FIP 2013: Vision for complex patients

highlights from the World Pharmacy Congress

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The Pharmaceutical Journal just gets better and better. Over 3,000 pharmacists from 107 countries met in Dublin to discuss the complexity of patients — that treatment can be challenging because it is influenced by a combination of human factors, such as biochemical and physiological characteristics, economics, health literacy and culture.

I came away inspired by some of the great work colleagues are doing in their communities, be it helping to prevent TB in Mumbai (p6) or providing access to telemedicine in Zurich (p5). And I couldn’t help make comparisons and feel proud of some of our achievements in the UK. What’s more, I managed to get some CPD done, learning about new biomarkers in diabetes (p7) and how real world evidence is being used to shape practice (p11).

I hope this special edition of The Journal will lead you, too, to reflect on the bigger picture of our profession and to consider attending next year’s congress in Bangkok!

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Ireland’s health minister: pharmacists’ vital role managing complex patients

PHARMACISTS have a vital role to play in the multidisciplinary approach required to manage patients with complex needs and in providing care to patients throughout their lives, said James Reilly, Ireland’s health minister, at the opening of the International Pharmaceutical Federation (FIP) 2013 World Congress of Pharmacy in Dublin. He added that the role of the pharmacist must continue to evolve to embrace more aspects of patient care and fewer aspects of the traditional preparation of medicines.

The theme of this year’s congress was “Towards a future vision for complex patients”, and Dr Reilly said that the complexity of treating patients does not lie only in the nature of the diseases to be managed but also in the nature of the medicines to treat these diseases as well as in the economic, cultural and social environment in which the patient is being treated.

Difficult balance
In particular, he pointed out the difficult balance in financing health and said that reducing drug prices is an issue the Irish Government is addressing through a series of reforms: “Substantial reductions in Irish medicines prices are crucial to the future sustainability of our health system... We must reduce the price of these medicines that we have available to us for quite some time, at the same time encouraging innovation and new medicines that can improve the health of our people.”

New legislation in Ireland provides for the introduction of “reference prices” to bring Irish generics prices down. For example, a reference price for atorvastatin products is to be set at 70 per cent of the current price. Furthermore, by May 2014 the 20 most expensive medicines will have their “interchangeability status” determined with a view to allowing a reference price to be set, the minister said. He also emphasised the “critical role” pharmacists can play in educating people on the benefits of a healthy lifestyle and the dangers of tobacco use. “It is important that, as we start to find better drugs and systems, we always remember the importance of prevention,” he said.

The congress was one of the top five largest business events to be held in Ireland this year.

Science and practice must work together, president says

PHARMACY’S future will be interdisciplinary at all levels, said Michel Buchmann, president of FIP, in his opening address. Our current depth of scientific understanding has resulted in the separation of numerous disciplines, requiring people to specialise. But a lone, isolated practitioner with generalist knowledge is no longer as effective in providing care, Dr Buchmann argued, nor is the specialist scientist working alone creating new medicines.

Through combining specialist scientific techniques and knowledge with the medical and scientific training of pharmacists, great advances can be made possible, Dr Buchmann continued. “Responsible drug use must be supported by judicious prescribing and appropriate pharmaceutical advice. Science lays the foundation for all progress and innovation while practice provides the necessary input without which the research would not lead to the desired success,” he said, emphasising that a drug molecule only becomes a medicine with the added input of pharmacy professionals.

Dr Buchmann added that individuals working across several domains as “integrators” would be required. In addition, he argued that the right balance of clinical and social scientists will be needed. This would build, on the one hand, good practitioners and, on the other, scientists that are aware of the needs of practice and patients.
Six ways to tackle medicines shortages

All countries should investigate establishing a national body charged with gathering and sharing information about demand for and supply of medicines within their jurisdiction, according to a report on medicines shortages released at the World Pharmacy Congress. This is one of six recommendations made as a result of an international summit held in Toronto, Canada, in June this year.

The 32-page report highlights that medicines shortages are multifactorial. It details causes and contributing factors on both the demand side (such as “mega tenders” for several hospitals leading to a demand peak) and the supply side (such as a market structure with single or limited suppliers). It goes on to present solutions and best practices to prevent or mitigate shortages. The other recommendations are as follows:

- Countries should establish a publicly accessible means of providing information on medicines shortages
- Countries should develop a list of critical or vulnerable products so as to identify those that require more attention in discussions on shortages
- Countries should institute an active procurement process taking into account and promoting the continuity of supply of quality medicines
- Countries should modify regulatory practices to remove unnecessary variability and improve transparency
- Countries should develop evidence-based risk mitigation strategies (for example, stockpiling, contingency plans, pandemic planning)

The report describes a recent survey of 346 hospitals by the European Association of Hospital Pharmacists, which found that 98.8 per cent of hospitals had experienced shortages over the past 12 months, while 63 per cent reported at least weekly problems associated with shortages. Medicines most commonly in short supply were those used in oncology, emergency care, cardiovascular disease, haematology, respiratory disease and paediatrics. The report is available at www.fip.org/publications.

Database to act as lever for global pharmaceutical good

An online workforce database that ultimately aims to help people around the world get equal access to medicines and pharmaceutical care got officially under way as the Royal Pharmaceutical Society signed a memorandum of understanding with FIP to work together on the project called “the global pharmacy workforce observatory”.

Ian Bates, director of the FIP education development team, told The Pharmaceutical Journal that FIP has been collecting workforce data for a number of years. For example, its 2012 workforce report contained data from 90 countries. The federation uses its workforce report to produce a subsequent database for the World Health Organization human resources initiative, as do doctors, dentists and nurses. A more efficient way of collecting information is needed and the notion of an “observatory”, where data about capacity issues around workforce can be collected contemporaneously rather than three-yearly, was arrived at, he said.

In short, the data are about “how many”. But even a question as simple as how many hospital pharmacists there are is “surprisingly hard” to get data on, even in the UK, Professor Bates said. And when you go around the world there are different systems and different levels of interest, he added.

Professor Bates explained that the observatory will also be looking at the numbers of pharmacies to get a grip on the accessibility of medicines. “We will be collecting other types of health economics [data] as well, such as country spend on medicines, units consumed, disease burden — things which are more difficult to collect, more research-oriented. We will be getting these capacity-related demographics in order to come up with more sophisticated ways of looking at how our workforce is being utilised,” he said.

He continued: “[The database is] a tool for leveraging health service developments. So if we can compare and contrast countries in terms of economics, GDP [and] service spend, we can also compare in that same frame pharmaceutical workforce as well. So that under-resourced countries — of which there are many, particularly in sub-Saharan Africa — can use that to argue for more students, more schools of pharmacy, better training,” he summarised. “Every patient should have equality of pharmaceutical care and this is one mechanism for helping governments to achieve that.”

