



Industrial *Pharmacist*

December 2007

FOREWORD

Dear Reader

Welcome to the December edition of the Industrial Pharmacists Group's newsletter. The processes to separate the regulatory and professional functions of the Royal Pharmaceutical Society and to create the General Pharmaceutical Council have begun. If the proposed timetable is followed, on 1 January 2010 we will have separate regulatory and professional bodies for pharmacy. While we may reflect with sadness on the loss of 75 years of combined regulatory and professional leadership, this presents an opportunity for us to help shape the future of professional leadership for pharmacy.

The IPG committee has worked on this with Society staff at our last two meetings. Initial feedback was presented in the last newsletter (August 2007) and our formal input to the Society submission to the Clarke enquiry is discussed in this issue.

The other topic of debate has been the fees increase for practising pharmacists. The IPG committee is disappointed at the Society's Council decision in terms of the extent of the increase and the timing of its introduction. While the total fee is, broadly speaking, in line with that of other professions, the additional benefits to members are unclear at this stage. IPG member response may be a good predictor of that of the future membership of the professional body, since most of us do not currently need to be members to work. Feedback suggests that many industrial pharmacists are thinking of leaving the Society. While that is a personal decision, I urge them not to act in haste. We hope industrial pharmacists remain fully engaged members of the profession and work with us to help shape the future professional body into an organisation of which we can all be proud.

Michael Parker
IPG chairman

MHRA launches a new strategy to curb trade in counterfeit medicines

The increasing availability of counterfeit medicines presents a threat to public health, prompting the launch of new measures to combat it. **Mike Murray**, IPG committee member and head of manufacturing and environment at the Association of the British Pharmaceutical Industry, reports

The Medicines and Healthcare products Regulatory Agency (MHRA) launched a new strategy at a conference in London on 22 November to combat the increasingly serious threat of counterfeit medicines and devices.

With counterfeit medicine availability growing worldwide, the chairman of the MHRA, Sir Alasdair Breckenridge, said that the MHRA was determined to tackle this issue head-on to protect public health. The worldwide effort is being led by the World Health Organization (WHO), which is leading the International Medical Products Anti-Counterfeiting Taskforce (IMPACT).

Speaking at the conference, Minister of State for Public Health, Dawn Primarolo, warned that this issue cannot be dealt with by one company, regulator or country and that the co-ordinated approach of the WHO is supported by the UK.

Counterfeits sold on internet

The UK has seen nine recalls in the past three years of products reaching the legitimate supply chain. Activity via the internet is increasing rapidly, with both lifestyle drugs and lifesaving drugs attracting counterfeiters' attention.

The WHO estimates that more than 50 per cent of internet sales involve counterfeit medicines on sites not disclosing a postal address. In the EU there has been a 380 per cent increase in the seizures of counterfeit medicine at EU borders between 2005 and 2006.

The UK is seen as an end user of counterfeits rather than a manufacturer, but counterfeiters are using the UK as a transit point to add credibility to the "apparent" source of the product. The perceived complexity of the UK supply chain, high prices, a large market and widespread internet connectivity are seen as factors encouraging counterfeiters.

Introducing the MHRA anti-counterfeiting strategy, Michael Deats, group manager, enforcement and intelligence, said that al-

though the frequency of events was quite low any counterfeit medicine or device was potentially dangerous to members of the public. The MHRA strategy sets out a three-year programme of communication, collaboration and regulation:

Communication by focusing on the public and health care professionals, including the launch of a 24-hour anti-counterfeiting telephone hotline and website contact address

Collaboration by working with the WHO IMPACT initiative, law enforcement agencies locally and, internationally, other regulators and industry

Regulation by continuously assessing the threat to the public, conducting market surveillance on medicines most at risk from counterfeiting, investigating reports, then prosecuting and confiscating assets, where possible; and by carrying out a thorough review of the supply chain in view of the recalls in 2007 and by making recommendations for change.

Ultimately, counterfeiting will be defeated through a global approach, according to Valerio Reggi of WHO. Dr Reggi presented the work of the IMPACT taskforce that is leading international efforts to eradicate counterfeit products from the supply chain, a project that the MHRA is closely involved in. The IMPACT group is seeking stronger global legislation (including penalties for offenders), enhanced regulatory oversight of all elements of the distribution chain, improved collaboration among government entities and a clear communication strategy to raise awareness.

