

europaean INDUSTRIAL PHARMACY



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Editor's note

The article referred to in the description of the last issue's cover photo has not been included.

Cover photo: Printing medicines (see article on page 7)

Message from the new President, Mr Jean-Pierre Paccioni

Since 21st April when I was elected as the new President of the European Industrial Pharmacists Group (EIPG), I have realised that following Professor Gino Martini is a real challenge. Throughout his presidency, Gino succeeded in developing EIPG as an Association that is, and can be seen to be, a key player in industrial pharmacy and a point of reference for industrial pharmacists. EIPG has a very professional Bureau, a new financial process, a firm foundation, growing influence and membership and a common vision of the importance and impact of industrial pharmacists on the pharmaceutical environment.

I am pleased to take over the presidency of EIPG to give a new impetus to the Association and to benefit from the pharmaceutical expertise of the different member countries. Industrial pharmacists in Europe should get to know each other better and raise their profile to be recognised by the European institutions.

Taking into account the current and future challenges facing the pharmaceutical industry, some of the strategic orientations of my 2013/2016 mandate are as follows.

- To reinforce the partnerships with key stakeholders, such as the European Commission, the European Medicines Agency, the European groups of community and hospital pharmacists, the European trade associations, universities and non-European Union (EU) representatives, such

as the International Conference on Harmonisation and the United States Pharmacopeia.

- To develop and support working groups, with leadership given to each country delegation, and a mixture of both general topics, such as ethics, pharmacist's roles and training promotion, public health concerns, and European regulations, and more technical aspects, such as recommendations on cold chain transport, ambient transport, medicine shortage services, international good distribution practice, good practice for over-the-counter products, generics and biosimilars, and raw material sampling.
- To widen the visibility of EIPG and its working practices through a strengthened website.
- To continue to develop the influence and work of EIPG by increasing members' participation across the EU and to encourage the presence of observers from non-EU countries.
- To implement new EIPG internal rules and establish a new finance commission.

I am confident in the success of EIPG, thanks to the active participation of its members, their personal involvement and background experience, all of which will contribute to the recognition of industrial pharmacists within Europe and globally.

Best wishes
Jean-Pierre Paccioni

Joe Ridge, pharmacist, publisher and CEO of Euromed Publications died of pancreatic cancer on 8th August. As well as a number of other scientific publications, Joe was Editor of "European Industrial Pharmacy", our EIPG Journal. An inveterate traveller and fluent in French, Joe enjoyed attending the General Assemblies of the EIPG. Joe was a clever, articulate and fine gentleman. He will be sadly missed by all our delegations. Our condolences go to his wife Shirley, their two sons and families and all staff at Euromed.

Joe Ridge 1937-2013

FROM PUSH TO PULL MARKETING IN HEALTHCARE

by Morten Hjelmsoe

- **Major industry and societal trends pose a challenge to traditional customer engagement.**
- **New technology offers the opportunity to think differently about communication.**
- **Digital sales tools enable us to switch from low-value message delivery to high-value individualised communication.**

Morten Hjelmsoe is CEO and founder of Agnitio, based in Copenhagen, Denmark. He explores the opportunities that the life science industry is now enjoying from a form of communication that's always just for you.

Trends driving change in healthcare communication

There are a number of trends, both in society at large and specific to the life science industry, that together pose a major challenge to how companies engage with their customers.

The first is a switch from products to services. This 'beyond the pill' world is rapidly coming into being, driven partly by the increased focus on patient outcomes. Consequently, companies have to now consider total treatment – ensuring not only effective medication but also compliance and lifestyle changes among many other factors. This move to services means that companies have to work ever more closely with healthcare professionals, seeking increased partnership and co-operation.

There is, unfortunately, a parallel trend that is the decreasing effectiveness of traditional customer engagement. Counter-intuitively, increasing advertising spends and scaling up sales forces appear to result in less time to communicate and less engaged customers. So while companies need to engage more closely with their customers, they are finding that the more that they try to reach out, the farther away customers seem to get!