Relevance to UK pharmacists

“A practical example of [the] usefulness of such a database is [the] benchmarking it provides, because many of the low-income, sub-Saharan countries have fragile infrastructures. And it’s useful for them to perhaps see what they need to build up to,” Christopher John, Royal Pharmaceutical Society workforce development lead, told The Journal. But the observatory database will also have relevance to pharmacists in the UK: “There’s a debate at the moment about [whether there are] too many pharmacists in the UK. If you look at the global data, we’re actually fairly middling. We don’t have a lot more compared with some other countries. So it adds another dimension to the thinking around workforce,” he said.

Although the FIP database already exists, an online platform is to be built and existing data gaps need to be filled. “Quality assurance will be a constant process. And, of course, things change. So we are always seeking to update, maintain and grow the database,” Professor Bates explained. The information will be collected from national associations, regulators and non-governmental organisations. The observatory will also be developing a database of country contacts, which Professor Bates says, will be a valuable resource. The aim is for all WHO-affiliated countries to be included but a milestone will be that all FIP member organisations, which currently number around 130, are given the opportunity to engage.

According to Professor Bates, the RPS was chosen as a partner because it had “shown an interest in supporting projects like this, advocating and wishing to take a leadership position to support FIP and all the other member organisations for a global good”.

In future, RPS members will be able to access the data provided to the WHO (ie, basic information about how many pharmacists there are in different categories) and more sophisticated data via the Society. Previous FIP global pharmacy workforce reports can be accessed at www.fip.org/educationreports.
.pharmacy domain to help consumers buy medicines online with confidence

DESPITE the authorities’ recent successes in closing down rogue websites selling medicines and seizing counterfeit drugs (2013;291:3), the battle against the criminals goes on.

“We’ve tried a number of ways to shut down the system but, as you can imagine, it can be very difficult,” said Carmen Catizone, executive director of the US National Association of Boards of Pharmacy (NABP).

Mr Catizone explained that the minute there is any sign of trouble, nefarious website operators will close the page or create a new page or change the look of the page. “The individuals behind these networks are very smart and will do whatever they can to mislead patients,” he said. A common trick used to lull consumers into a false sense of security, for instance, is to put a UK or Canadian flag on the site when in fact customers are buying from China, India or eastern Europe.

The rogue website problem is serious. For example, a recent NABP review of over 10,000 websites showed that only 3 per cent were operating in compliance with US pharmacy laws, a statistic Mr Catizone called “shocking”. And the potential for patient harm is great, with reports of cases of spiralling blood pressure or uncontrolled diabetes because a medicine bought on the internet was fake or sub-dose. He pointed out, also, that many patients worry about reporting problems and getting into trouble because they have gone outside the system to buy their medicines. Many are also unaware they are being sold around the world.

Nevertheless, the supply of medicines via the internet seems here to stay. We have generations coming through that are more comfortable ordering things on their phone or iPad than doing things face to face. They are doing things on a global scale and regulators need to meet that big challenge, Mr Catizone warned. One strategy that has been adopted to do this is to persuade banks and credit card companies to stop processing payments to dodgy sites, but this has had varied success.

Global pharmacy community

An imminent strategy, however, looks promising: the NABP has successfully applied to the Internet Corporation for Assigned Names and Numbers (ICANN) to own and operate the generic top-level domain “.pharmacy”. This means that in a similar way to .gov or .edu, a coalition of pharmacy groups can issue the domain to any legitimate pharmacy or entity within the pharmacy distribution chain. “We hope that will separate for consumers the illegal sites from the legal sites. Illegal sites [will not be able to] obtain a .pharmacy registration. ICANN will not allow anyone else to have it. It’s not something they can copy. They cannot mimic or create it.”

Everything done on the internet prevents them from doing that,” Mr Catizone said. In addition, it is hoped that .pharmacy will create a global community because it will be available to any legitimate entity in any country where the regulator has worked with the NABP and FIP to establish parameters, which, in turn, will lead to uniform standards across the world, he said.

The plan is for the .pharmacy domain to be operational by the end of the year. Mr Catizone acknowledged that, having invested .com or .org, some companies might be reluctant to use .pharmacy. However, he said the intention is that they would keep these domains and use .pharmacy as an identifier to direct to their original site. He added that the NABP is prepared to work with all countries willing to establish the global community.

A document explaining how .pharmacy will be run and how sites will be screened is available at www.nabp.net.

Two UK pharmacy academics designated as FIP fellows

IAN BATES, professor of pharmacy education at UCL. School of Pharmacy, has received a fellowship from the International Pharmaceutical Federation. Professor Bates, who acts as an independent expert adviser for the Royal Pharmaceutical Society and who was made a Society fellow in 2010, told the Pharmaceutical Journal that he was deeply honoured to be receiving the professional recognition the global leadership body for the pharmacy profession.

Professor Bates is part of the team of experts and leaders within FIP’s education initiative and global pharmacy education taskforce, which he helped initiate in 2006. Included in the work of this team has been the negotiation and signing of an agreement between FIP and UNESCO for a global UNITWIN network (UNITWIN is the abbreviation for UNESCO’s university twinning and networking programme established in 1992)

He added that this year the team will start work on interprofessional aspects of workforce development and advanced practice frameworks to assist with professional recognition and advancing scope of practice.

“It is an exciting area of work and FIP is an inspirational organisation to work with, he said.

Geoff Tucker, emeritus professor of clinical pharmacology at the University of Sheffield was also awarded a fellowship. Professor Tucker was made an honorary member of the RPS in 2010.

Other fellows named were Toby Clark (US), Andrew Gray (South Africa), Wayne Hindmarsh (Canada), Tatsuro Irimura (Japan), Kamal Midha (Canada) and Carmen Peña-Lopez (Spain).

This year’s Høst Madsen Medal was presented to Daan Crommelin, professor at the department of pharmaceutics at Utrecht University, the Netherlands.
Swiss pay €12 for pharmacist triage

ACCESS to telemedicine is being offered to patients from 200 Swiss pharmacies. The service, called Netcare, gives pharmacists a gate-keeping role in which they triage patients by following one of 24 decision trees developed by doctors and pharmacists. It allows people suffering from problems including cystitis, sinusitis, back pain and dyspepsia to receive quick and convenient treatment.

Explaining the system, Martine Ruggli, project manager at PharmaSuisse, said that following a decision tree can lead to one of three outcomes. The first is that the pharmacist can give advice or supply an over-the-counter treatment to the patient, or both. The second is that the pharmacist asks the patient if he or she would like a video consultation with a doctor. If the patient agrees the consultation goes ahead there and then from the pharmacy. Any prescription as a result of the consultation is faxed to the pharmacy for dispensing. The third, for urgent cases, is direct referral for a face-to-face consultation. In all cases the pharmacist gives the patient a follow-up call three days later.