In the EU the Enterprise and Industry Directorate is studying distribution channels in two phases. Martin Terberger, head of the European Commission's pharmaceuticals unit, said that phase I, to be reported in 2008, was focused on medicines looking at "combating counterfeit products" and "safe products in



parallel trade” with phase II reviewing medical devices (to be reported in 2009).

Key topics included in the reviews are internet trading, traceability of medicines, regulatory provisions, import and export control, oversight and enforcement. Ultimately, these assessments will determine whether there is a need for more specific legal requirements to ensure that the EU priorities of public health and protecting intellectual property rights are met.

At a UK level the MHRA anti-counterfeiting strategy is laying out the foundation for co-ordinated action by interested parties, including the Royal Pharmaceutical Society, to help safeguard public health. Guidance on counterfeit medicines specifically for pharmacists is available on the websites for the Society and the MHRA. Buying from reputable suppliers, being vigilant to aid detection, communicating issues quickly to the MHRA and helping manage the interests and worries of the public are all areas where pharmacists can play a leading role in combating the dangers of counterfeits.

Counterfeit drugs can kill and pharmacists can play an important role in helping to eradicate the dangers. Mounting concern about counterfeit medicines has fuelled a range of initiatives by manufacturers to use technology to track and trace medicines. (see Panel).

2-D data matrix coding: a system to combat counterfeiting

The pharmaceutical supply chain is complex, with millions of packs moving around the EU and global markets each year. Fragmentation of the market continues, with a significant growth of wholesale intermediaries and traders involved in the flow of medicines and a decrease in the transparency of the supply chain. The result is that it is more difficult to track and trace medicines.

Health care professionals across the world are increasingly concerned with finding ways of ensuring that the patient receives exactly the medicine ordered by the prescriber and that there is a record of this. As a result, manufacturers conclude that a standardised system of coding medicines would offer a more secure, effective and efficient supply chain.

A number of systems have been offered as possible solutions, including the extended use of barcode systems, radio frequency identification (RFID), and two dimensional (2-D) data matrix codes.

The system that has found most favour with industry in Europe and which has been advocated by European Federation of Pharmaceutical Industries and Associations, the European pharmaceutical trade association representing research-based companies, is the 2-D data matrix system.

The data matrix code is a 2-D matrix barcode consisting of black and white square modules arranged in a square or a rectangular pattern. The

information to be encoded can be text or raw data and the usual data size ranges from a few bytes up to two kilobytes. The length of the encoded data depends on the symbol dimension used. A data matrix symbol can store over 2,300 alphanumeric characters.

The 2-D data matrix system offers the best option of the printed code systems in terms of smaller size on the pack — an important consideration given the increasing requirement for other information on a well populated print space.

In addition to using a 2D code as the data carrier, industry anticipates using a serial number as a unique identifier for each and every unit of use. This will allow a system of validation at the point of dispensing, ensuring that what has been prescribed is dispensed. It will enable the pharmacist to check against the manufacturer’s database to authenticate the product and thereby prevent counterfeit medicines reaching the patient.

The major problem with implementing any recommended system is that of the availability of equipment in the market to read the codes and the need to rationalise existing systems to do this. In this respect there is a wide debate globally on systems for future use in tracking and tracing medicines. Hopefully, this system will offer some resolution to this complex problem in the not too distant future.

ABPI launches website to promote careers in industry

The pharmaceutical industry offers the variety, challenges, opportunities and rewards that accompany the discovery and development of new medicines. In the UK, around £9m per day is spent researching and developing and improving treatments for diseases. The British pharmaceutical industry is credited with discovering more leading medicines than any country except the US. In Britain it employs around 73,000 people directly, with another 250,000 in related industries. People often do not grasp the extent of career choice, which encompasses research and development, manufacturing and supply, and commercial and other areas.

To help address this lack of awareness, the Association of the British Pharmaceutical Industry (ABPI) has developed a career information website for school, college and university students. It includes an area for those,

such as science teachers, who advise young people on possible careers.