This brings us to the next trend, one that I call the rising price of brain real estate. We all see

thousands of marketing messages and have media streaming, beaming and blasting information at us 24/7. As our minds fill up, we're increasingly choosy about what we decide to put in there. For healthcare professionals, the situation is no different – perhaps even more extreme. Increasing demands on their time, challenges to their authority and a feeling that they are already over-marketed to, means that they are actively closing themselves off from the industry.

At the same time, medical professionals also have to deal with increasingly complex treatments. They have to know more than ever – especially now that we see the beginnings of another major trend that is individualised medicine.

It all adds up to an interesting dilemma: physicians do need information but are increasingly resistant to traditional approaches, while life science companies need to be more involved in patient treatment but are finding it ever harder to connect. What to do?

A question of relevance

To respond to these trends, I believe that we need to rethink our approach to communication. With traditional marketing, there is an underlying problem: relevance. Because industry communication doesn't address healthcare professional's specific circumstances

and needs, it doesn't receive much attention. Why would it? Time is scarce, there are lots of things on the physician's mind, and the communication is seen as not particularly important. So it gets ignored. Consequently companies feel that they now have to communicate more and shout louder. This increases the frustration from customers who, understandably, make themselves harder to reach. And so it continues, resulting in the industry and its customers drawing ever further apart.

To reconnect with our customers, I believe that we need to change our understanding of what pharmaceutical marketing is for. Rather than see the problem as one of getting attention (more reps, more advertisements, bigger conferences), we should, instead, see that it's really about transferring knowledge. If we look at it like this, we shouldn't really be 'attention seekers' but rather 'information transporters'. So the question then becomes: how do you best transfer knowledge?

From push to pull communication

The introduction of new technologies enables us to think differently about communication. While we often talk about Closed Loop Marketing here, I actually prefer the term 'pull marketing' or 'pull communication'. It's not a big deal, but it more clearly demonstrates the difference from traditional 'push' forms of customer communication. Put bluntly the difference is:

- a push communication is what I want you to know;
- a pull communication is understanding what you need to know.

'Push' is what we've been doing for years. It's the mass communication of messages. It's fundamentally about dealing with people as groups rather than individuals. In effect, that means providing the same message for everyone and delivering it in the same way and at roughly the same time.

I like to think of this as acting like bus drivers. We have a destination in

mind for healthcare professionals; we plan out a route to get them there – all according to a strict timetable, with everyone travelling together and at the same speed (Figure 1).

The problem with this is that customers are all individuals. They each have their own particular set of knowledge, interests and needs.

Sometimes, they'll know a lot about a topic, so don't need a lot of information to understand it. Sometimes, they have a low level of knowledge and will need to stay on this topic for longer. And sometimes, they'll want information that simply isn't on the route. Push marketing can't easily account for such personal needs. The result? We're pushing our customers to go places they have no interest in being.

By contrast, pull communication requires that we act more like taxi drivers (Figure 2). This is a much more empowered position. Here, our job is to react to people's individual needs and work out the best route for them. Asking "where do you need to go?" is fundamentally different from asking "do you want to go here?" It's also much more likely to get a positive response!

A virtuous circle

It's technology that has enabled this switch from acting like bus drivers to being customer-responsive chauffeurs. We can now put physicians in charge of the conversations. For example, digital sales tools not only make things look engaging, they actively engage – allowing healthcare professionals to choose the topics that they are interested in. So, during a discussion with a company representative, for example, medical professionals can actively pull the information they want.

This is just the starting point. Smart digital sales tools allow us to take note of each medical professional's particular interests as

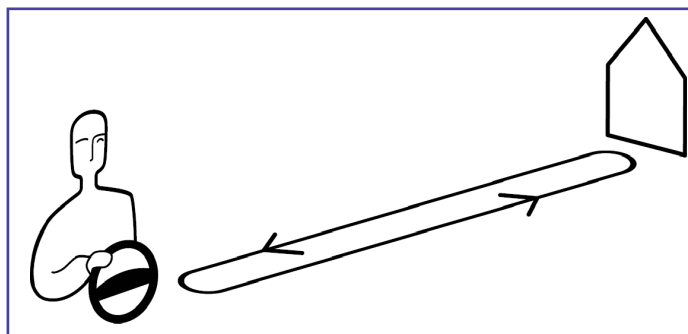


Figure 1: Traditional push communication.

they interact with the systems. That way we can return later to provide more relevant information on a topic that they've already expressed interest in. And it continues this way – continually developing a better customer understanding that further powers the provision of high value and very relevant information.