Billing for the whole consultation is carried out in the pharmacy. There is a €12 fixed fee for the triage service, a €40 fee for the telemedicine consultation and additional costs for any over-the-counter medicines or prescriptions. However, many patients are funded by their health insurers. For example, Ms Ruggli said that the biggest health insurer in Switzerland has ring-fenced money for the scheme and patients do not have to pay for the triage. A third of Swiss citizens and tourists have to pay for the video consultation but so far that has not been a problem, she added. “We find that people are willing to pay — there is no need to wait hours in an emergency room or search for a doctor . . . Within 15 minutes you have a physician available if needed . . . no appointment is required,” she explained. However, pharmacists seem to have found it difficult to offer the service and especially to ask for payment because they believe that patients are not used to paying to speak to the pharmacist, she said.

It is a new way of working for the pharmacist and there has been an implementation gap. Pharmacists’ fears over being able to use the technology and competition with dispensing doctors are factors, and pharmacists need coaching, Ms Ruggli said. Nevertheless, she described Netcare as “already a success” with 3,000 services being provided since the pilot began in April 2012, and extension plans. Participating pharmacies are permitted to offer the service during their normal opening hours but the telemedicine operator is open 24 hours so there is scope for pharmacies to offer the service round the clock.

The triage is documented and a record is kept in the patient record and by PharmaSuisse. “It’s a great project . . . We can improve care in peripheral regions where there is a shortage of physicians,” Ms Ruggli said. Other benefits are the better use of the existing pharmacy infrastructure and cost savings due to pharmacists preventing unnecessary visits to emergency departments. Data so far show that, using the decision trees, pharmacists have been able to help patients themselves in 80 per cent of cases, with no need for a physician. “Netcare is a perfect addition to today’s primary care . . . It shows the added value of the pharmacist,” she concluded. A study to prove the efficacy and economic value of the service is ongoing.

We can play a useful role in mental health but many need further education on stigma to deliver effective care

A PILOT in the US has demonstrated the effective role community pharmacists can play in identifying and referring people with symptoms of depression. Suzete Costa, executive director of the Centre for Health Evaluation and Research in Portugal, described the project, which was run in 32 locations of a large pharmacy chain. A two-item patient health questionnaire was used to screen 3,726 patients. Those who screened positive (67; 1.8 per cent) were given a second, nine-item questionnaire and as a result of this second screening, 25 per cent were referred to a doctor. Five patients with suicidal thoughts were referred urgently. (Rosse et al, Journal of the American Pharmacy Association 2013; 53:22).

Despite this demonstrated potential, however, it seems that pharmacists still have some way to go in delivering effective care for mental health patients. Claire O’Reilly, lecturer at the University of Sydney, said that pharmacists tend to be more confident with physical illnesses than mental illnesses and said that stigma had implications for the delivery of care by pharmacists. She pointed out that mental illness may lead to disadvantages in many aspects of life, including personal relationships, education and work. It can also impact on physical health. For example, people with schizophrenia die 15 to 20 years younger than people without mental illness and the life expectancy gap has widened since 1985.

“Traditional education is not enough to improve attitudes and decrease stigma and the lack of mental health education is the main barrier to successful service provision,” Dr O’Reilly said. “A possible solution is to use ‘consumer educators’. These are people who have previously received mental health care and who work to inform and educate professionals and students on mental illness and its effects on individuals, families and society. Studies indicate that the use of consumer educators with students have a long-term impact on mental health stigma and attitudes to providing mental health services, with greater insight into mental illness, leading to self-reported behaviour change in practice, she said. However, contact education needs to be a positive experience with the consumer as an equal so participants can see the person behind the illness, she added. In addition, although this method is effective it is time limited.

Dr O’Reilly recommended investigation of how positive changes can prevail over time and how the education can be integrated with the rest of the pharmacy or medical curriculum. Anti-stigma training must be combined with professional leadership and role models, she said. “Pharmacists have an enormous opportunity to contribute as part of the mental health care team,” she concluded.
COMMUNITY pharmacists can play a significant role in the control of tuberculosis and in the care of infected patients, a project in India has demonstrated. Project team leader Manjiri Gharat told participants at a session on the complexity of health challenges in 2020 that her country carries one fifth of the world’s TB burden, with 1.8 million new cases each year. Diagnostic delays, a variety of providers, prescribing inconsistent with World Health Organization guidelines (ie, non-directly observed treatment, short-course; DOTS) and no treatment monitoring in the private sector (50–60 per cent of patients) all lead to unknown treatment outcomes. The story of this community pharmacy based TB programme began in 2006, starting with stakeholder discussions and overcoming a number of apprehensions — before this project the country’s 700,000 community pharmacists had not been involved in any national health programmes, Mrs Gharat said.

The pilot, started in Mumbai, has created recognition for the role of pharmacists as health educators, counsellors, case finders and treatment providers. It trains them to:

- Raise community awareness about TB and DOTS
- Refer people with chest symptoms
- Provide free treatment and monitoring
- Give patient information on DOTS and counselling for adherence

Up to 30 per cent of the cases referred by the pharmacists tested positive for TB and the project has lead to policy change. The model was being scaled up to three states and there are plans for pharmacy services for other communicable diseases such as leprosy and malaria. The programme is also being replicated in other countries with a high TB burden, Mrs Gharat added. The project was funded by Eli Lilly.

Syndromic management of STIs in Nigerian pharmacies

A PROJECT in Lagos, Nigeria, indicates that community pharmacists can provide appropriate management of sexually transmitted infections if trained to use a syndrome-based approach and monitored. In Africa a lot of patients present late for treatment, said Arinola Joda, a lecturer at the University of Lagos. She described a frequent “wait and see” attitude where only when a problem becomes unmanageable do people seek healthcare. “Many times something that could have been dealt with simply has become a very complex problem,” she said.

Dr Joda pointed out, also, the stigma associated with seeking healthcare. Patients prefer to use community pharmacies because anyone can go into them, whether to buy toilet rolls or condoms. But with dedicated STI clinics, everybody knows that whoever enters has an STI problem, she said.

Early treatment of STIs will prevent serious long-term problems such as infertility as well as reducing public health problems related to spread of infection, she said. However, in Africa, diagnosis is often inaccurate due to unreliable laboratory results and many do not come back for the results of tests and so are lost to treatment. According to the World Health Organization, few developing countries’ health facilities have the laboratory equipment or skills needed for diagnosis of STIs. Syndromic management is based on the identifying consistent groups of symptoms and easily recognised signs and providing treatment suitable for most serious organisms responsible for the syndrome.

The WHO advocates the use of syndromic management in these countries but in Nigeria uptake has been slow because many healthcare providers were not involved when syndromic management was brought in. Only doctors were involved and trained, Dr Joda said.

