



Industrial *Pharmacist*

May 2005



Dear Reader

Welcome to the second IPG Newsletter of 2005. My colleagues and I were encouraged by the feedback received after the first newsletter.

Since then, the IPG has been busy. In April, we co-hosted a two-day summit on paediatric medicines, a report of which appears in this issue. We intend to return to this topic on Wednesday 28 September, during the IPG session at this year's British Pharmaceutical Conference. Guest speakers include Pat Crowley and Julie Williams. IPG members are invited meet the speakers over lunch.

Also in this issue is an article, by Glyn Taylor, about a visit by pharmacy students from the Welsh School of Pharmacy to Eli Lilly. Hosting such visits is an important means of encouraging students to think about a career in the industry. If you are thinking about hosting visits, and need information on how to structure these, please do contact me at: steve.wicks@pfizer.com.

Many think that in order to become an industrial pharmacist, you must have a PhD or have done preregistration training in industry. This is absolutely not the case. In an attempt to dispel this myth, the IPG will publish career profiles for a number of industrial pharmacists. The first appears in this newsletter, on p14.

Steve Wicks
IPG chairman

Better formulations for children

There is a need to standardise the range of paediatric formulations so that there is consistency in supply, according to Tony Nunn, clinical director of pharmacy, Royal Liverpool Children's NHS Trust. To do this there needs to be co-operation between hospitals, industry and specials manufacturers. There must also be discussions between paediatric pharmacists and paediatricians to rationalise the range of products used.

An opportunity for discussions between various stakeholders arose in April, when a conference, organised by the Industrial Pharmacists Group in association with the Neonatal and Paediatric Pharmacists Group, looked at how to provide consistency in the formulation of children's medicines. Julia Dunne, from the Medicines and Healthcare products Regulatory Agency's post licensing division, emphasised the need for age-appropriate doses for children and outlined approaches being taken to encourage licensing of appropriate formulations (eg, patent extensions).

Drivers for the development of paediatric medicines include disease prevalence, patient demand and the degree of unmet medical need, according to Julie Williams, head of regulatory chemistry manufacturing and controls, at Pfizer. Many companies operate on a global basis and product development is, therefore, affected by rules in other countries. For example, in Japan and the US, the choice of excipients and the levels used in products are restricted, Dr Williams said.

The sharing of information is important and there is a willingness to do so, but there are concerns over whether this could be viewed as promoting "off-label" use. Tim Root, London specialist pharmacist clinical governance and technical services, said: "an unlicensed medicine should be used only when the clinical needs of the patient cannot be met by a licensed medicine." Mr Root said that if a licensed product was not available, using a licensed product from the same class or importing a product licensed in another country should be considered. "Every patient should have access to the medicines they need," he added.

Information

Dr Williams made a plea that information exchange between industry and the NHS flowed both ways. "The NHS has a lot of generic information that would be useful to



the pharmaceutical industry, such as on the acceptability of different dosage forms in children of different ages," she said. The audience agreed that it was important to move away from the assumption that all children cannot swallow tablets — not all medicines are needed in a liquid form.

Selecting the right molecule in the first place is crucial according to Pat Crowley, vice president, product line extension, Glaxo Smith Kline, Philadelphia. There is no point in producing a medicine that no one will take. Taste can be especially important for children, and although the use of sucrose in paediatric

EU Clinical Trials Directive

Don't forget to register for our next meeting, "One year on: the impact of the EU Clinical Trials Directive". This will be held in Lambeth on Thursday 19 May, in association with the Joint Pharmaceutical Analysis Group, the Academy, the RSC and the Hospital Pharmacists Group. Details are available at: www.rpsgb.org/science
Contact Judy Callanan (tel: 020 7572 2261 or science@rpsgb.org)



formulations has fallen out of favour it is still useful in improving palatability, he said.

Dr Crowley highlighted the lack of general information on factors affecting absorption and bioavailability. For example, little is known about gastrointestinal transit rate in children and even less is known about how this varies with age and with different illnesses. This was partly due to the ethical difficulties in performing studies in children.

In addition, when looking at formulations for children, it is important to be aware of a range of idiosyncratic adverse drug reactions (eg, Reyes syndrome with aspirin, hepatotoxicity with valproic acid and cutaneous toxicity with lamotrigine).

