



Industrial *Pharmacist*

February 2005



Dear Reader

I am pleased to be able to present the activities of the Industrial Pharmacists' Group (IPG) through *The Pharmaceutical Journal*. The IPG's goal is to maintain links between the Royal Pharmaceutical Society and pharmacists working in the pharmaceutical industry and related areas. The IPG committee met in Ware at the end of 2004 and resolved to focus our efforts in two key areas: supporting schools of pharmacy and pharmacy students to prepare for careers in industry and working with practising pharmacists to develop their industrial careers while retaining options to enter other sectors of the profession.

At a time when many industrial pharmacists are questioning the value of having links with the Society, I hope that the IPG committee can work constructively to show how the industrial pharmacist can get the best deal from the profession. As many organisations are now embracing diversity to strengthen themselves, we also want to collect and focus the intellect and energy of industrial pharmacists to influence the development of the Society in the coming years. I hope that you enjoy this account of our work. We would welcome your ideas and feedback at: steve.wicks@pfizer.com.

Steve Wicks
IPG chairman

The IPG: its functions and aims

The Industrial Pharmacists' Group is a special members' section of the Royal Pharmaceutical Society. Our aim is to represent pharmacists working in pharmaceutical companies, regulatory agencies and consultancies but we welcome participation from any pharmacists with an interest in industrial pharmacy. Membership is not restricted to pharmacists who work in industry. For example, many pharmacists who are academics are also members of the IPG because education plays a vital role in the pharmaceutical sciences.

The IPG encourages pharmacists to work in industry and supports their career and continuing professional development activities. Where appropriate, it will facilitate the transition of pharmacists to, and from, other areas of practice (eg, community and hospital pharmacy). We highlight the benefits of employing pharmacists in the pharmaceutical industry and the value of our contribution to the Royal Pharmaceutical Society and public health.

Some of the activities of the IPG Committee include:

- Organising educational meetings for industrial pharmacists on a wide variety of topics (these meetings are co-ordinated with the Academy of Pharmaceutical Sciences)
 - Participating in the accreditation of pharmacy degrees
 - Providing communication networks for industrial pharmacists
 - Administering the QP accreditation process for pharmacists, in partnership with the Royal Society of Chemistry and the Institute of Biology
 - Arranging visits to pharmacy schools (via an IPG subcommittee)
- In this ever-changing climate affecting the profession (eg, the practising vs non-practising pharmacist debate and mandatory CPD etc), it was decided that the new committee (see Panel, p3) should meet and review strategic objectives for the next three years.
- In a change of convention from previous years, it was decided that this strategy meeting would be held at GlaxoSmithKline's R&D facility at Ware, Hertfordshire. In addition to the IPG, participants included Kevin Altri and Ann Dufton, from GSK, who both facilitated the strategy day, Carol Thomson, from GSK, who is an elected member of the



The IPG at their strategy meeting at GlaxoSmithKline in December 2004



Academy of Pharmaceutical Sciences, Sue Kilby, Society representative and head of practice, and Ann Harrington, a representative of the Society, and Hywel Rees from GSK.

The strategy day covered the following key areas for discussion, debating and brainstorming:

- The purpose and role of IPG: the major concern was the poor visibility of the group as a result of the suspension of the previous newsletter
- The organisation and membership: due to data protection act legislation, the true demography of the IPG has become blurred and there is a concern that industrial pharmacists or pharmacists with an interest in pharmaceutical sciences are being missed
- External drivers of change: this includes the changing role of the profession into a regulatory body and the need for CPD. One worrying trend was the fact that fewer pharmacists were entering industry

In addition, Dr Wicks gave an overview of the IPG to approximately 80 pharmacists from several GSK sites north of London.

Following the presentation, the committee chatted with the audience and garnered their views and concerns. Key outputs and priorities arising from this meeting were as follows:

- To improve visibility of the group and of the industrial sector itself (eg, it was decided that IPG would accept the offer of a pull-out newsletter in the *Pharmaceutical Journal*)
- To conduct a thorough survey of the membership to allow the IPG to update its records
- To collate a CPD advice pack or guidance for industrial pharmacists and ensure it is effectively communicated
- Encourage more pharmacists to enter industry and, therefore, strengthen the IPG university and schools visits

Thanking GSK for hosting the meeting, Dr Wicks commented: "Having listened to the many diverse views, it is clear that CPD, the practice vs non-practice dilemma and managing switches to other branches of pharmacy (eg, community), are major areas of concern that we will address in the coming year."