The advantage of syndromic management is to improve access so that wherever patients find healthcare providers they can find STI management and they do not have to wait for test results and can go home that day with treatment.

Dr Joda described the syndromic chart used, which details five major syndromes: urethral discharge, abnormal vaginal discharge, lower abdominal pain, genital ulcers and neonatal conjunctivitis.

Pharmacists were selected, given a baseline evaluation and invited for training. It was found, at baseline, that knowledge and practice was poor. Many referred patients to a laboratory or a doctor. Many pharmacists were not interested in managing patients with STIs. In addition, according to Dr Joda, it is part of African culture that when people are told to go to see a doctor they may not go. “I always tell pharmacists that when you refer patients, put the fear of God into them — something terrible may happen to you. Instil fear in them that [they] have a serious problem. Refer them with the urgency which this deserves,” she said.

Management is simplified by the use of clinical flow charts and standardised prescriptions along with the “4Cs” of STI management: counselling, compliance with the drug regimen, contact tracing and correct condom use.

The study found that after training, the respondents’ knowledge about and possession and use of the charts improved significantly. However, Dr Joda warned that monitoring was needed: “if nobody [went] back to check that [the pharmacists] were still doing what they said they would do, there was a relaxing of the guard and they would go back to pre-training levels.”

The work was done as part of a self-funded PhD but Dr Joda said she hopes to get sponsorship to run the programme in other parts of Nigeria.
New biomarkers in diabetes and why pharmacists need to know about them

Traditional measures in diabetes may need to make way for new biomarkers such as VCAM-1, ICAM-1, αGST and TNFR-1, which promise better prediction of complications

UNDERSTANDING diagnostics and biomarkers will prepare pharmacists to improve their input into multidisciplinary patient care, particularly with regard to complex conditions such as diabetes.

Debra Higgins, research fellow at University College Dublin, said that for many clinicians the major part of controlling diabetes is to limit the development of the macro- and microvascular complications, including cardiovascular disease, retinopathy and kidney disease. And this is where biomarkers come in, giving an insight into disease progression beyond the capacity of the traditional measures of fasting plasma glucose, oral glucose tolerance tests and HbA1C.

For example, Dr Higgins described part of a recent Finnish study (FinnDiane) indicating that, rather than looking at absolute values for HbA1C, looking at the deviation of serial HbA1C in patients over six months may be of use. It was shown that diabetic patients with a higher standard deviation of HbA1C are more likely to develop cardiovascular disease.

Mean serial HbA1C was not predictive.

Blindness

The incidence of blindness in diabetic patients is increased 25 fold and the prevalence of diabetic retinopathy increases with disease duration in both type 1 and type 2 diabetes. By the time symptoms develop it is usually too late for effective treatment. In some cases patients already have retinopathy by the time of diagnosis, reflecting the insidious of onset of hyperglycaemia, Dr Higgins said.

“Biomarkers that have emerged recently in terms of detecting diabetic retinopathy are therefore important. Measuring these now allows us to predict who is likely to have retinopathy in 10 years,” she explained. In the Diabetic Control and Complications Trial (Ophthalmology 2013;131:514-21), a cohort of 1,441 patients with type 1 diabetes and aged between 13 and 39 years had a number of inflammatory markers measured and compared with the incidence of stages of retinopathy. Elevated levels of highly sensitive C reactive protein (hsCRP), vascular cell adhesion protein 1 (VCAM-1), intercellular adhesion molecule 1 (ICAM-1) and tumour necrosis factor receptor 1 (TNFR-1) were found to be predictive of the progression of retinopathy. So a single measurement at the beginning allowed clinicians to predict who was going to develop retinopathy.

Nephropathy

Turning to kidney disease, Dr Higgins quoted percentages of 30 and 50 for patients with type 1 and type 2 diabetes, respectively, who will develop diabetic kidney disease in 15–20 years. Glomerular filtration rate is not a sensitive enough measure of renal function, one of the reasons being that it declines over time in everyone. Persistent albuminuria may be used for diagnosis (in the form of albumin:creatinine ratio) but there are no good data to guide the optimal timing of sampling. In addition, patients may have transient positives with exercise or infection, and false negatives are more likely in certain ethnic groups.

“We need to identify novel kidney disease markers with increased sensitivity and potentially ones that can be used as prognostic markers to identify patients who will be at risk later on,” she said. “The idea is to move the time of diagnosis from stage 3 kidney disease [where there is already reduced function] back to stage 1 so we can treat earlier and more aggressively, slow kidney injury, improve health and reduce costs,” she added. Dr Higgins noted that although diabetic kidney disease occurs after retinopathy in type 1 diabetes, this may not be the case in type 2 diabetes.

Urinary biomarkers undergoing testing include alpha glutathione S-transferase (αGST; reflects damage in proximal tubules), nGST (reflects damage in distal tubules) and collagen IV (indicates glomerular injury).

Recent research in patients with diabetic kidney disease have found elevated levels of αGST and collagen IV, suggesting that damage is distal tubular and glomerular rather than proximal tubular, Dr Higgins said.

Liver fatty acid binding protein (LFABP) is another potential biomarker, with low levels found to be associated with an 18 per cent increase in microalbuminuria. However, a high level at baseline led to a 40 per cent incidence in macroalbuminuria, she pointed out. Research also indicates that TNFR-1 is a potential prognostic marker of kidney disease in type 2 diabetes, involving a single measurement at baseline. Having an increase of two-fold will predict incidence of kidney disease at 12 years (Journal of the American Society of Nephrology 2012;23:507–15). TNFR-2 may also be a possible candidate.

Act now

Despite the promise of future possibilities, Dr Higgins stressed that pharmacists can be playing a valuable role in diabetes now. She highlighted that a patient with a body mass index over 35 is 42 times more likely to develop type 2 diabetes than someone with a normal range BMI. However, the normal and early overweight BMI range (BMI 25–27) is sometimes overlooked even though someone is in this range has already doubled their risk of developing diabetes. “The World Health Organization recommends that 30 minutes of moderate intensity physical activity on most days coupled with a healthy diet can drastically reduce the risk so it is something that we can change [now]. We just have to get the message out there that this is something you can do,” she said.
We will have virtual twins to test our drugs and allow tailored advice giving

THE future of medicine may lie in the virtual twin — a “person simulator”, according to Hans Westerhoff of the University of Amsterdam and the VU University Amsterdam, and professor of integrative systems biology at the University of Manchester, during the first congress session. He said that “revolutionary progress” in the life sciences has not paid off because most diseases are multifactorial and so they are network diseases but they have hardly been looked at in this way.

