Royal Pharmaceutical Society of Great Britain

Industrial Pharmacist

November 2005

FOREWORD

Dear Reader

I hope you enjoy this edition of the Industrial Pharmacists Group newsletter.

Our progress continues in 2005 with the launch of a joint website with the British Pharmaceutical Students' Association, containing industrial careers information (including electronic versions of IPG brochures) for students. We hope all IPG members will use this facility as a resource and as a means to attract students towards a career in industrial pharmacy.

We are also pleased to announce a new series of continuing professional development roadshows. Members have asked us how they can become compliant with the Royal Pharmaceutical Society's system. Janet Halliday from the IPG committee has organised sessions to explain how to interact with the recording system via practical demonstrations, and will share her experiences as a participant in the Society's CPD pilot project. The IPG hopes to work with the Society to explore ways in which we can accredit large company CPD systems to avoid duplication of effort. For the time being, we recommend full compliance with the Society's system and if you wish to participate in CPD roadshows, send an e-mail to me at steve.wicks@pfizer.com.

Our seminar programme continues and we ran a successful meeting at the British Pharmaceutical Conference 2005 on delivering medicines tailored to the needs of children. This meeting coincided with the publication of the British National Formulary for children and provided a forum for Ian Costello, editor of the formulary, to explain the challenges involved in producing it. We hope to run another meeting on POM to P switches in January 2006.

Steve Wicks
IPG Chairman

Medicines for children — the challenges facing pharmacists

The theme for the Industrial Pharmacists Group session at the British Pharmaceutical Conference 2005 was "Better formulations for children". It was chaired by Steve Wicks, IPG chairman.

Tony Nunn, associate director at the Medicines for Children Research Network (MCRN)) stated that, at present, up to 65 per cent of drugs used in children are used off licence. Even if medicines are licensed for use in children there is often inadequate dosing information or no paediatric dosage form.

This creates all sorts of issues for pharmacists. Ian Costello, editor of the British National Formulary for children (BNF-C) highlighted the problems that pharmacists face when dispensing medicines for children. Evidence for the use of most medicines in children is limited and to find this information it is necessary to look at a number of different sources; the BNF-C has helped to simplify this. Mr Costello emphasised the importance of using an unlicensed medicine only if there was no alternative licensed preparation. It could be necessary to consider using a product licensed in another country. He did, however, recognise that at the present time there is still a need frequently to use unlicensed products in children.

In many cases, even if a medicine is licensed for children, there is not a suitable formulation available and pharmacists often have to consider how to produce a suitable one. This could involve crushing or segmenting tablets, producing powders, using injections orally, cutting suppositories or producing extemporaneous preparations. All of these potential solutions have associated problems, eg, there could be a health and safety risk from dust as a result of crushing tablets or producing powders, especially if a cytotoxic is involved. There is no guarantee that if a solution is made from a solid dosage form that the active ingredient will be uniformly dispersed, so there are concerns over dose uniformity, bioavailability and stability. For these preparations there is also a lack of information for the child or parent with there being no patient information leaflet for the product.

Many extemporaneous preparations or "specials" have no standard formulation, eg, clobazam suspension, for which there is known to be at least 15 different extemporaneous formulations. The dose uniformity and bioavailability of the preparations may vary and in most cases has not been studied.

As there is no standard formulation for most "specials", problems arise when children are managed by GPs, as the GPs are often unfamiliar with how to prescribe the medicines and may write prescriptions without stating a strength or formulation. Community pharmacists can be equally unsure as they may not know what is to be dispensed, where to access the product or what information to provide. The patient could therefore receive a product with a different bioavailability and end up under- or over-dosing.

Pat Crowley, vice-president, product line extension, GlaxoSmithKline, Philadelphia, outlined the factors that need to be taken into consideration when formulating medicines for children. He stated that children are different and should not be seen as small adults. He outlined how children have differences in

gastrointestinal function and how this affects drug absorption. Disposition, metabolism and clearance also vary in children depending on their age. This all means that there is a risk of increased toxicity for some drugs.

Julie Williams, senior director of regulatory chemistry, manufacture and controls at Pfizer, stated that there were a number of challenges for paediatric formulations. As children's needs vary with age there is a need to have a diversity of formulations, eg, liquids, suspensions, and chewable tablets for different ages, but they must all permit accurate dosing. There may also be regional variation in acceptance of colour and flavour.

Mr Crowley posed the question: "Will there be a need for greater diversity of dose regimens in paediatrics, consequent to advances in molecular biology, knowledge of pharmacogenomics and clinical medicine?"

