



# Industrial *Pharmacist*

August 2007

## FOREWORD

### Dear Reader

Welcome to the August edition of the Industrial Pharmacists Group's newsletter. I am pleased and honoured to have been elected chairman of the IPG for 2007–08 and equally pleased that Gino Martini from GlaxoSmithKline has been made vice-chairman. This year will be challenging with both governance and leadership of the profession undergoing fundamental change. I look forward to ensuring that industrial pharmacists have a role to play in determining a vision for the future.

I would like to offer my thanks to the outgoing chairman, Steve Wicks. He has provided high quality, energetic leadership to the IPG for three years. Mr Wicks has been elected to the English Pharmacy Board but has agreed to be co-opted back to us so that we may continue to benefit from his wealth of experience and his link with the new board.

Mel Smith, another former chairman of the IPG, is also leaving the committee. We thank him for serving the group with dedication and tenacity for many years.

I look forward to input from Brian Dougherty, who has joined the committee for the first time. We also have Steve Robertson with us. He has done a great job in recent years promoting industry roles to pharmacy students and linking the IPG with schools of pharmacy.

Although there is to be a formal consultation conducted by the Royal Pharmaceutical Society, we would value your thoughts on the regulation and leadership debate, particularly since our membership fee is set to increase by 50 per cent. Please let us know what would attract you to join a voluntary membership organisation. Send an e-mail to: [michael.parker@astrazeneca.com](mailto:michael.parker@astrazeneca.com)

**Michael Parker**  
IPG chairman

## IPG committee meets to discuss White Paper on regulation

Sadia Khan, IPG secretary, and Michael Parker, IPG chairman, provide a summary of points raised by the IPG committee when it met to discuss the recent White Paper on regulation

**M**embers of the Industrial Pharmacists Group committee recently met to discuss the White Paper "Trust, assurance and safety: the regulation of health professionals" as well as potential functions for a professional leadership body.

The meeting was facilitated by David Pruce, director of practice and quality improvement at the Royal Pharmaceutical Society, and initially centred on discussions concerning the following four challenges:

■ **Supporting specialist and generalist practice (challenge A)** What are the key issues that need to be discussed and resolved so that the professional leadership body will support both generalist, advanced and specialist practice?

■ **Role in education and training (challenge B)** What are the key issues that need to be discussed and resolved around the

role in education and training that the new professional body will have?

■ **Reflecting devolution (challenge C)** What are the key issues that need to be discussed and resolved so that the new professional body can appropriately reflect devolution?

■ **Achieving wide membership (challenge D)** What are the key issues that need to be discussed and resolved so that the new professional body will be able to achieve a wide membership?

The committee agreed that the viability of the new leadership body would largely be determined by the finances it could attract.

In terms of challenge A, it was thought that those working in industry could be regarded as having a specialist (as opposed to a generalist) role. Support needs will take different



The new IPG committee (from left to right): Sylvia Hikins, Jane Nicholson, Janet Halliday, Brian Dougherty, Steve Robertson, John Jolley, Michael Parker (chairman) Gino Martini (vice-chairman) and Mike Murray. John Kerridge and Steve Wicks were absent



forms (political, academic, etc) depending on the type of practice, but it is important that the professional body is seen to support all roles in the different sectors by engaging with pharmacists in these and understanding their needs while providing overarching general support activities which are common to all sectors. A key feature here is defining how the professional body wishes to position itself between the regulator and the profession: is it a college, which has the interest of the public at its centre (as per the Society's Charter), or is it more aligned to its members' interest and their protection?

Challenge B focused on education and training issues. The committee noted that the IPG already provides ongoing support to members (through road shows and seminars, etc) to help meet the Society's continuing professional development requirements. Some pharmacy students may not have a clear idea about the roles in industrial pharmacy and more could be done in this area.