A network disease, Professor Westerhoff explained, is caused by a combination of possibly remote factors. Adding to the complexity is that the diseases can be caused by a combination that differs between patients. “And so a network disease should be approached by a combination of drugs and that combination may differ between patients,” he said. He went on to predict that in 10 years’ time, pharmacologists will be teaming up with physicians and patients to design an individual drug cocktail using virtual twins. Such twins could be used to predict how various changes in nutrition and lifestyle, or the use of medicines, will affect health and well-being. They could be used to pre-test therapies before real-life use.

He commented that medicine is lagging behind the airline industry in that aeroplanes are continuously and intensely tested, modelled and simulated. Flight simulators answer what would happen if one thing goes wrong and whether back-up systems are robust enough. No one would dare to fly if a plane had not been tested and yet we all take medicines when there has been no substantial simulation of how they work, he said.

He acknowledged that the complexity of networks in humans is high and there is an enormous amount of data which would have to be integrated by projecting it onto a computer replica of the individual. However, he said that the challenge was not impossible.

Now is the time to tackle suboptimal medicines use, policy makers decide

POLICY makers are starting to recognise the value of medicines but it is up to pharmacists to keep the momentum going, the audience at a session presenting the outcomes of a symposium of senior pharmacy policy makers heard. The symposium, held two days before the World Pharmacy Congress, explored the responsible use of medicines, which was defined as when “the activities, capabilities and existing resources of health system stakeholders are aligned to ensure patients receive the right medicines at the right time, use them appropriately and benefit from them”, said symposium project manager Leonie Clarke.

Policy makers heard that 8 per cent of health spend could be avoided by optimising the use of medicines. The challenges they face include a need to consider what works in the real world, aligning programme funding and remuneration so that specified outcomes and quality indicators are achieved, moving away from the past, and the need to make the most of limited resources. However, it was proposed that initiatives to promote responsible medicines use have real potential and that financial crises can provide an opportunity.

The following conclusions emerged:

- Increase responsible use and outcomes will improve
- Improve cost-effectiveness and free resources for new medicines
- Involve patients in decision-making
- Keeping people well is key
- Pharmaceutical care and medicines management is key to responsible use
- Monitor use and target support to patients
- Multidisciplinary collaboration is critical
- Introduction of new services must be evidence-based and have ongoing evaluation

Another conclusion was that pharmacists have a key role in tackling the problem of suboptimal use. However, Norman Morrow, former chief pharmacist for Northern Ireland, warned that the profession tends to be too “self serving” and needs to take the wider view and input more effectively into policy development. A fuller report of the symposium is expected to be published by FIP next month but some of the documents presented are available now at www.dohc.ie/issues/symposium.

Virtual learning may have wider promise

KNOWLEDGE around virtual learning resources for pharmacy students could help progress the concept of virtual practice — meaning that pharmacists might be able to work from anywhere, according to two speakers from Monash University, Melbourne, Australia. Marian Costelloe of the faculty of pharmacy and pharmaceutical sciences said the university has developed a number of such resources to create flexible, dynamic and interactive learning. These include “MyDispense”, a program that teaches dispensing skills in a virtual environment and “Pharmville” a virtual community of patients in a range of ages, races and diseases. Senior lecturer Ian Larson explained how one resource, Pharmacatopia, has allowed 12 hours of laboratory classes on how to use a tablet press to be replaced with a program that takes an hour. Such resources may have broader applicability to a variety of learning and workplace environments, he said. This is more information at www.monash.edu/pharm/innovative-learning/.
Could drug testing and patient contracts help solve our painkiller death problem?

A toxicologist describes measures being taken to reduce painkiller misuse and abuse in the US, and predicts an opportunity for pharmacists in Europe.

MONITORING prescribing and educating patients and providers are not the only ways in which pharmacists can help prevent unnecessary deaths from prescription painkillers. The use of drug testing in pain management clinics is growing fast and something that pharmacists need to learn more about, said Majid Moridani, a clinical toxicologist at AIT Laboratories, Indianapolis.

He described an epidemic of painkiller misuse and abuse in the US, quoting a current average of around 15,000 prescription painkiller deaths a year. For every one death there are about 10 hospital admissions for abuse and 32 emergency department visits for misuse and abuse. And, in 2010, as many as one in 20 people in the US reported using prescription painkillers for non-medical reasons, he added. The drugs involved in these figures include oxycodone, hydromorphone and fentanyl, and also tramadol, for which the number of related deaths reached a new high in England and Wales last year (BMJ 2013;346:f536).

People who abuse prescription painkillers get them from a variety of sources; over half obtain them from relatives and friends but 17 per cent get them prescribed by one doctor, Dr Moridani said. He pointed out also, that in the US, people might “help out” non-insured relatives by reporting that they have back pain (for which there are no diagnostic tests) in order to obtain free prescribing. Those at most risk of harm include “doctor shoppers” (people who visit several prescribers), people who take high daily doses of prescription painkillers and those who misuse multiple abuse-prone prescription drugs.

Decision-making

To help combat the problem in the US, a number of prescribers are now asking their patients to sign a contract, accepting the risks of taking the prescribed analgesic and agreeing to rules for safe use. In addition, drug testing is being used to help prescribers decide whether to prescribe a painkiller, to “fire” the patient or to refer him or her because they believe he or she has an addiction. Some patients are required to pass a drug test before they can have a repeat prescription.

Tests look for use of alcohol and illicit drugs, which could present a dangerous combination with the prescribed medicine, or monitor compliance. For example, if a drug is not detected by testing that is a strong indication that it is being diverted to another person, Dr Moridani explained.

Urine testing is the mainstay for both these purposes, although it does not provide information on the ingested dose, and in the US one or two establishments are now promoting blood as a matrix for monitoring in high-dose patients.

Understanding test results for compliance monitoring would help pharmacists recommend doses and get involved with pain or psychiatry clinics and GP surgeries, Dr Moridani advised. He went on to point out that the interpretation of results for compliance monitoring for pain management is more complex than usual toxicology testing — the purpose and cut-offs are different. It is about whether a patient is positive or negative for certain drugs but also about whether the result is consistent or inconsistent with expectations, he explained.

An understanding of detection times is also important — retention time in blood and urine are different. Urine testing is preferred because it is non-invasive and gives a larger window (because drugs generally remain for a few days compared with a day in blood, depending on the half-life) but Dr Moridani warned that some patients will take the medicine two days before the test to produce a positive result when they have sold the other doses. Blood can be used when patients cannot produce a urine sample, when they fail a urine test because of tampering or for dose-concentration correlation, he said.

Opportunity for pharmacy

Drug testing has become important for US physicians because their licences are on the line. “They have a big responsibility for monitoring [pain] patients,” Dr Moridani said. He went on to give an overview of the methods of testing used: urine cups (qualitative results but a high cut-off), immunoassay and mass spectrometry. He noted that doctors are beginning to set up laboratories for immunoassay in their surgeries and predicted that, in future, such services could be found in pharmacies. Pharmacists, especially those in Europe, have an opportunity to get involved with testing, he said. He pointed out that positive immunoassay results are “presumptive positive” (because the test looks at the shape of the drug so may test positive if on a similar structured drug, eg, methamphetamine and phentermine) and may have to be confirmed by mass spectrometry.