Importantly, such rich data isn't possible with traditional push marketing. If you're only pushing information, you can only learn how 'pushy' you are being. It's like measuring the bus driver – you can track the route, time, stops, delays, etc., but you'll know little or nothing about the passengers or where they actually want to go.

To get to a virtuous circle of continually improving customer understanding (and, therefore, better communication), you need to be capturing rich data and that's only possible if you're having a rich data conversation. In other words:

you have to be doing pull marketing.

Applying technology in this way not only empowers the physician but us too. Good digital sales tools aren't about automation but rather empowerment. With the right tools, we and especially our sales forces get 'upgraded' from deliverers of messages to

responsive consultants who ensure that each of their customer's needs are met. In other words, our reps can make individual strategies to respond to the greater understanding that they now have of their customers. This is something that our sales executives have been dreaming of for many years.

Personalised channels

In addition to empowering us to meet individual customer's information requirements, we can now also pay attention to how they want it delivered. After all, what's the point of talking at exactly the right knowledge level, if the information isn't available when and where it is needed? What we must do is get the right information in the right channel at the right time (Figure 3).

We live in an age when digital information should flow to wherever we need it. Mobile communications

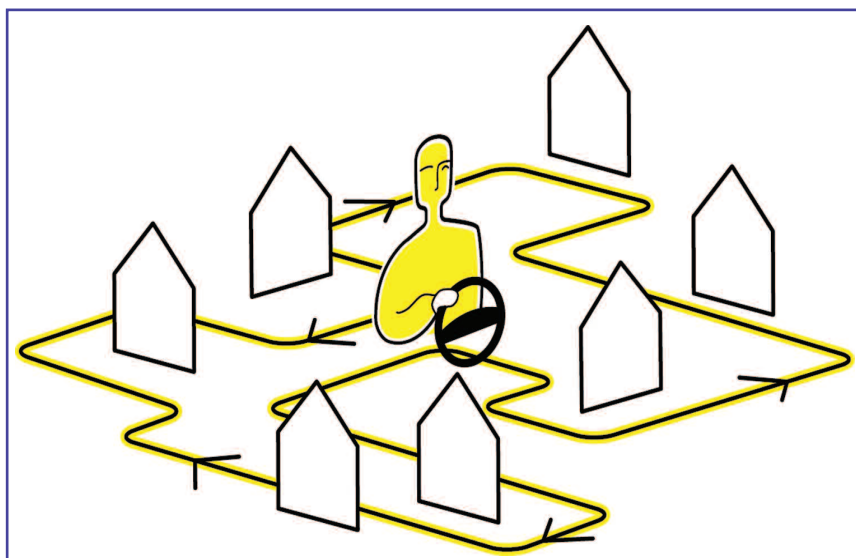


Figure 2: Individualised pull communication.

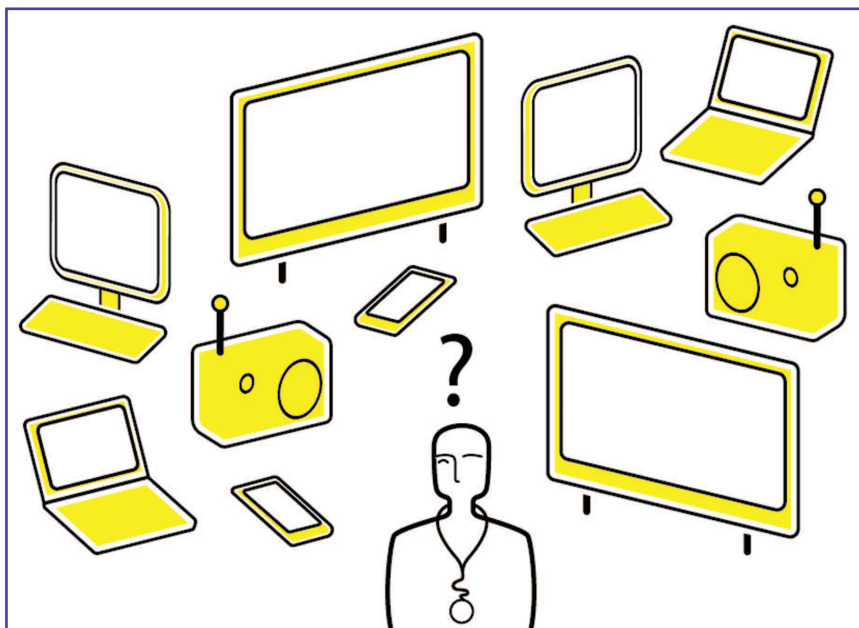


Figure 3: Mobile and multichannel communication.