There also needs to be a balance between the scientific and clinical components of the undergraduate degree course. Again, the key aspect is to agree the role of the professional body. For example, the College of Optometrists runs the preregistration trainee year and the examination on behalf of the regulatory body. It also authorises the use of letters that can be put after a member's name to signify membership. It offers higher diplomas in specialties and generates professional guidelines. If responsibility for continuing professional development lies with the

General Pharmaceutical Council, the professional body could offer learning and development opportunities to support pharmacists in this component.

In terms of challenge C (devolution), the committee agreed that most industry issues applied equally across Great Britain.

Challenge D focused on achieving a wide membership and stimulated the most debate. The group discussed ways to encourage industrial pharmacists to join the new professional body. Training and development opportunities were mentioned and comparisons drawn with services available from the following organisations: the Organisation for Professionals in Regulatory Affairs ([www.topra.org](http://www.topra.org)), the Institute of Directors ([www.iod.com](http://www.iod.com)) and the International Society for Pharmaceutical Engineering ([www.ispe.org](http://www.ispe.org)). The committee suggested that the new body might be able to attract 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. It was thought that consideration should also be given to the possibility of different tiers of membership (members, fellows, associates, etc) and working with or merging with other industry-related groups. Any approach to widening membership would need to be carefully done. The new professional body had a role in making representations to the GPhC and would need to be able to engage with its members.

## Functions for a leadership body

Reference was made to Appendix A of "Establishing a professional leadership body" ([www.rpsgb.org/pdfs/cwpsummplb.pdf](http://www.rpsgb.org/pdfs/cwpsummplb.pdf)).

Following a debate it was agreed that in terms of potential functions for a professional leadership body there were three main conceptual areas that needed to be considered:

- Relationship of the professional body with the GPhC — how it might be able to influence or set standards (legal, ethical, technical and educational including undergraduate accreditation)
- How the professional body could help individuals do their jobs more effectively and assist with career aspirations (eg, offer employment, legal and ethical advice, training, conferences, publications, indemnity insurance, networking and post-nominals, etc)
- Services to non-members and what they may require

The committee intends to provide feedback to the Society's Council on issues relating to the White Paper and proposed functions for the new professional leadership body. If you are an IPG member and wish to have your views incorporated please e-mail one of the following committee members by Friday 21 September at: [Michael.Parker@astrazeneca.com](mailto:Michael.Parker@astrazeneca.com) (north of England), [Luigi.G.Martini@gsk.com](mailto:Luigi.G.Martini@gsk.com) (south of England), [Janet.Halliday@ctscotland.com](mailto:Janet.Halliday@ctscotland.com) (Scotland).

## European Medicines Agency reflection paper broadens debate on the developing role of the Qualified Person

In March 2006 the European Medicines Agency (EMA), on behalf of the heads of medicines agencies, issued a reflection paper ([www.emea.eu.int/Inspections/docs/QPdiscrption.pdf](http://www.emea.eu.int/Inspections/docs/QPdiscrption.pdf)) on the handling of minor deviations from the details described in marketing authorisation for medicinal products.

Essentially, the paper described procedures for dealing with exceptional, unplanned and one-off deviations to the manufacturing process and analytical control methods for medicinal products. The paper required that active substance(s) and finished product specifications still be complied with. Any use of the process to deal with the observed deviations had to be under the responsibility of the Qualified Person.

At the time, the European Commission indicated that it was ready, depending on feedback regarding the practical aspects, to support the principles being implemented as an amendment to Annex 16 to the EU's "Good manufacturing practice guide on certification by a Qualified Person and batch re-

lease". In March 2007 the EMA issued a follow up paper seeking the experience of industry on the application of the principles set out last year and asking a number of questions on the practicalities of using the procedures described.

The principles set out in the reflection paper emphasise the important responsibilities of the QP and recognise the professional competence of QPs to assess the significance of deviations in quality terms.

This issue broadens the debate on the developing role of the QP brought about by the amendments to the Medicines Directive 2001/83/EC that came into effect in October 2005. These require certification by manufacturers of medicinal products that active pharmaceutical ingredients used are manufactured in accordance with GMP.