Only about 4 per cent of pharmacists working in the UK are employed by the pharmaceutical industry, but they play a vital role in the complex processes of developing and supplying medicines to the market. In research and development, pharmacists provide a key interface between scientists and clinicians. Working as part of a project team, they investigate the biopharmaceutical properties of the compound, formulating and testing the dosage and developing packaging. In clinical research, pharmacists can help assess the safety and efficacy of new medicines and contribute to the entire clinical trial process from planning the trial and supplying the medicine to clinical researchers, to monitoring and reporting on complex studies.

A vital role in manufacturing

Pharmacists play a vital role in manufacturing medicines and a significant number achieve the status of Qualified Person, the individual responsible for approving batches of medicine before they are released to the market. Other areas where pharmacists work include regulatory affairs, patenting, medical information, pharmacovigilance, and sales and marketing.

Work experience or a preregistration placement in a pharmaceutical company is

not essential for a career in industry, although it would help identify opportunities and improve the skills of a new graduate.

The ABPI careers website features profiles and case studies of individuals, showing what different jobs entail, and may suggest areas that would-be entrants had not considered. Some people come into the pharmaceutical industry from other sectors. Clodagh Beckham, a senior medical advisor at Bristol-Myers Squibb, joined the industry as a medical information pharmacist about four and a half years ago, having worked in medical information in the NHS. She sees several options for her future: “There are a wide range of options for me. I could progress to become a disease-area head; I could get a job in our European offices, based in Paris or operating from the UK, or I could move sideways into a more commercial role, such as sales or marketing.”

To find out more about careers in the pharmaceutical industry in the UK visit the website at www.abpicareers.org.uk. If you are already working in the pharmaceutical industry and would like to provide feedback or additional information on any aspect of the site, or if you would like your profile to appear on the site, contact careers@abpi.org.uk. For general information about the industry in the UK see www.abpi.org.uk. — Sarah Jones, head of education, APPI

The code at the coalface

Date: 19 February 2008

Venue: Royal Pharmaceutical Society

Contact: Angela Canning (e-mail angela.canning@rpsgb.org, tel 020 7572 2412).

Topic: Legal requirements and the requirements of the ABPI Code of Practice in relation to medicines advertising

How a sponsor helps a candidate to succeed

Gillian Renouf and Sue Mann, Qualified Person assessors at the Royal Pharmaceutical Society, discuss the sponsor's role in QP accreditation

Achieving Qualified Person (QP) status is not only about attending a viva or submitting an application, it requires knowledge and understanding gleaned through experience, education, support and mentoring by a sponsor. A typical route to QP status takes two to four years. The sponsor needs to support the candidate and provide feedback at every step. The sponsor form, submitted as part of the process, is a key document used to assess the candidate's suitability.

The first thing a candidate needs to do when they have decided to work towards a QP qualification is to find a sponsor who is a member of one of the three recognised professional bodies. Ideally, he or she will be a practising QP; although a well regarded professional as well as the counter signature of a QP could be used. A sponsor should be able to help the candidate determine their route to qualification, which will include theoretical knowledge, experience and ongoing assessment and feedback. When asked by a candidate to act as their sponsor, at the least the proposed sponsor needs to:

- Evaluate how well they know the candidate professionally and whether the candidate has the attributes to be a successful QP
- Assess whether the candidate is capable of making grey area decisions and if the candidate would be able to act as sole decision-maker when significant issues occur

- Determine if they have the time and skill to support the candidate on the QP journey

If the answer to these questions is "no" then the proposed sponsor should think about how this gap could be closed or if this is the most appropriate career direction for the candidate. The proposed sponsor should be honest with the candidate if they feel this career path does not suit the candidate's skills. These discussions need to take place before the candidate embarks on the journey to QP qualification, not after a failed viva. The proposed sponsor also needs to ask themselves:

- How well do I know the content of the study guide?
- Am I up to date with the current law and administration expectations?
- Do I fully understand the entire process a candidate must undergo to become an eligible QP?