aren't mobile because we carry them around in our pockets. It's truly mobile when it's always there – delivered in a form that's right for the context that you're in. Everyone increasingly expects this from his or her media and it's what healthcare professionals are expecting too.

This is actually a major opportunity to make our communications more relevant. We can now not only

personalise the information to individual requirements, but the delivery mechanism too. Whether the physician wants the knowledge on a mobile device, through eMagazines, eTraining or a face-to-face meeting with a sales rep, they can get what's most relevant for them.

In fact, we can personalise further with the perfect match of desired

content and delivery mechanism. What this means is that the move from push marketing to pull communication is a switch from saying "here's what we want you to know in the form that we think is best" to saying "here's the precise knowledge you're seeking – presented in a way that's just for you."

Future trends

The good news is that, while there are major communication challenges, our industry is responding. There is now an awareness of the issues and a desire to make changes. New ideas are emerging and opportunities previously under-exploited – not least the application of new digital technologies – are now being widely introduced. We are moving towards more responsive and personalised forms of communication. We really are shifting from a push to a pull. This not only dramatically improves the quality of service that we provide our customers but also means a better perception of the industry as a whole. If we stay on this track, the future trend for the industry looks very positive.

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PRINTING MEDICINES

by Simon Gaisford

Printing technologies have advanced significantly over the past 20 years and many 2D (liquid) and 3D (solid) printers are commercially available. Modern 2D (ink-jet) printers are capable of producing upwards of 20,000 5–15pL droplets of solution per second. While they are typically designed for producing images on a flat substrate, the capacity to jet small volumes with such exquisite control has led to the use of ink-jet printing in many diverse fields, including the pharmaceutical sector, usually for controlled deposition of actives onto a substrate. The latest design of 3D printers use a heated nozzle to melt an extruded polymer – the molten polymer solidifies on a build plate and the printer constructs an object in 3D layer by layer. 3D printers have many potential biomedical applications (such as printing bone or tissue scaffolds) and have recently been used to print unit dosage forms. In either case, printing technology has the potential to revolutionise the manufacture of medicines over the next decade.

Dr Gaisford is a Reader in Pharmaceutics at University College London and runs a research group looking at the effect of physical form on pharmaceutical product performance. He uses thermal ink-jet printing to prepare oral dispersible films and inhalable particles and to isolate polymorphic forms. He has published more than 60 papers, 5 book chapters and 2 books. Email: s.gaisford@ucl.ac.uk; Web: <http://iris.ucl.ac.uk/iris/browse/profile?upi=SGAIS88>

2D printing of drug solutions is the most straightforward application of ink-jet technology, since this is analogous to printing an image (it is also possible to print suspensions, if the particle size of the disperse phase is suitably small that the print head nozzle does not become blocked). The solution is printed onto a substrate to create the final dosage form. The substrate can be a tablet, powder or polymer film. One immediate benefit of printing the drug onto a substrate is that it is possible to manufacture a wide range of unit doses (by varying either the concentration of the drug solution or the area being printed), which brings the paradigm of personalised-dose medicines closer to reality. It would, in principle, be possible to manufacture, at the point of dispensing, medicines with a dose specific to individual patients. The advent of multi-colour

cartridges also means it is possible to print combination products (containing more than one drug).

One consideration with ink-jet printing is that the volume of liquid printed is usually small, which means that the dose range achievable is usually narrow. In my experience, a single print pass can achieve doses of up to 50 µg/cm² (the value is dependent on the solubility of the active pharmaceutical ingredient). As such, ink-jet printing lends itself to formulation of highly potent, low-dose actives. The fact that it is likely that a potent drug will also have a narrow therapeutic index (meaning the dose will vary from person to person) further highlights the potential of the technology for manufacturing personalised-dose medicines.