Pharmaceutics

A high proportion of medicines for children are either dispensed extemporaneously or are “specials” produced by NHS manufacturing units or licensed specials manufacturers. Ann Lewis, Secretary and Registrar of the Royal Pharmaceutical Society, outlined the professional responsibilities involved in dispensing and supplying extemporaneous preparations and specials. A safe system of work (ie, having standard operating procedures, keeping relevant records and training staff appropriately) is required. Risk assessment and risk evaluation are essential and it is important to check the source of materials used in preparations by having audit trails and quality assurance processes in place.

Knowledge in pharmaceutics is essential for extemporaneous dispensing and specials formulation. However, V'Iain Fenton-May, chairman of the national quality control working party on dispensed non-sterile extemporaneous products, highlighted the concern that pharmacists with skills in this area are being lost from hospitals. The experts are retiring and there is no one to take their places. There is a need to develop clinical pharmacists with a knowledge and understanding of pharmaceutics, Mr Fenton-May said.

Future developments

Dr Crowley considers that pharmacogenetics will be important in the future for deciding appropriate medication for children. Understanding how this varies with age will influence choice of product, dose and frequency. Another suggestion put forward by Dr Crowley was that in the future prescribers may be able to enter a child's pharmacogenetic profile into a computer and a software programme would then chose a medicine. A prescription would then be sent electronically to a pharmacist so that an individually tailored dosage form could be dispensed to meet the child's need. This might involve the use of intermediates (eg, granulates or mini tablets dispensed in smart containers). Pharmaceutical companies might then be responsible for developing and licensing such software as well as producing the product.

Qualified Persons' symposium



Left to right: Graham Davison, pharmaceutical consultant; Peter Gough, David Begg Associates; Cheynee Whipps; David Belshaw, Bioforce Ltd; Sue Mann, Shire Pharmaceuticals; Lynne Byers; Mike Russell, pharmaceutical consultant; Roger Draper, Abbott Laboratories

The law and regulations affecting Qualified Persons are changing at an unprecedented rate, and QPs have recognised their professional obligation to keep up to date with these changes. Nigel Hodges, chairman of the Royal Pharmaceutical Society's QP panel of assessors, said at the eighth joint symposium on the Qualified Person, “Legislation — understanding the practicalities”.

The symposium was hosted by the Royal Pharmaceutical Society, in association with the Institute of Biology and the Royal Society of Chemistry on 15 February, and was chaired by Cheynee Whipps, chairman of the Institute of Biology's panel of assessors. It

covered recent legislative changes affecting the Qualified Person.

The first speaker, Lynne Byers, group manager, inspectorate and licensing at the Medicines and Healthcare products Regulatory Agency, gave an overview of the structure of the MHRA, key changes in legislation and inspectorate findings and sanctions against QPs. Mrs Byers also discussed the role of pharmacovigilance QPs and inspectorate findings relating to pharmacovigilance QPs.

Other topics included the International Conference on Harmonisation guidelines Q8, Q9 and proposed Q10 relating to quality, the Clinical Trials Directive, the Herbal Directive and the issue of dealing with recalls and complaints.

Dr Hodges said: “The joint symposium serves an important role, and the involvement of the MHRA makes it especially valuable”.

The symposium was popular, with 147 people attending. Feedback received from delegates was positive and the technical content and quality of presentations received particular praise. The QP officers of the joint professional bodies welcome suggestions for any future symposium topics. Further information about the Qualified Persons scheme and copies of presentations from the 8th joint symposium are available on the Society's website (www.rpsgb.org). — *Sadia Khan, QP officer, Royal Pharmaceutical Society*

IN BRIEF Student recruitment programme

Steve Robertson, strategic projects director, Controlled Therapeutics (Scotland) Ltd is working to restructure our recruitment visit programme to UK schools of pharmacy. The promotional literature used by IPG visitors has been revised and updated and will be placed on the British Pharmaceutical Students' Association website. The IPG hopes to strengthen its relationship with the BPSA. The BPSA will help publicise visits and, in return, the IPG will provide sponsorship for BPSA events.

Welsh School of Pharmacy visits Eli Lilly



Students from the Welsh School of Pharmacy, Cardiff University, meet staff from Eli Lilly

On 9 February, I found myself driving a group of pharmacy undergraduates along the M4. We had been invited by Eli Lilly to visit its Basingstoke site. Amid the high banter and enthusiastic chatter, I was reminded of a similar trip some three decades earlier, and of being a fresh-faced student and talking with my tutor about career opportunities. Throughout the day I would reflect on how students and the pharmaceutical industry have changed over the decades.