There is also the evolving implementation by the European Commission of the application of GMP for certain excipients as required under the amended Directive. The QP

will also have an integral role in the incorporation of Q8, 9 and 10 (on pharmaceutical development, quality risk management and quality systems, respectively), from the International Conference on Harmonisation guidelines, into GMP principles.

Parallel with all this has been the emergence of the stipulated role of the QP in releasing investigational medicinal products under Directive 2001/20/EC — the "clinical trials directive".

The Industrial Pharmacists Group is seeking to foster debate on these issues with all parties with an interest in the developing role of the QP. It also wishes to encourage pharmacy students and graduates to recognise the ideal nature of the pharmacy degree which helps to meet the required qualifications for becoming a QP.

Progress on this debate as it develops will be reported in this newsletter. — *Mike Murray, IPG committee member, and technical and environmental affairs executive at the Association of the British Pharmaceutical Industry*

# Industrial pharmacists need to be aware of changes on the revised code that will affect them

Lynsey Cleland, head of professional ethics at the Royal Pharmaceutical Society, discusses the revised code of ethics and its relevance to industrial pharmacists

The Royal Pharmaceutical Society's new Code of Ethics for Pharmacists and Pharmacy Technicians and its supporting documents came in to effect on 1 August. A fundamental review of the previous codes for pharmacists and pharmacy technicians was undertaken in response to the changing roles, responsibilities and working practices of the pharmacy profession. The new code has been designed to promote and support the use of professional judgement and reflects the professional considerations facing modern pharmacy.

The revised code is based on seven principles, which govern the conduct, practice and performance of all registered pharmacists and pharmacy technicians. Each is supported by requirements that explain the types of actions and behaviours expected of pharmacists and pharmacy technicians when applying the principles in practice. The seven principles are outlined in the Panel below.

## Fundamental changes to the code

- The revised code applies to both pharmacists and pharmacy technicians on the basis that the same ethical principles should be applicable across the profession
- The principles are intended to be applicable across all sectors of the profession, irrespective of whether an individual is involved in direct patient care or otherwise
- The code has been designed to promote and support a culture of accountability and professional judgement
- The code does not contain detailed technical requirements as in the previous edition but, instead, provides seven supporting documents where further stan-



dards and guidance are required — these are in the areas of patient consent, patient confidentiality, the sale and supply of medicines, pharmacist prescribers, pharmacists and pharmacy technicians in positions of authority, advertising and internet pharmacy

To ensure the new code is applicable to all sectors of the profession, a working group was formed to oversee the review process including representatives from each sector of pharmacy as well as patient and public interest representatives. Gino Martini, a member of the Industrial Pharmacists Group, stood as a representative for industrial pharmacy. Additionally, I attended IPG meetings during the consultation process. Input from the IPG and the wider industrial pharmacy sector was invaluable in helping to shape the code.

The code recognises that the work of pharmacists and pharmacy technicians takes many different forms and, accordingly, not all of the principles will be applicable to every situation an individual finds him or herself in. However, principles that make specific reference to patients, eg, “make the care of patients your first concern” (principle 1), are still applicable to pharmacists and technicians who do not have direct contact with patients. For example, many industrial pharmacists may not interact with patients on a day-to-day basis, but their actions and decisions can still impact on patient safety and care.

Industrial pharmacists need to be aware of the changes on the revised code, which will affect their practice. Principles that may be of particular relevance to industrial pharmacy

include “exercise your professional judgement in the interests of patients and the public” (principle 2) and “take responsibility for your working practice” (principle 7).

The profession of pharmacy has developed considerably since the code of ethics was last reviewed. The revised code reflects and supports modern pharmacy practice while continuing to ensure patient safety and public confidence in the pharmacy profession.

## IN BRIEF

### The Pharma awards

The Pharmas are an exciting new date in the pharmacy calendar. With the support of 21 representative organisations and bodies ([www.pharmawards.co.uk/aboutus.php](http://www.pharmawards.co.uk/aboutus.php)), the new awards dinner will celebrate and reward outstanding achievement in the field of pharmacy. The Pharmas embrace all aspects of pharmacy, bridging together community, hospital, academic, industry, veterinary, and primary and secondary care. With 20 award categories, ranging from “local pharmacy leader of the year” to “lifetime achievement”, there is an award suitable for every pharmacist and pharmacy technician who deserves recognition for his or her contribution to the profession.