A dosage form becoming increasingly popular is the oral-dispersible film (ODF). These are polymer films designed to dissolve on the tongue. Popular for consumer healthcare products (such as breath fresheners), they are increasingly being used for delivery of drugs (for instance, benzocaine for relief of flu symptoms and simeticone for relief of bloating). ODFs are usually cast from a solution of drug and polymer and so the drug is homogeneously dispersed throughout the film. Ink-jet printing can be used to print the drug onto a substrate film. As noted above, this increases the range of doses that can be manufactured. It also means that the drug is located

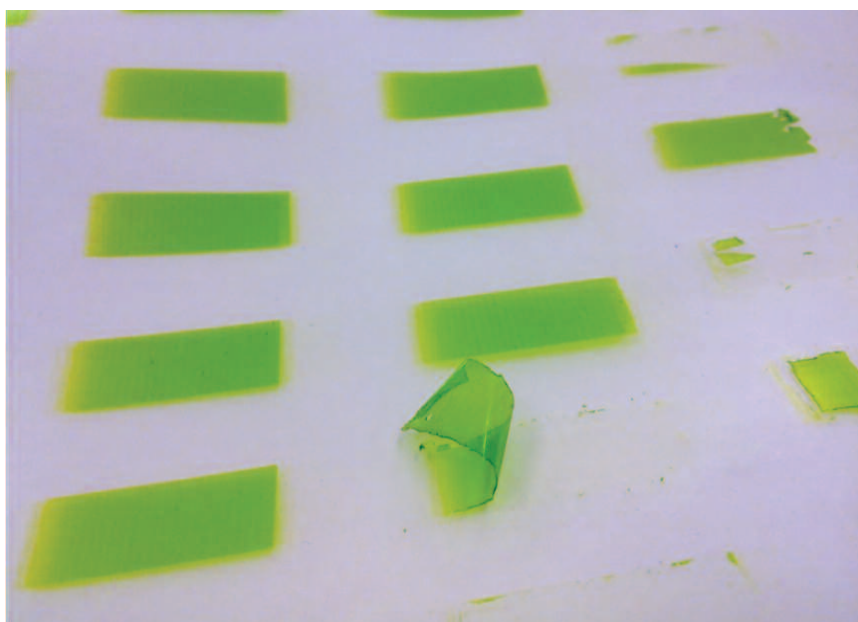


Figure 1: Individual ODFs printed with a 2D ink-jet printer.

on the surface of the film, rather than throughout the polymeric matrix. In the case of cast films, if the drug concentration is above its solubility, there is the possibility that crystallisation might occur during storage. There is also the possibility that the drug itself may act as a plasticiser for the polymer in a cast film, altering its mechanical properties. Both these issues are avoided with printed films. An additional formulation advantage of printing the drug is that it can be located on one surface of the film, so if the film is designed for buccal delivery, it can be ensured that the drug is in direct contact with the site of absorption.

Ink-jet printing may also be used to manufacture an ODF directly, by adding a polymer to the solution to be printed (Figure 1 shows a film that was printed onto an acetate backing sheet). This means that the drug could be co-printed with the polymer to produce a film analogous to those made via conventional casting. One immediate benefit of this approach is that it is possible to ensure drug-loaded film does not come into contact with a cutter during punching (a process that often creates nucleation points and so can potentially lead to crystallisation of the active upon storage).

2D printing can also be used in the production of 3D dosage forms and devices. For instance, if the print head is mounted above a liquid reservoir, then it is possible to produce colloidal suspensions (by printing a drug solution into an antisolvent), liposomes (and liposomes incorporating drugs), reservoir-type microparticles, polymer microparticles for sustained drug release and inhalable particles (Figure 2, the latter by printing into liquid nitrogen and freeze-drying the resulting frozen solid). It is also possible to coat pre-manufactured medical devices with drug or tissue cells. For instance, ink-jet printing has been used as the final manufacturing step in the production of drug-eluting stents. Recently, a bio-ink has been