It's too early to resign from the practising Register, says John Jolley

I expect that this year's notice of retention fees renewal and the requirement to provide evidence of continuing professional development will make many industrial pharmacists question remaining on the register. But I would like to suggest that there are still some advantages to remaining on the practising register and that it is too early to think of resigning.

I will not attempt to justify the level of retention fee, which is necessary because of the state of the Society's finances but I hope that, in time, the Council will revisit this issue.

We are told that CPD is a requirement of the Section 60 Order, which will become part of our regulations but, since this order is not due to come into force until the end of 2005 and the Society will not review CPD evidence before 2006, there is time to reflect and decide what is in your best interest — resigning from the Register is a serious step and may be difficult to reverse.

CPD is not new. Anyone who has had an annual assessment will have discussed their career development and agreed their training needs for the year. What is new is the way in which the Society would have us write up the record of CPD.

To help members and dispel many of the myths that exist about CPD, we are running

a series of regional workshops. So please do not resign from the Register. Contact me at johndrjolley@aol.com, include your registration number and local branch and I will let you know when and where we shall be holding a CPD workshop near you.—
John Jolley is an industrial pharmacist and the Society's Treasurer

IPG committee members

The new committee of the IPG is as follows:

Chairman

Dr Steve Wicks (Pfizer)

Elected members

Jane Nicholson (Bristol-Myers Squibb)

Dr John Kerridge (Eli Lilly)

Dr Mike Parker (AstraZeneca)

Mel Smith (Reckitt-Benckiser)

Michael Murray (ABPI)

Dr Janet Halliday (Controlled Therapeutics)

Co-opted members

Dr Luigi Martini (GlaxoSmithKline)

Wanda Jay (consultant)

Noel Wicks (RPSGB Council member)

Hassan Argomandkhah (RPSGB Council member)

Sue Kilby (head of practice, RPSGB)

BPC 2004: Life cycle management

It was standing room only at the IPG session on life cycle management at the British Pharmaceutical Conference on 29 September 2004. George Swayne opened the session and gave an extremely interesting presentation on patents which highlighted their importance and the increased costs at the end of the patent's life.

We then moved onto a session by Paul Gellert (AstraZeneca) who described how products in some cases were launched for one indication and then at a later stage gained a licence for another. For example, Zoladex started with prostate cancer and then the licence was extended to breast cancer and benign gynaecological disorders. He also illustrated product development using Zomig as an example. First launched as a subcutaneous injection, the first extension was a tablet, followed by a fast melt tablet and a nasal spray.

Lucozade, a product without a patent, was used as an example of re-branding by Steve Jones (GSK Consumer Healthcare). He showed how the advertising campaigns had changed over the years, initially targeted at people who were sick; the product was then relaunched to combat tiredness and is now aimed at the sport and social market.

The final presentation was given by Linda Dodds (primary care trust pharmacist) who gave the NHS perspective. She highlighted the financial restraints that the NHS was operating under and the need to work to the Quality Outcome Framework. Pharmaceutical advisers have concerns over many of the product extensions — as to whether they offered value for money. However, she would like to see more joint working with the industry to develop new drugs that were really needed, improved devices (eg, better designed eye drop bottles so that they are easier to use) and innovative packaging to improve patient safety.

The session was chaired by the IPG chairman Steve Wicks who was delighted by the interest shown in this topic from pharmacists across the profession. Janet Halliday (IPG committee member) commented that it had been a useful and informative session which highlighted areas of general interest across the industry.

Useful Links

To find the industrial pharmacist page on the RPSGB website (www.rpsgb.org) click on "About the Society" then "Membership groups" and then "Industrial pharmacists group". This also leads to information about the qualified persons scheme

General assembly of the EIPG, Cologne 2004



Delegates at the European Industrial Pharmacists Group general assembly

Continuing professional development, in particular the competencies of the Qualified Person and the need for a common European standard for undergraduate and continuing education and training were the main themes of the general assembly of the European Industrial Pharmacists Group (EIPG) held in Cologne last year. As a result, working parties were set up to explore, make recommendations and report on both of these areas.