He considered that greater flexibility in dosing will be required so that medicines are "personalised" for the paediatric patient. The traditional methods have been dilution of liquids and subdividing dosage forms; however, in the future, medicines may be assembled from the required number of "low dose" mini or micro-units for individual patients.

When considering formulations for children, it is especially important to have needle-free injection techniques and palatable oral, liquid medicines. It maybe a trade off between solubility and taste but there is no point in producing a product with a bitter taste that a child will not take.

There is a need to consider making adult dosage forms more child-friendly by facilitating extemporaneous conversion to a liquid. This can be done by using excipients that disperse readily in liquid vehicles, that do not have a poor taste or mouth feel and with tablet coat components that dissolve readily.

Dr Williams outlined changes to regulations which are expected to encourage increased licensing of medicines for children. The changes have already been a success in the US where the six-month extension of exclusivity has boosted paediatric research. By the end of July 2005, 113 approved drugs had been granted exclusivity and there had been 93 labelling changes. Further information can be found on the website: www.fda.gov/cder/pediatric/wrstats.htm.

The Medicines and Healthcare products Regulatory Agency (MHRA) and the Department of Health (DoH) have requested marketing authorisation holders (MAHs) to submit existing paediatric data. The MHRA has offered free paediatric scientific advice and fee waivers. In May 2005 the European Medicines Agency (EMEA) requested paediatric data from MAHs for centrally approved products.

The EMEA has produced a reflection paper on formulations of choice for the paediatric population. This provides general information to consider when formulating medicines for children. It looks at the needs of the different age groups and discusses routes of administration and dosage form options. It is thought to be the precursor to a potential guideline.

To increase the availability of licensed paediatric medicines Dr Williams stated the need for a solid regulatory framework, a strong academic infrastructure for clinical research and a strong pharmaceutical industry.

To help increase and support research in August 2004 the DoH announced the Medicines for Research Network (MCRN).

Ian Costello speaks at the BPC session

This was awarded to the University of Liverpool consortium. The MCRN will establish local research networks and clinical study groups. It will also liaise with other countries and the pharmaceutical industry to streamline trial adoption. The clinical study groups will cover a range of topics including asthma, infection and immunity, anaesthesia and intensive care, gastroenterology, hepatology and nutrition, neonates, neurology, pharmacy and pharmacology, respiratory conditions and cystic fibrosis.

The MCRN proposes to work with industry to act as a single point of access to explore trial feasibility, provide consistent standard procedures for trial set-up, research and development approval, contracting and costing. It will help to increase trial recruitment as it will have access to UK-wide multiprofessional academic and NHS resources. Potential access to a large UK population for multi-centre trials will particularly help in recruitment for trials in rare diseases. There will be simultaneous collection of outcomes, resource utilisation, symptom control and other types of data, in addition to more traditional primary and secondary endpoints. It is envisaged this will reduce the time necessary to produce the required information for licensing. Further information about the UK MCRN can be found on the website: www.liv.ac.uk/mcrn.

At the present time, pharmacists are still faced with using a significant number of medicines off licence for children, which may need to be made into extemporaneous formulations. Mr Costello said that until there is a standardisation of paediatric formulations there is a need to have clear policies and procedures for the management of paediatric "specials" across a locality, which would include both primary and secondary care.

Slides from these presentations will be available on the IPG page of the Society's website: www.rpsgb.org.uk/members/society/ipg.htm. — *Sue Kilby, head of practice, Royal Pharmaceutical Society*

MEETINGS

Contact for all meetings: Judith Callanan at science@rpsgb.org.

Managing pharmaceutical quality throughout the product life cycle

Disseminating the most current news and views from the International Conference on Harmonisation working groups and to discuss experience obtained by regulatory authorities and the industry. Joint meeting with the RPSGB and the International Pharmaceutical Federation.
Date: 21–22 November
Venue: RPSGB, Lambeth

Residential course: tableting technology

The formulation, production and properties of pharmaceutical tablets. Includes basic concepts of equipment selection, granulation and end-point determination, formulation optimisation and prediction, in-process monitoring, film coating and official and non-official dissolution tests, and development pharmaceutics for registration purposes.
Date: 28–30 November
Venue: De Vere University Arms Hotel, Cambridge

Intelligent method development

Joint meeting with the Pharmaceutical Analysis Group.
Date: 8 December
Venue: RPSGB, London

Challenges in small scale manufacturing

Joint meeting with the Academy of Pharmaceutical Sciences and RPSGB.
Date: 7 February 2006
Venue: AstraZeneca, Loughborough

Launch of careers website with BPSA

Gautam Paul and Steve Wicks: encouraging students to access information

The Industrial Pharmacists Group hosted a lunch at the British Pharmaceutical Conference 2005 to launch a website with information on career opportunities for pharmacists in industry. This website can be found by visiting the British Pharmaceutical Students' Association (BPSA) website or directly at www.pharmcareers.co.uk.