John Kerridge, the site quality leader, and his team gave us a fantastically warm welcome. First we were given a brief history of the company and an overview of the various operations at the Basingstoke site. The students were then split into two groups. One group toured the factory while the other had a series of 15-minute, one-to-one discussions with pharmacists selected from a variety of sectors within the company. The pharmacists

were eager to describe their career histories to the students and talk about their reasons for choosing to work in industry. A number of them had chosen to work at Eli Lilly after working in other branches of pharmacy for a number of years. The students were keen to learn about the day-to-day activities and career prospects for industrial pharmacists and generally glean as much information as possible in the allocated time. Indeed, some students were so interested to find out more that it became difficult, at times, to get them to move on to the next “interview station”.

Many of the students later commented that they were completely taken aback by the variety of different roles for pharmacists in industry. From my own perspective, it was particularly noteworthy that the pharmacists had diverse curricula vitae and had trained beyond the traditional roles allocated to pharmacists.

The lunch-time break was equally educational, with a number of competitions that were both intellectually and practically challenging. After lunch, the groups swapped over. We were given a tour of the factory by one of the old hands who regaled us with stories of how production and quality assurance processes had changed dramatically during his working life. His enthusiasm for the job was infectious and inspired numerous questions from the students.

The Welsh School of Pharmacy is grateful to Eli Lilly for helping our students see and hear about the opportunities in the pharmaceutical industry. The students were highly impressed by the whole event. Their enthusiasm was not quelled by the long drive home and it was rewarding to listen to their sustained interest in the roles of industrial pharmacists and prospective career opportunities.
— Glyn Taylor, senior lecturer, Cardiff University

IN BRIEF

Membership issues

From communications to the IPG, it is clear that the current main concern of industrial pharmacists is Society membership. It seems there are three key questions:

- Should I remain on the Register?
- If I retire from the Register what is the risk that I will not be able to re-register in the future, should I wish to?
- I understand what CPD is and why I should do it, but how do I do it?

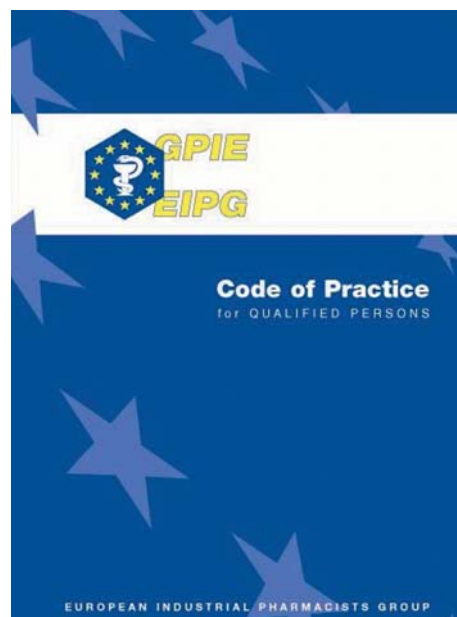
In response, the IPG is designing a series of road shows, to be run in several UK locations. Pfizer (Sandwich), GSK (Herts), Controlled Therapeutics (Glasgow) and Napp (Cambridge) have already offered their hospitality. Contact Angela Canning (angela.canning@rpsgb.org)

EIPG Code of Practice updated

The work of the Qualified Person is carried out across Europe. Local variations that have typically been applied to the pharmaceutical industry in recent years now need to take account of regulations applicable in all member states.

After extensive consultation with representatives of its member associations, the European Industrial Pharmacists Group has updated its Code of Practice for Qualified Persons.

The code is essential reading for Qualified Persons wishing to practise in the EU or release products into member states. It can be obtained from Angela Canning (angela.canning@rpsgb.org) at a price of £2 per copy, including postage and packaging.





GlaxoSmithKline employees pass on insights to Skills for Health

Skills for Health is part of the new network of UK-wide Sector Skills Councils (SSC). The councils bring together employers, trade unions, professional bodies and government to develop the future skills that UK business needs. Each SSC has four key goals:

- To reduce skills gaps and shortages
- To improve productivity, business and public service performance
- To increase opportunities to boost the skills and productivity of everyone in the sector's workforce, including action on equal opportunities
- To improve learning supply, including apprenticeships, higher education and national occupational standards

Skills for Health was established in April 2002 and is licensed by the Secretary of State for Education and Skills, in consultation with ministers in Scotland, Wales and Northern Ireland, to tackle the skills and productivity needs of the health sector. This includes UK pharmacy.