The EIPG plays an important role in influencing European legislation that is not open to individual country delegations. Pharmacy undergraduate education in most countries is moving from a pharmaceutical science base to a health care focus. In some countries, this is causing a shortage of pharma-

cists in industry and several use active programmes to recruit pharmacists in industry.

The assembly included a feedback session from each of the delegations and a number of common themes emerged. One of these was the need for management skills to be part of all pharmacists' basic training. Another was the importance of a common level of control of industry's sales force activities. Currently, there is major variation between countries on the management of advertising and marketing of medicinal products and more uniform standards should be achieved.

Following industrial consolidation the range of activities available to pharmacists in the traditional areas of R&D, manufacture and quality assurance have become limited in countries such as Finland and Portugal.

The low profile of industrial pharmacists within each national professional organisation was mentioned by delegations. In the Netherlands, Belgium and Portugal, there is a formal process including an agreed period of experience in industry in order for individuals to use the term "industrial pharmacist".

Sue Kilby, head of practice, Royal Pharmaceutical Society, said she found the meeting particularly interesting and useful. It was an opportunity to learn and share experiences. The feedback from the various delegations was particularly informative especially the different ways countries were tracking the distribution of medicines to prevent counterfeiting.

Further information on the EIPG can be found at www.farmaceutbundet.se/eipg/

IN BRIEF

Preregistration programme

GSK is reintroducing a pharmacist preregistration programme after a gap of a number of years.

BPSA

IPG is to work with the British Pharmaceutical Students Association to raise awareness of the different types of jobs open to pharmacists within the pharmaceutical industry

Computer-aided learning

A computer aided learning package on industrial development of drugs is now available. IPG has agreed that this will be supplied free to all accredited schools of pharmacy within UK. Early feedback has suggested that this is a useful learning tool for students.

For further details contact Steve Moss e-mail: prsshm@bath.ac.uk

What pharmacists can do about counterfeit medicines

At the end of August 2004, counterfeit tablets of Cialis were identified on the market in several European countries (lot numbers A031410 and A041410). The matter came to light thanks to a user of the product in the UK. This man was in the habit of taking only half the normal dose by cutting the tablets into equal parts with a knife. One day, he noted that the new tablets obtained from his pharmacy could not be divided as easily as before and crumbled into small pieces each time he tried to cut them. He discussed the matter with his pharmacist who contacted the manufacturer. The batch was investigated and was found to be counterfeit and of sub-standard quality.

This case illustrates that awareness of the risk of counterfeit medicines is of utmost importance for all parts of the drug distribution chain. This is particularly important for pharmacists because they represent the final step in the supply chain. In Europe, the incidence of counterfeit medicines is generally assumed to be low compared with developing countries. However, several recent cases of coun-

terfeit medicines have been detected, so the risk is clearly not negligible.

Counterfeits are increasingly sophisticated. Once counterfeit batches have entered the regular distribution chain, they are hard to detect. Each part of the distribution chain is responsible for doing whatever is necessary to prevent their entry by respecting the rules of good distribution practice. The most important rule is to buy only from reliable sources and suspect unknown sellers and special offers.

This attitude can and must be demanded from pharmacists, but what about the public? For example, an increasing number of people buy medicines through the internet. Pharmacists should inform their patients about the risks of obtaining medicines from sources that can only be judged by an attractive internet page.

Pharmacists should be prepared to look into any abnormalities that come to their attention and inform manufacturers and regulatory authorities if there is any suspicion of counterfeiting.



QP symposium

Legislation — understanding the practicalities. Joint meeting with Royal Society of Chemists and Institute of Biologists.

Date: 15 February

Venue: RPSGB, Lambeth

Cost: £200 members, £300 non members

Contact: Angela.Canning@rpsgb.org

Paediatric medicine

Safe and effective delivery of extemporaneous formulations for children. Joint meeting with the Neonatal & Paediatric Pharmacists group

Date: April (to be confirmed)

Venue: RPSGB, Lambeth.

Contact: Julie.L.Williams@pfizer.com

Clinical trials

Clinical trials — the impact of the new legislation one year on. Joint meeting with Joint Pharmaceutical Analysis Group, The Academy of Pharmaceutical Scientists and Hospital Pharmacists Group

Date: 19 May

Venue: RPSGB, Lambeth.