The IPG made the decision earlier this year that instead of producing another careers brochure, which would quickly become out of date, that it would work with the BPSA to put the information on its website. It would reach the target audience and be available to students and pharmacists whenever they wanted it. The information would also be easy and quick to update. Steve Robertson (director of strategic projects, Controlled Therapeutics) and Richard Taggatt (IT officer, BPSA) worked together to get the information in an appropriate style and onto the website.

The BPC lunch was well attended by students and pharmacists working in industry who heard speeches from Gautam Paul (president of BPSA), Steve Wicks (chairman of IPG) and Gerald Alexander (Vice-President of the Royal Pharmaceutical Society) welcoming this step forward.

The students and pharmacists were delighted that Hemant Patel (President of the Society) made a surprise appearance at the lunch, taking time out from his busy schedule. He wanted to offer words of encouragement to the students for their careers as the future of the profession rests with them.— *Sue Kilby, head of practice, Royal Pharmaceutical Society*

Upcoming CPD roadshows

Non-company pharmacists are welcome to attend these roadshows. As places are restricted please check availability via the relevant e-mail contact or alternatively: Janet.Halliday@ctscotland.com.

Date: 21 November
Venue: AstraZeneca
Location: North West
Contact: Mike Parker
(michael.parker@astrazeneca.com)

Date: 7 December
Venue: Pfizer
Location: Kent
Contact: Steve Wicks
(steve.wicks@pfizer.com)

Date: 24 January 2006
Venue: Controlled Therapeutics
Location: Scotland
Contact: Janet Halliday
(Janet.Halliday@ctscotland.com)

Date: February 2006
Venue: GlaxoSmithKline, Ware
Location: Hertfordshire
Contact: Gino Martini
(luigi.g.martini@gsk.com)

Date: March 2006
Venue: Napp
Location: Cambridgeshire
Contact: Derek Prater
(Derek.Prater@napp.co.uk)

General assembly of the EIPG meets in Varese, Italy, 21–22 May

Industrial pharmacists from associations in the Czech Republic and Malta joined the European Industrial Pharmacists Group (EIPG) for the first time as full members during the EIPG general assembly in Varese, Italy. A new association from Ireland, the Technical Industrial Pharmacists and Pharmaceutical Scientists Association also joined.

The working group for "Undergraduate education and training" was updated on the Italian education system by Professor Carla Caramella from the University of Pavia. The meeting noted that the majority of countries in the EU appear to be adopting the Bologna declaration and working with the model of 300 credits over five years. It was agreed that competencies of the workforce in the pharmaceutical industry for 2010 need to be evaluated and that minimum competencies, in terms of subject knowledge and teaching methods, should be reassessed in conjunction with other pharmacy streams and the European colleges of pharmacy. Subjects considered missing from European undergraduate courses will be discussed with European community and hospital pharmacists groups.

The working group for "Continuing professional development and the Qualified Person (QP)" discussed a survey undertaken among the membership by the Italian delegation. Key points discussed were the "Annex 16 requirements", points 8.3 and 8.4 from "Minimum requirements" and the professional obligation to broaden one's knowledge when moving from one area of manufacture to another. It was agreed that "Minimum requirements" should be satisfied by continuing education and responsibilities lay with the QP, the providers of continuing education (CE) and with the competent authorities who should assess, audit and certify CE providers and QP compliance. It was agreed that the working group should put together proposals on the methods of implementation.

At the meeting, Silvia Fabiani from the Italian Regulatory Agency discussed the work of the Committee for Human Medicinal Products and future challenges for the European Medicines Evaluation Agency.

The results of a usage survey carried out on the EIPG website were also presented and policy rules for the website will be agreed.

A 2005–06 strategic plan for EIPG was agreed upon and the Danish delegate was elected vice-president for the next three years. — *Jane Nicholson, regulatory affairs manager, Bristol-Myers Squibb.*

Exploring industrial pharmacy as a career option: Sharon Mackay writes about her experience

After completing my first year of pharmacy at the Robert Gordon University in Aberdeen I was eager to explore industrial pharmacy. I considered it to be one of the most appealing sectors on offer with its strong emphasis on science and the opportunity it presents to work with other scientific professionals.