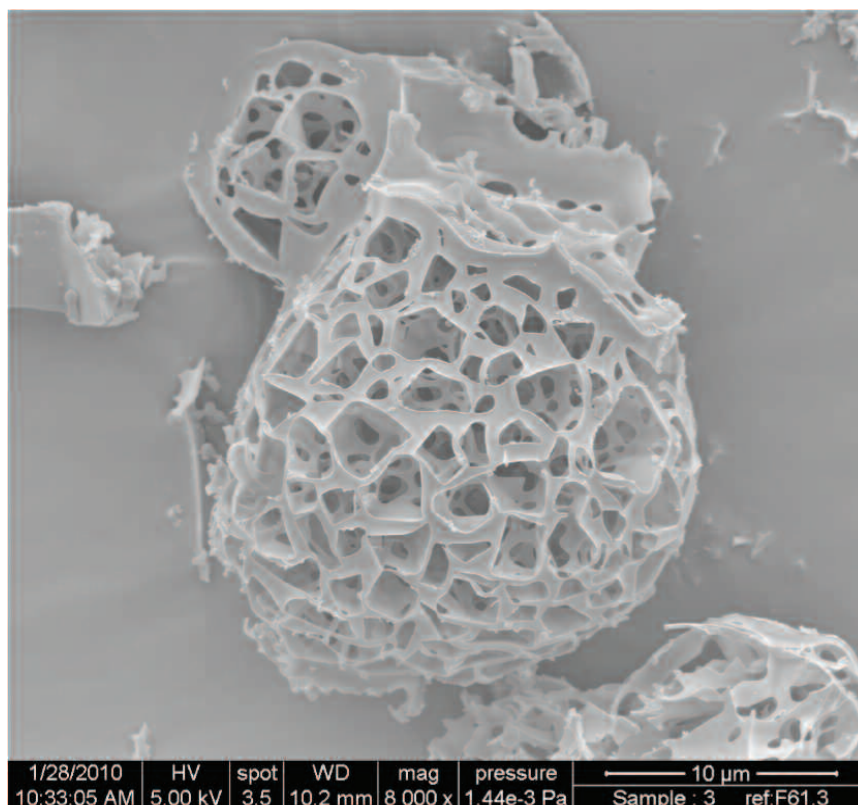


Figure 2: Inhalable particles of salbutamol sulfate, prepared by printing an aqueous drug solution into liquid nitrogen.

developed that maintains the viability of living cells while in the printer cartridge and that prevents blockage of the nozzle during printing.

3D printing permits the manufacture of larger structures and/or solid unit dosage forms, usually by controlled layer-by-layer hot-melt deposition of an extruded polymer or drug-polymer blend. It is possible to print modified release tablets with layers comprising different polymers and/or drugs and so control the drug release profile. It is also possible to print tablets of varying size, and so, again, there is application to production of personalised dose medicines. Increasing in complexity, it is also possible to print a polymeric or cellulosic scaffold upon which tissue cells can be printed, with application to replacement skin, cartilage and organ regeneration.

In summary, printing technology has the potential to revolutionise the manufacture of pharmaceuticals, especially in the context of personalised dose medicines and in

the construction of 3D matrix devices.

Further reading

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PHARMACY IN NORWAY

by Wenche Gordon

Throughout history, pharmacists have had the responsibility to provide high-quality medicinal products to the population, and contribute to the wellbeing of the people they serve. This may also be one of the reasons why the manufacture of medicinal products has long been heavily regulated and carried out by members of a profession with the particular qualifications enabling them to succeed in this intricate work.

Wenche Gordon obtained an MSc Pharm degree from the University of Oslo in 1971. She has been employed in community and hospital pharmacy in Norway and England for 10 years, and worked for a brief period at the Norwegian Medicines Agency. She has more than 30 years' experience in the pharmaceutical industry in various positions and with several companies, but with regulatory affairs as her main field of occupation. She is currently employed at Pronova BioPharma in Oslo as Regulatory Project Director.

Historical background

The regulations of the pharmacy profession in Norway were introduced with the Royal Decree/Medicinal Act of 4 December 1672, at a time when the country was still under Danish rule. This law served as a guarantee for supply of high quality medicines to the population and as a contract between the pharmacy owner on the one side and the King and society on the other by leaving the pharmacists a generous enough economy to purchase materials of the best quality for the products they compounded. This law was, in principle, in force until 2001 when a major deregulation took place, allowing "anybody" to actually own a pharmacy as long as a qualified pharmacist was employed to take care of the actual dispensing. A more than 400-year-old tradition was thus abandoned.