If the answer to any of these questions is "no" the proposed sponsor needs to assess how they could close this gap to fulfil their duties as a sponsor. The sponsor is a critical part of the process as the candidate prepares to become a QP. The journey requires a clear plan: personal experience from the sponsor, current guidance notes, annexes, directives and the application form itself are key components necessary when planning the journey. The journey often involves particular education and experience requirements. The

way these are achieved needs to be agreed by the candidate and the sponsor. The sponsor may need to help the candidate overcome roadblocks by, for example, ensuring appropriate time, resources or knowledgeable contacts are made available to her or him.

Once the journey has been planned it requires regular review, evaluation and discussion to assure the candidate's success. The sponsor may also need to set up mock viva sessions to prepare the candidate for this unfamiliar environment.

When a candidate has achieved the necessary knowledge and experience he or she is in a position to submit their application form. This is a chronology of experience and education and should be reviewed and "approved" by the sponsor before it is submitted. The sponsor must provide their report on the candidate before he or she is offered a viva. The sponsor's report should be a well thought through, honest and critical evaluation of the candidate's technical and professional knowledge along with an assessment of their personal attributes in the context of operating as a QP. The sponsor's report is a critical component to enable the assessment panel to evaluate the candidate's suitability and to provide the candidate with the best chance of success.

In summary, the role of a sponsor can take a significant amount of time, but it has the capacity to provide both the sponsor and the candidate with a rewarding experience and positive outcome.

A message for undergraduates seeking a start in industry

Traditionally, many students have found it difficult to get a start in the pharmaceutical industry. There are several reasons for this, but as advice to all who might be interested, I would like to suggest the following.

First, the student should compose a well typed curriculum vitae and a written letter of application. Advice on this can be obtained from a professional in the careers advisory service or, perhaps, a parent.

If the student has a particular interest then this should be stated in their CV. If the student has worked on a project on a topic they found exciting, a one-page summary of that can be included as well. The student should make themselves look interesting and motivated.

To dispel a few myths about working in industry: a PhD is not necessarily required, the student does not need to be amazing academically (eg, rocket scientist of the year)

and the pharmaceutical industry is not a male-dominated workplace.

Working in industry is not "all about pharmaceuticals" and working at a bench, although if that is one's thing then it can be done. In addition, one does not necessarily have to do one's preregistration training in an industrial role to get a position later.

The student should take time over the Christmas period to decide who they would like to work for during the summer months and compile a list. They do not need to restrict themselves to large pharmaceutical companies. Medium and smaller organisations could be considered as well as medical device and diagnostic companies, and, perhaps, even start-ups.

Be motivated and persistent

Some time in the early part of the year students should send their information to

human resources departments at their target companies and follow that up with a call within a week. Students should be prepared to do work that is perhaps more menial than they might wish and be prepared to contribute to their accommodation costs. The Royal Pharmaceutical Society website lists some companies that recruit summer students every year. There are many other organisations that do not put this on the site. Additionally, there is terrific information, created by the Association of the British Pharmaceutical Industry, at www.abpi-careers.org.uk

Obtaining preregistration experience in this sector is difficult, but there are many more opportunities for summer employment. One must be motivated and persistent. There are jobs out there, but one has to go and find them. — *Steve Robertson, IPG committee member and IPG liaison visit co-ordinator*



Future professional body should be responsible for driving the development of the profession

Michael Parker, IPG committee chairman, discusses recommendations that the IPG has put forward as part of a submission for the Clarke inquiry

The Clarke inquiry was established by the Royal Pharmaceutical Society to consult on the future professional body for pharmacy and to report back to the Society's Council with recommendations. The Society is submitting its views and each sector group has been invited to provide input to help shape the Society submission. The IPG committee discussed this topic at a session in October and put forward a range of recommendations to the Society.

It is the view of the IPG that the future professional body should be responsible for driving the development of the profession and its members. It should have a dual role as a public interest body (as enabler and assurer of quality as far as the public is concerned, through delivering the standards defined by the General Pharmaceutical Council) and it should also promote the profession at a strategic level (lobbying and influencing stakeholder groups).

The new body should have a strong relationship with the GPhC and should seek to influence the setting of standards (legal, ethical, clinical and educational, including undergraduate accreditation) by the GPhC and develop guidance for the profession on how to meet the defined standards.