In October 2004, 5S Consulting Ltd was appointed to work with Skills for Health and the Royal Pharmaceutical Society to implement a mapping project. The aim of the project is to prepare a report containing a functional and occupational map of the pharmacy sector including details of further work required to develop occupational standards. The report will also include information about career progression routes, education and training requirements and existing qualification structures used in pharmacy.

5S is working closely with a steering group that represents pharmacy across the UK and regional consultations are being held in Scotland, Wales and Northern Ireland. As part of the initiative, Rodney Amster, project manager from 5S, visited GlaxoSmithKline pharmaceuticals R&D laboratories in Harlow to find out about the various roles and responsibilities that pharmacists undertake in the discovery and development of Medicinal Products. Luigi Martini, Hywel Rees and Maggie McGarry from GSK provided 5S with an insight into the high level of qualifications, competencies and training

required by many personnel in industry in order to perform their day-to-day activities.

Mr Amster was given a tour of the site, including the analytical laboratories and manufacturing and warehousing areas, to demonstrate the various skills required to work in such a highly regulated area of the pharmaceutical sector. Dr Martini emphasised that unlike other branches of pharmacy, such facilities (be they from GSK, Pfizer or AstraZeneca) are regularly inspected by regulatory agencies, such as the Food and Drug Administration, as are the training records and competency of the staff that run them. Inspections can occur at anytime and with minimal notice. A high level of training required to maintain awareness in the latest technological advances and regulatory guidelines from around the world.

The visit allowed 5S to garner an accurate picture of the highly skilled nature of pharmacists roles in the industrial sector of the pharmaceutical profession.

A website has been set up for the mapping project at www.5sconsulting.com/pharmacy

Profile of a pharmacist: Luigi G. Martini, manager, strategic technologies, pharmaceutical development at GlaxoSmithKline

In order to have a career in industry, you do not need to have undertaken your preregistration training in industry. I am a good example of this. After graduating in pharmacy at the University of Manchester, I embarked on a career as a community pharmacist for the Boots The Chemists, completing my pre-registration training in the Wirral.

Although I enjoyed my time in community and learnt a lot about how medicines are used (and sometimes abused) by patients, I realised that my true vocation lay in understanding how medicines are discovered and formulated. I was fortunate to have been taught some industrial pharmacy at university by the likes of David Attwood, John Collett and John Fell — something I would like to see continue, not only at Manchester but in every school of pharmacy in Britain.

I returned to the University of Manchester to start a postgraduate programme and, in 1994, I was awarded a PhD in pharmaceutical sciences. Later, I joined the RP Scherer Corporation (now Cardinal Healthcare) as a senior drug delivery scientist, then SmithKline Beecham in 1996 as a senior formulation scientist.

After a number of roles in pharmaceutical development, I now manage a transnational team at GlaxoSmithKline Pharmaceuticals Laboratories. What my team and I basically



do is explore new formulation technologies and apply them to products in order to improve therapeutic performance. If, for example, we can take a tablet that needs to be taken three times a day and develop a new formulation which only needs to be taken once a day and has fewer adverse side effects, patient compliance and quality of life improve dramatically.

I divide my time between Harlow, Essex, and Philadelphia in the US, where the rest of

my team are located. Being a transnational team allows us to ensure that we are aware of new developments in other industries, such as those in the food, chemicals and cosmetics sectors, on both sides of the Atlantic. We can then assess if and how we can apply these new approaches to our pharmaceutical products.

My working day normally starts at around 8am. The first half an hour is reserved for going through e-mails, a high number of which are from my colleagues in Philadelphia. On a day-to-day basis my responsibilities and interactions vary greatly. I could be meeting with the product teams, discovery teams, other teams within pharmaceutical development, manufacturing groups, marketing teams and patent specialists, to name but a few.

My job has provided me with fantastic opportunities to travel and has allowed me to experience a variety of cultures which, perhaps, I would not have been exposed to in hospital or retail.

Another rewarding aspect of my job is my work with a number of postgraduate students and universities around the UK. Through GSK's collaborations with academia, I manage five PhD and four MSc students and I feel privileged to be able to help develop the pharmaceutical scientists of the future.