In the US, diagnostic services such as therapeutic drug monitoring and documentation are also used for medicolegal reasons and this could happen in Europe, too. For example, insurance companies do not pay life insurance if a patient dies of an overdose. On the other hand, drug testing documentation would prove that fatal levels of a painkiller found in the blood was not the cause of death — rather the patient suffered chronic pain when he or she was alive and was tolerant to the painkiller, requiring higher than normal doses.

Another way in which pharmacists can help prevent deaths from prescription drugs is to establish a regional or national computer database network, Dr Moridani said.

He added that pharmacists should also appreciate the influence of genetics on the risk of painkiller deaths. CYP2D6 genotyping into extensive, intermediate and poor metabolisers for drugs such as tramadol and oxycodone is possible. Poor metabolisers will tend to have the highest steady state plasma concentrations and a relationship has been found with pain relief and adverse drug reaction reporting. So this suggests that patient care may be improved by genotyping and following therapeutic drug concentrations, he said.

In order to limit misuse or abuse, some prescribers in the US are also requiring their patients to have repeat painkiller prescriptions dispensed from a single pharmacy.
Turn patient counselling on its head

THE wave of change coming over pharmacy is not only technological but also includes changes in our knowledge of behavioural science, said Dirk Broeckx, a pharmacist and trainer from Belgium. Why is it that the advice pharmacists give to patients on changing behaviour so often does not work? Before giving out a medicine pharmacists should first make sure that patients are “on board” with treatment. Perhaps we should be telling them that they won’t get their medicine until they first convince us that they will be using it, otherwise it will be wasted, he proposed.

We know now that health is behaviour, behaviour is motivation and that this is not rational. Only 20 per cent of our behaviour is determined rationally (eg, influenced by evidence based medicine, information and instruction). The other 80 per cent is influenced by factors such as culture, education, habits, perceptions, expectations, emotions and instincts. “We have been working on and studying the 20 per cent but we have to address the other part and, in future, pharmacists will be prepared to change this part,” he said.

Motivation is the key to adherence. And this is about how the patient sees his illness in his own head. He will either actively seek to improve his health or he will be more postponing about it. Secondly it is about how the patient sees his treatment, he said.

Mr Broeckx went on to describe five “pillars of adherence” for pharmacists to learn. The first is to speak to the patient about his or her treatment, he said. The second is to explain stuff and then we don’t start by explaining stuff and then we don’t speak more than we do,” he added.

Let the patient tell us first and then fill in the gaps, he advised. A tip he gave is to use storytelling and images to explain conditions like high blood pressure. “It’s the other way around from what we do today. . . . Today we start by explaining stuff and then we don’t care anymore whether they know it or not, or whether they understand it or not. . . . The patient should speak more than we do,” he added.

The second pillar is to let patients explain first how they will use the medicine, then correcting them if necessary. The third is to give good information on the aim and expected effects and side effects of the therapy, the fourth is co-creating a medication scheme with the patient and the fifth is providing an “after purchase service”.

“We intervene only when the patient has a problem but we should provide regular check-ups. Do we offer service after sale? For example, do we contact patients after a week of antibiotics or a month of treatment for chronic illness?” he asked.

Mr Broeckx added that his vision is that, by 2020, pharmacists will work backwards, starting with motivation rather than advice giving.

Need for proven examples of effective interprofessional communication

SHOULD pharmacists be wearing the “cone of shame” when it comes to interprofessional communication, asked David Allred, senior lecturer at University of Bradford. Such communication is fundamental to safe medicines use, especially following admission to hospitals or care homes, he said.

E-prescribing and e-discharge advice notes are an improvement on manually faxed discharge records between hospital pharmacies and GPs, which are sometimes illegible or incomplete and are easily misplaced. And the electronic transfer of prescriptions may result in better information transmission between GPs and community pharmacies. Summary care records and access to GP prescribing systems also offer practical solutions. However, Dr Alldred said that communication between hospital and community pharmacy is still “generally not happening”. Most information is still faxed or posted and predominantly relates to patients with special requirements (eg, specific formulations or monitored dosage systems). Messages can be inconsistent and lacking in quality, he added.

Dr Alldred cited figures from the 2009 Care Homes’ Use of Medicines Study, which include that seven out of 10 residents were exposed to at least one medication error. He said that the reasons were multifactorial but included fragmented systems and a lack of understanding of the responsibilities of the personnel involved. The reliance on second hand information from relatives by care staff was also a concern, he said.

He pointed out that the recording of information varies between different health professionals. For example, when he reviewed the records of 121 residents in 31 care homes, 31 residents had more than one drug sensitivity. However, GP records noted 73 per cent of these compared with 60 per cent in care home records and just 6 per cent on the medicines administration records. Only two drug sensitivities had been recorded on all three types of record.

In addition, Dr Alldred said that poor communication between hospital pharmacies and care homes results in discharge medicines being wasted because they are not dispensed in a form compatible with the home’s system. One solution by Leeds Teaching Hospitals NHS Trust was to create a database of local homes’ preferences, including length of supply, medicines delivery system used and whether all medicines or just new drugs should be supplied.

Despite some examples of good practice, more are needed. We need to develop, innovate and evaluate models of patient-centred care across the sectors, he said.

How much should we tell patients?

WHAT patients want to know about a medicine often includes what it is for, the side effects to look out for, what action to take if any occur, contraindications, how the medicine should be used, how it should be stored and any drug-drug interactions, said Parisa Aslani, associate professor of pharmacy practice at the University of Sydney. But the issue for pharmacists is how much to discuss, she said.

It has to be recognised that patients may have “poor to minimal” health literacy. For example, it is estimated that 60 per cent of the population in Australia fall into this category. Numeracy is another factor to be considered, particularly when discussing risk, she said.

Patients’ beliefs also deserve consideration, Dr Aslani added. For example, the attitudes of three individuals to side effects could be:

- The glass half empty — “I’m the one of the three in 100 who will experience a side effect”
- The glass half full — “I am one of the 97 per cent who will not experience a side effect”
- Go with the flow — “I just go with the flow or do not know what my likelihood is of a side effect”

Take these differences into account when dealing with individuals, she told pharmacists.
Get ready for greater use of real world data to inform healthcare decisions

Today's technology makes it easier to follow patients and these data have a number of uses

IT IS a misconception that real world evidence — in other words, the opposite from clinical trial data — is mainly about pharmacovigilence and finding problems, said Per Troein, vice-president of strategic partners at IMS Health. Real world evidence is data about patient progression through care and is being used to inform decisions on using our assets — existing drugs — in a better way to increase their value, he said. An example Mr Troein gave was Nexium on the US market. “There was a lot of scepticism whether it was really an advantage versus Losec, especially when Losec went off patent. Health care planners said it’s the same; we should only use the cheapest one. But as real world evidence built up we saw that patients who were switched from Nexium actually ended up costing more than before and the decision was reversed,” he said. Payers’ use of the data is not only to prove that a price should be lowered but also about value — how much additional benefit we can get from using a drug more, he emphasised.