For more information or to nominate a person for an award please visit: [www.pharmawards.co.uk](http://www.pharmawards.co.uk).

## Seven principles of the code

1. Make the care of patients your first concern
2. Exercise your professional judgement in the interests of patients and the public
3. Show respect for others
4. Encourage patients to participate in decisions about their care
5. Develop your professional knowledge and competence
6. Be honest and trustworthy
7. Take responsibility for your working practices



## International analytical validation and regulatory issues for the pharmaceutical industry

Date: 1–3 October

Venue: Hilton Hotel, York

## Risk assessment in pharmaceutical research, development and manufacture: the measurement and management challenges

Date: 11 October

Venue: Church House, London

## The ABC of medicines advertising — is it accurate, balanced, clear?

Date: 30 October

Venue: Royal Pharmaceutical Society headquarters, London

Contact: Angela Canning

(tel 020 7572 2412,

e-mail [angela.canning@rpsgb.org](mailto:angela.canning@rpsgb.org))

## Careering towards the future: debating pharmacy education from undergraduate to where?

Date: 12 November

Venue: Royal Pharmaceutical Society headquarters, London

## Critical process parameters in the manufacture of APIs, biologicals, tablets and parenterals

Date: 26–27 November

Venue: RPSGB headquarters, London

Contact for meetings unless otherwise indicated: Julie Churchill at [science@rpsgb.org](mailto:science@rpsgb.org)

# Internships are first step to identifying future GSK scientists

Owen Bain, a student entering his final year of pharmacy at Manchester University next month, recently completed an eight-week internship at strategic technologies, part of GlaxoSmithKline, Harlow. Under the supervision of Christopher Bottrill, senior scientist at the company, he performed particle engineering research involving spray drying, particle size reduction and particle characterisation.

Mr Bain describes his experience: "I applied for a placement in industry to gain experience to further my career and I have achieved this and more. The placement was well organised and enabled me to work on my own projects, talk to other pharmacists and GlaxoSmithKline staff across the business, and gain an insight into the company, industry and career paths open to me. I adapted well to industry and developed a strong work ethic and an understanding of the differences between university experiments and "real world" research. I hope to do my preregistration training at GSK and, after that, a PhD."

Dr Bottrill spoke about the placement: "Supervising Owen has been a rewarding experience, both in terms of the experience I have gained, but also in watching him develop skills and knowledge. He met with staff from the strategic technologies, product development, manufacturing operations science and technology, physical properties and developability, and inhaled product development departments as part of his placement and this helped him to understand the future opportunities open to him when he graduates. He combined providing good research and results with a friendly and open attitude. We all enjoyed having him on the team."

Mr Bain approached GSK after visiting its stand last year at the British Pharmaceutical Conference. His persistence and initiative in



finding the "right person" within the organisation paid off. He contacted Gino Martini and was recruited by me via the Scientific Recruitment Group (agency). I am pleased that we have contributed to this programme, which was fully supported by line management. Mr Bain applied himself to real problems faced by product development scientists investigating how process and formulation variables can affect product performance. I am aware of the need of the company to attract applications from driven and determined graduates and how this can be a first step to identifying good candidates for future GSK scientists. Mr Bain will now be undertaking his preregistration training at GSK. — *Simon Lawrence, Strategic Technologies Manager, GSK*

Advertisement

## CPD workshops

Industrial Pharmacists Group workshops are led by Janet Halliday, IPG committee member and director of research and development at Controlled Therapeutics.

Edinburgh: 29 August

Newcastle upon Tyne: 18 September

London: 20 September

Cost: Free of charge

For further details and registration contact [janet.halliday@ctscotland.com](mailto:janet.halliday@ctscotland.com)