I invested a lot of time and energy researching contacts within the pharmaceutical industry using resources such as the internet and literature. I wrote to many companies explaining my interest in undertaking work experience with them, and my efforts were rewarded when Controlled Therapeutics in East Kilbride replied. They invited me to spend a period of five days "shadowing" the industrial pharmacists.

First impressions

On arrival at Controlled Therapeutics I met another pharmacy student from Strathclyde University who was also curious about industrial pharmacy. She had just begun her preregistration year in community pharmacy but had arranged to spend the day at CT to find out more about industry. It was a nice surprise to meet another student to compare our thoughts about our degree and industry. We were soon both introduced to Janet Halliday, director of research and development, who welcomed us warmly to the company.

Janet Halliday and Sharon Mackay at Controlled Therapeutics

Dr Halliday began by introducing us to the company, its history, and the research and development the company undertakes. This was a good starting point for me as I was not aware of the company's activities in detail.

I learnt that CT is a secondary manufacturing company because it buys drugs from a primary manufacturer and combines it with a patented drug delivery system; a hydrogel polymer which enables controlled release of the drug into the body. Their products cover different therapeutic indications and include a product for inducing labour in women, one for the treatment of bacterial vaginosis, and another for xerostomia, a symptom of Sjögren's syndrome.

Roles within manufacturing

We were fortunate enough to speak with John Jess who spoke to us about the role of a pharmacist in manufacturing. He delivered an interesting picture of this function and introduced to us the role of a Qualified Person, which I had never come across before and which sounded interesting.

Dr Halliday listed various websites set up for industrial pharmacists for me to explore. This was useful to me as I could follow up on information about Qualified Persons in industry and browse through career profiles of industrial pharmacists.

After speaking with Dr Jess I met two other QPs at Controlled Therapeutics. They spoke to me about their positions. I also learnt about the role of a pharmacist in the clinical and regulatory sectors, which are further alternative pathways for industrial pharmacists.

Roles within development

I had the opportunity to speak with Denis Carr, an analytical chemist, who explained the analytical department and the careers that on offer in this field.

I was lucky enough to watch two company presentations from chemistry MSc students on their projects. I was able to pick up on good presentation skills for the future. It was also interesting to learn of the outcomes of their research. I spent time with Dr Halliday in meetings concerning costings for clinical studies and formulation. Although I had no input to the discussions, it was good for me to experience this type of business meeting on commercial making, to watch the sharing of professional viewpoints agreement on topics concerned (synergy).

I met Mark Livingstone who spoke about the formulation department within the company. I was particularly interested in this area as it covers a wide range of roles and seems to require an indepth grasp of chemistry knowledge which was appealing to me.

Conclusion

I thoroughly enjoyed my time at CT and would recommend and encourage other pharmacy students to venture into work experience early in the course of their degree. I would advise not to let distance be a limiting factor when applying to companies. I was lucky enough to work during the summer break and save in order to fund myself financially to undertake this placement. I was also fortunate to have two lecturers willing to act as referees in support of my applications.

I would like to thank Dr Halliday and her colleagues for organising events and accommodating me. — *Sharon Mackay, Robert Gordon University, Aberdeen*

IPG liaison visits to schools of pharmacy — speakers list for 2006

Each year the Industrial Pharmacists Group liaison visits take place at participating schools of pharmacy. The office holds a list of speakers which is used by team leaders to select their panel members in preparation for these visits. There is a need for more volunteer speakers and, in particular, industrial pharmacists who are at the beginning of their careers, as students relate most to this situation. We would also welcome industrial pharmacists with wide experience in the pharmaceutical industry, as students are interested to hear about career path histories and are keen to find out more about opportunities and scope for promotion.

If you would be interested in giving presentations and informal chats with students please contact Angela Canning (e-mail angela.canning@rpsgb.org or telephone 020 7572 2412) who will provide you with a form to complete with your details.

Calling all pharmaceutical companies

The Student Exchange Programme is offered to pharmacy students all over the world via the International Pharmacy Students Federation (IPSF) and is administered in the UK by the British Pharmaceutical Students' Association. The BPSA would like to encourage all members of the pharmaceutical industry to consider being a host. It is a very rewarding and beneficial scheme.

For more details and an information pack e-mail: seo@bpsa.com.