Examples of real world evidence include the registries maintained by different countries for groups of patients such as those with rheumatoid arthritis or diabetes but it is not only payers setting the real world agenda. Mr Troein said that manufacturer-generated real world evidence has influenced a number of decisions. He also highlighted the development of a mobile evidence platform to support the launch of an antidiabetic in the UK — pioneers are training their sales representatives to use real world data in visits to clinicians so they can talk about their patients rather than referring to a four-year-old study in another country.

Real world evidence makes it possible to evaluate outcomes and adverse effects but it can also be used to look at adherence, Joakim Söderberg, head of development at Health Solutions AB, said. “In clinical trials you have adherence of 90 per cent plus whereas looking at drugs in real life, you have adherence of 60 per cent and this really affects results,” he explained.

Mr Söderberg said adherence is largely ignored in today’s models for many reasons. And yet there is a lot of real life data collection that pharmaceuticals could do in this area: “[With] all the customers [they] meet who are using a drug, [and] all the drug statistics [they generate], pharmacists are probably the people who have the best view on adherence.”

He went on to describe how real world evidence is being used in Sweden by clinicians and how this is happening in real time, using a decision support system called Real Q. “The main purpose of this system is not research but to give physicians a better overview of their everyday work. . . . Instead of traditional quality registers, we wanted to do something that physicians need in their everyday care; a really useful tool.” So, for example, an HIV clinic using the system can access data that are a second old, including the number of patients with a new HIV diagnosis, the number that are treated, the number who have been treated for at least four months, how many have an RNA viral load of 50–199 and the number on a drug holiday. And clinicians can compare with benchmarks, such as national targets and results in other practices. “So people then start doing things based on these figures. The main advantage is to get control of patients in the clinic,” he explained. However, Mr Söderberg made clear that this is not evidence-based medicine and said: “We’re pushing out a lot of stuff that’s almost research but [it is] not peer reviewed or statistically controlled, but we’re doing something new here.”

**Paradigm shift?**

“Traditionally in research we’ve been collecting data [at] the medical research level. We also use quality registers. The real paradigm shift is when we start using the data that get generated in the clinic every day; you have to think completely the other way,” Mr Söderberg continued. “We have to understand what’s available and how we get that data in a qualitative way. You’re not planning how to do a study but you’re planning data collection. When this is real-life, that’s a paradigm shift and slowly we’re moving in that direction for many reasons,” he added.

He predicted that such a shift would create a parallel world to phase III trials and that pharmaceutical companies will have to involve other parts of the markets, looking to the top clinicians instead of the top researchers. They would have to enable these physicians to collect the right data in a qualitative way and think about consent strategies too. Continuous feedback and reaction to results is needed, as is transparency over what will be done with the data. “There’s a lot of thinking to be done regarding real world [evidence] but I don’t think we’re going to get around this. It is happening,” he said. There is also a power issue. Real world evidence moves a lot of power away from the pharmaceutical industry to the payers, which will affect the market, he said.

In May this year IMS published a report on how far the use of real world evidence has come in 10 countries. Mr Troein said that this could be judged by assessing the accessibility of data, its usefulness and application, and what frameworks are in place in those countries. For example, the US has a lot of data and they are very accessible — there are a lot of commercial players that have it available — and countries like Sweden and Denmark typically have very rich data sets (through the use of social security numbers), whereas in other countries, such as Spain, it is hard to access data, he said.

The IMS report has rated the UK as having come the furthest. “It has a reasonable but not fantastic set of data but it has more framework than anyone else: it has defined a lot standards for how we want this to be analysed and how to use it, and it does affect decision making,” Mr Troein said.

On a question of how much trust can be placed on real world evidence, he replied: “Clinical trials have a regulatory authority to review what you’re publishing. As real world data does not [have this], the peer review methodology is probably one that will have to be there for quite some time until trust is built up — peer review of whether the methodology is sound and whether the conclusion that’s drawn is appropriate.”

The IMS report “RWE market impact on medicines: a lens for pharma” also highlights the opportunities and problems in delivering results with real world evidence and is available at www.imsconsultinggroup.com.
Campaign for access to health records

FORMERLY, the only information required by pharmacists was what was on the prescription, but this is no longer enough to provide them with the information they need to provide new services, said Stephen Goundrey-Smith, the Royal Pharmaceutical Society’s (RPS) pharmacy IT adviser.

“The pharmacist might need access to information on, for example, allergies, adverse events, diagnosis, medical history, lab results and hospital referrals. . . . The role of the pharmacist is changing from being product-focused to being patient-focused, a clinical professional, advising people about medicines,” he said.

Mr Goundrey-Smith described the current situation in the UK, where for many pharmacists, the only patient information available to them was the current medication record which they themselves have built up from prescriptions and patients. Some pharmacists might have access to the NHS summary care record by local arrangement and others, in pharmacies co-located with medical centres, might have access to the GP record system, again by local arrangement.

In some places innovative work is being done to give community pharmacists access to important patient information. For example, the East Lancashire Hospitals NHS Trust is developing its electronic discharge prescriptions to include specific referrals to pharmacies for medicines use reviews or advice on new medicines, so that community pharmacists are involved with the discharge process. But there is still much to be done to enable pharmacists to have access to all the patient information they need to fulfil their new roles, he said.

Mr Goundrey-Smith went on to say that some members of the public and civil liberties groups do not want community pharmacists to have access to records, because they see them as shopkeepers rather than clinical professionals. Sometimes even other health professionals do not want pharmacists to have access, he said. On the other hand, he noted that many patients assume pharmacists have access to electronic health records and are surprised to find that they do not.

All these factors mean that there is little public and political pressure for pharmacists to have access to electronic health records. However, there are other factors why electronic health records are not shared more readily, including records being restricted to organisational silos (servers and infrastructure), lack of a common data platform or terminology to enable record sharing and restrictions on appropriate record sharing because of information governance procedures. Mr Goundrey-Smith explained that much is taking place in Britain to address such issues. For example, the RPS is conducting a national campaign for records access by pharmacists. It is also engaged with the record standards work of the Academy of Medical Royal Colleges and the Professional Records Standards Board, so that there might be common record formats.

