton, former Director of Advocacy with the Quality and Patient Safety Directorate of the HSE.

Mr Stephen McMahon, Irish Patients Association, who is an experienced patient advocate and representative.

Raymond Anderson

Mr Raymond Anderson, former President of the Council of the Pharmaceutical Society of Northern Ireland and current President of the Commonwealth Pharmacists Association.

Ms Marie McConn, experienced community pharmacist practitioner, who is a former member of the PSI Council, and has also held positions with the Irish Pharmacy Union and is a former member of the Irish Medicines Board

Mr Tom McGuinn, former Chief Pharmacist of the Department of Health, former member of Irish Medicines Board and GMS Payments Board

Tom McGuinn

Dr Brenda Corcoran who is a Consultant in Public Health Medicine in the HSE National Immunisation Office and a member of the National Immunisation Advisory Committee

Dr Kevin Connolly, member of the National Immunisation Advisory Committee, who is also a member of the Irish Medicines Board's Advisory Committee on Human Medicines and is the Irish representative on the European Medicines Agency Paediatric Committee

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LISTERINE®
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Adds zero alcohol to the LISTERINE® TOTAL CARE range

Suitable for patients 6+.

References: 1. Data on file 45348, McNEIL-PPC, Inc. **2**. Data on file, microbiology dossier, McNEIL-PPC, Inc. **3**. Data on file 103-0214, McNEIL-PPC, Inc. **4.** Le Geros RZ et al. *Am J Dent* 1999; 12(2): 65-71.

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