Contact: John.Clements@rpsgb.org

Join the IPG

This is the first of the new style Industrial Pharmacists' Group newsletter. The content was written by the IPG committee members and the newsletter was produced by the staff of *The Pharmaceutical Journal*, whose support is greatly appreciated. This is a members' newsletter and, hopefully, it will improve communications with pharmacists who are working in the pharmaceutical industry (whatever area), regulatory agencies, academia and consultancies plus those who have an interest in this area of pharmacy.

We are keen to hear from pharmacists working in these areas (at the moment we do not know who is working in industry or associated areas) and to receive contributions for future newsletters. If you work in this area or have an interest in industrial pharmacy then please send your details to the following e-mail address: Angela.Canning@rpsgb.org.

We may, for the purposes of improving communication between industrial pharmacists, wish to share your contact details with other members of the IPG and with the committee; please let us know if you object.

CPD for pharmacists in industry

At the centre of the CPD debate and the “to practise or not to practise” question is the confusion over pharmacy as practised by those of us in the pharmaceutical industry. In today’s work environment few pharmacists in industry have a job description that states the post must be filled by a qualified pharmacist. However, most have their retention fee reimbursed by their employer, which implies a regard for the qualification.

The news feature in *The Journal* on 4 December (p809) was clear in its description of “practise”. Applying the guidance to industry, if a company employs or consults you because of your training as a pharmacist and weight is given to your advice because you are a pharmacist, then you are practising. Enclosed with the retention fee payment form was a useful leaflet to clarify the situation with regard to deciding whether a pharmacist was practising or non-practising. To be a pharmacist one must be on the Register and one must be able to demonstrate maintenance of competency in the field. This means doing CPD and documenting it.

CPD

In common with many other pharmacy specialties people working in industry are expected to show personal and professional development throughout their careers. Good Clinical Practice will have touched all pharmacists working in industry in one or more forms. All of these require evidence to demonstrate appropriate training, level of competence and in some cases expertise in a particular field. Thus pharmacists working in synthesis, formulation, analysis, clinical trials, regulatory and marketing are all expected to keep up to date in their knowledge and document such activities. Indeed those pharmacists who are registered QPs (unfortunately a dwindling number) are expected to keep up to date as a requirement of maintaining their QP status.

A pharmacist, or indeed any professional person, working in the industry acquires new knowledge and updates their existing knowledge in several ways. Thus someone working in a QC role will keep abreast of new regulations concerning detection levels for impurities, a regulatory person will be up to speed on 1 May directives in clinical trials and a marketing expert will be sure to comply with allowed label claims and corresponding promotional activities.

These points all refer to the technical component of a person’s job. In addition, the management and “soft skills” required for career success also need to be kept up to date and improved. So, a seminar on motivation is equally relevant to all managers, irrespective of their qualification, and can count as CPD. Participation in team building courses, qual-



ity improvement programmes and training in modern communication skills are all relevant to CPD as an industrial pharmacist.

Clinical skills

One of the most often asked questions is how an industrial pharmacist can continue to work as a locum in the community or hospital sector. The answer to this is by keeping their CPD up to date for that role. Depending on the area in which your industry commitments find you then you may well be an expert in treatments for hypertension or in the latest statin debate or acutely aware of the need for safe effective anti-arthritis therapy. However, if you wish to continue fulfilling a role as a pharmacist in more front-line clinical areas you must undertake appropriate CPD activities. In association with your service to the NHS the continuing education packages presented throughout the UK are available to all. An evening five times a year is surely manageable for someone who already has time and energy to combine two roles. Articles in the *PJ*, distance learning packages and GP practice based seminars will all serve to keep you up to date. This is without the follow up to questions your colleagues in industry ask about the various treatments they, or members of their family, are taking.

Moving outside the industry to a brand new role is a special case and so the CPD requirements for your new role will require to be assessed and fulfilled. Your employer will surely wish to ensure that you are competent for your new role and the Society sees your preparation for the role as a professional obligation. So what you learn is ideal information for your CPD record.

Clarification

This article has endeavoured to clarify the situation for industrial pharmacists. If your expertise as a pharmacist is being used in your job you are practising. If you are a practising pharmacist then you must be registered as such. If you wish to stay registered then you must be doing CPD. CPD is related to the role that you are using your skills in. So the circle is completed. CPD is no more or less than you would be doing already as a professional. The difference is in recording it, something a pharmacist in industry will already have great skill in.