He added that implementation of the “Information governance review” (Caldicott 2) is hoped to address some of the artificial governance barriers to sharing records, while safeguarding record confidentiality, and to improve access for community pharmacists. The NHS summary care record addresses some of the information needs of community pharmacists, and there is benefit in pharmacists having access to it, where possible. But pharmacists should still support the development of innovative local health records projects, such as the East Lancashire e-discharge initiative. “All pharmacists have a role to play in their area of practice to campaign for access to health records,” he concluded.

eHealth record system launched despite public concerns

THE tragedy surrounding the Australian radio presenters and their spoof telephone call about the Duchess of Cambridge’s morning sickness showed that lack of confidentiality can be a dangerous thing. Betty Chaar, lecturer in pharmacy practice at the University of Sydney, used this example to introduce a session on confidentiality and the risks of electronic sharing of patient data.

Dr Chaar explained that the two world wars of the 20th century had brought about a fundamental change in public attitudes, where the human rights of the individual have become a dominant factor in society, and legislation has been developed to protect those rights as a priority. Now, in many societies, the rights of the individual and respect for autonomy are regarded as far more important than the classic principles of medical ethics, such as first doing no harm and serving the best interests of the patient, Dr Chaar said.

Confidentiality — the human right of individuals not to share information about themselves — has, therefore, become a major concern in healthcare, and this underpins public sensitivities around the sharing of electronic health records.

Many patients have specific and justifiable fears about disclosing their electronic health records — dealing with a stigma of a particular medical problem, the impact of a medical condition on employment or health insurance, or simply a concern that the public interest might override their rights. Another factor is that some citizens abuse the system, wasting resources with multiple consultations with health professionals or repeated supplies of medicines. The availability of a central record system, to which all encounter data were communicated, would expose such abuses. Because of all these issues, there are considerable political sensitivities concerning use of, access to and sharing of electronic health records, she explained.

Dr Chaar described the development of the Australian personally controlled e-health record programme, launched last year, which provides an online health record for every Australian. It holds details of medical conditions, medicines, allergies, vaccinations and specific health-related events. Each person can access his or her own record and can grant access to any healthcare professional. Over AUS$466m has been invested in this single central system and although it represents a huge step forward, it has taken a long time to develop because of public concerns. Nevertheless, benefits that connected electronic health records bring are great, including improved communications between healthcare professionals and providers and a more streamlined and efficient health service and improved patient safety. However, Dr Chaar warned that considerable problems could arise if the system is abused and patient confidentiality is not respected.
THE approval of amendments to Directive 2005/36/EC by the European Parliament due next month will ease some of the challenges the UK pharmacy regulator currently faces in assuring the professional competence of pharmacists from other member states, said Duncan Rudkin, chief executive of the General Pharmaceutical Council (GPhC) at the World Pharmacy Congress.

Around 3,000 pharmacists and pharmacy technicians on the GPhC register are EEA or Swiss nationals. “It’s an important subset of the register and one that from time to time presents its challenges and is under a certain amount of scrutiny in terms of media attention and from a political point of view... Our hope is that once the directive is in place some of the challenges that we have will be addressed, although we don’t think we’re entirely where we would like to be still,” Mr Rudkin said.

One such challenge is where somebody is qualified in a member state and wishes to work in another but may have not been practising for some time or may, in fact, never have practised. He explained that under the mutual recognition law the regulator is not currently able to carry out any checks or impose any requirements additionally on somebody who has not practised — it can look at his or her qualification only and not, for example, at whether he or she has done any continuing professional development. “We are able, to a certain extent, to address [whether people are up to date] but we do have a concern, and this is a concern shared with other health regulators in the UK, whether the directive, even in its amended form, is going to allow us to protect the public quite in the way we would like when it comes to currency of practice,” he noted. Mr Rudkin went on to say that the GPhC has worked with the other regulators in the UK to propose an amendment to the directive to enable them to look at currency of fitness to practise notwithstanding that someone had a recognised degree. Although the amendment was not accepted, Mr Rudkin believes that the point about currency was recognised in a way: a requirement on all member states in terms of CPD has been strengthened. “I think we will still say that requirement does not really address the substance of our concern because

An accepted amendment to the directive will introduce an alert mechanism so there should be better exchange of information about fitness to practise

Mr Rudkin said that with the exception of the Republic of Ireland and Northern Ireland, the GPhC has worked with its EU counterparts. “There is a risk that [if] somebody who is on our Register and, say, on a register also in another part of Europe and if there’s an event there which leads to them being struck off the register in their home state, we may not know about it and we may not be informed about it,” he said.

“Our experience so far has been that there’s a lot of improvement to be achieved on this front. Some of that has been about processes and systems, some is also about culture and attitudes to fitness to practise, registration and regulation. We have, in the past, come across competent authorities in Europe which have taken the view that fitness-to-practise history is something that is protected in terms of data protection and therefore can’t be shared with other statutory regulators in Europe. We find that bizarre and indefensible and are keen to work with colleagues to strengthen the law in this area,” he added.

However, an accepted amendment to the directive will introduce an alert mechanism so there should be better exchange of information about fitness to practise and the GPhC hopes it will strengthen protection of the public.

Turning to the issue of language proficiency, Mr Rudkin explained that in this case it is the UK law that needs amending to allow the regulator to carry out language assessments. “Our view is that the [current] European law itself would allow us to do what we need. . . At the moment GB legislation doesn’t work in that way, which is an obstacle for us,” he said. “We have never sought to impose a blanket requirement on anybody coming from elsewhere in Europe to undergo a particular form of language assessment.”

What we seek is the facility to ask somebody to undertake a language assessment where there is evidence that that person’s particular level of English is not what it should be for practice in GB,” he added. The amended EU directive clears the way for this but there will be further work to do within Great Britain to ensure that local legislation enables the GPhC to carry out assessments.

In the meantime, Mr Rudkin said there are those two key protections for the public: The first is a professional responsibility only to work when it is safe — and that means being able to communicate — and the second is the onus of employers to make sure that all of their pharmacy staff have the skills that they need, including being able to communicate with patients in English.

The 74th FIP World Pharmacy Congress will be held in Bangkok, Thailand, from 20 August to 4 September 2014. The theme will be “Access to medicines and pharmacists today, better outcomes tomorrow.” The congress returns to Europe in 2015 with “Better practice – science based, evidence driven” (28 September to 3 October 2015) in Dusseldorf, Germany.

Duncan Rudkin: around 3,000 pharmacists and pharmacy technicians on the GPhC register are EEA or Swiss nationals.

change to EU law expected to improve quality assurance of EU pharmacists

The UK pharmacy registrar outlines amendments to mutual recognition checks

The UK pharmacy regulator currently faces in assuring the professional competence of pharmacists from other member states, said Duncan Rudkin, chief executive of the General Pharmaceutical Council (GPhC) at the World Pharmacy Congress.

An accepted amendment to the directive will introduce an alert mechanism so there should be better exchange of information about fitness to practise