The professional body should support the evolution of the pharmacy curriculum and work out how education standards, set by the GPhC can be delivered. The body should act as the learned society in its interactions and consultations with the GPhC. It should tender for services to the GPhC to administer the degree accreditation scheme and the pre-registration scheme, examination and procedures. The professional body should tender to run the continuing professional development/continuing education/revalidation support activities on behalf of the GPhC.

Finally, the new body should offer services to help members undertake their roles more effectively and help with career aspirations, for example, offering employment, legal and ethical advice, training, conferences, publications, networking and post-nominals.

The committee previously discussed ways to encourage industrial pharmacists to join the new professional body. Training and development opportunities were mentioned and comparisons drawn with services provided by entities, such as The Organisation for Professionals in Regulatory affairs (TOPRA) and the International Society for Pharmaceutical Engineering (ISPE). The committee suggested the new body might at-

tract more industry members if it could demonstrate engagement with licensing bodies, convene more high quality conferences and training courses, and make the most of pharmacy as a unique selling feature.

The professional body, building on the successes of the Society, should consider developing existing services rather than adding services, such as credit cards and insurance. For example, the professional body should focus on developing its website, library or conference facilities and providing central single support to the subgroups within the organisation to support their delivery of beneficial services, such as meetings and conferences.

The IPG committee is broadly supportive of the new professional body having a wider membership. This is likely to be essential for sustainability. Although probably confined to graduate entry, membership should be open to those who work across the industrial pharmacy environment, but who are not necessarily pharmacists, including pharmaceutical scientists, engineers and regulatory or marketing professionals. Students and other linked health care professionals should be attracted to join.

Avoid creating a "class system"

Consideration needs to be given to different categories of membership (fellows, associates, affiliates) and post-nominals should be used to distinguish between categories. Care needs to be taken to avoid creating a "class system" within the membership. Perhaps pharmacists could have a different set of post-nominals to designate their additional professional qualification and the link to registration with the GPhC.

Engagement of the professional body with other pharmacy groups will be important if the new body is to have credibility in speaking for the profession. This should be seen as an opportunity to unite some of the disparate groups under the new professional umbrella.

Engagement with industry depends on what industry sees as the benefit. The professional body could make employers aware of the skills and competencies of its members and the potential value to their organisations. The body could provide assurance to industry that its members were of the appropriate quality to deliver what industry needs. This could be through degree accreditation, diplomas, CPD or CE. The professional body would engage industry through its leadership of key initiatives, such as anticounterfeit strategies, and

would attract interest from industry if it were seen to be influential with stakeholders, such as government and regulatory bodies.

A lobbying role

The professional body should seriously consider its role in lobbying and influencing stakeholders. The ISPE began life as a body that ran conferences and training for engineers working in the industry. Now it is seen as a major influence group due to its credibility, reputation and relationship with the US Food and Drug Administration.

A future professional body for pharmacy should, therefore, consider its lobbying role opposite the Department of Health, Medicines and Healthcare Products Regulatory Agency. Industrial pharmacists and industry-based potential members of the new organisation can offer significant input to the new body through their understanding of how lobbying works. Indeed, they may already be active in this area through other groups.

The Qualified Persons (QP) situation is relevant. There is opportunity for the professional body for pharmacy to take a lead role in the QP environment through the tripartite QP governance arrangements. Keith Ridge, chief pharmaceutical officer for England, recently made reference to the role of hospital QPs at a lecture at the London School of Economics. The Committee requested clarification on whether discussions will take place between the MHRA and the GPhC with respect to who will take account of QPs, for example, who will be expected to maintain the QP register.

From our perspective, pharmacy is a single profession within the whole of the UK and should not be devolved. Geographical and political devolution has resulted in specific Scottish, Welsh and Northern Irish issues, but these should be dealt with within a single professional body if this can be reasonably achieved.

The Society offers resources: intellectual capital, experience, expertise, and some key delivery mechanisms and services (eg, the national boards and branches, processes for quality improvement, advice services, CPD support, library, policy development, practice research, governance policies and procedures). The IPG committee believes that the Society will form a good foundation for a future professional body and that a suitable name for the new body would be The Pharmaceutical Society of Great Britain.