Historically, the training of pharmacists took place in the pharmacies with the final exams being made under the auspices of certain pharmacy proprietors and the Medical Faculty of the University. After the responsibility of education of pharmacists was taken over by the University of Oslo in the early 1900s, the great discoveries within medicine and biology of the late 19th century had a large impact

on the teaching programmes¹. The broad scope of the education of pharmacists in Norway thus gave the profession a good basis for positions in the pharmaceutical industry from the time this industry emerged, and this tradition has been sustained to the present time. Since the number of students admitted to the Institute of Pharmacy was very limited until recent years when pharmacy training was also established at other universities, the meticulous selection of students also contributed to give the profession an additional high quality. This provided a good foundation for pharmacists to succeed in the pharmaceutical industry.

However, in most positions in the pharmaceutical industry, pharmacists do not have a professional monopoly like in the pharmacies, but have to compete with other academically trained professionals. The majority of pharmacists have nevertheless chosen community or hospital pharmacy as their place of work, for which the training is directly adapted.

Pharmaceutical industry in Norway

Manufacture of pharmaceutical products was gradually separated from pharmacy shops, whose

premises, until the 1980s, were also equipped as small manufacturing plants, and shifted to the pharmaceutical industry where only large-scale manufacturing not dispensing of medicines took place. The latter was restricted to be carried out in pharmacies only. The first pharmaceutical companies were established in the latter half of the 19th century. In 1913, there were 24 manufacturers of "pharmacy products and poisons that had not been produced by pharmacies", and, in 1914, a law concerning the processing of toxic substances and other pharmacy products was passed in parliament. This law specifically required that the technical director of a company should have a degree in pharmacy as well as pharmaceutical experience, which caused a certain resentment among pharmacy proprietors and their employee pharmacists, and an attack on the "speculators in patent medicines" was published in the, at that time, existing pharmaceutical journal. Above all, the most offensive issue was the fact that the venues for the manufacturing of medicinal products were outside of the traditional pharmacies².

However, the principle that a qualified pharmacist should be responsible for the manufacturing was maintained in the industry, in the sense that the law required such qualified staff to approve final production batches. Since Norway is a member of the European Economic Area and has fully implemented EU regulations with regards to the manufacture of medicinal products, and, in this respect, is accepted by the EU at the level of other members, this position is carried out by the Qualified Person function, for which a pharmacy degree is more or less mandatory. Pharmacists have, therefore, had an important position in industry from the very start, and this has been continued throughout the years.

The first pharmaceutical companies in Norway were established and owned both by pharmacists and those with other backgrounds. As they grew in size

and expanded their activities, they were gradually taken over by multiple owners, and some were structured as share companies from the start. In the beginning, the manufacture was intended for supplying the domestic market. Later, several of the companies succeeded in considerable export of their products. In addition to their own products, they could also be representatives and partners for foreign pharmaceutical companies, and could have a wide portfolio of imported product for sale in Norway. This part of the business gradually changed as the foreign companies established their own sales offices in Norway. We, therefore, saw two categories of industry being established, manufacturing-based companies and office-based affiliates of foreign companies. The latter often had pharmacists as their leaders when they were set up, but this has gradually changed over the years to include other professions.

Health policy and the pharmaceutical industry

From a political viewpoint, the pharmaceutical industry has traditionally been seen as a supplier/vendor of pharmaceuticals to the health sector and an expenditure on the national health budget, not as a contributor to the domestic product and an important employer of highly qualified workers. The domestic industry has, therefore, had little governmental support, and several of the previously Norwegian owned companies have ended up with foreign ownership through mergers and acquisitions. This has invariably led to reduction of activities and a considerable downsizing. Only one foreign company has built up a new manufacturing site in Norway. This took place nearly 40 years ago, but the plant, now owned by Fresenius Kabi, is still operating very successfully.

The current policy with regards to medicinal products is partially based upon the 2004–2005 White Paper (Stortingsmelding Nr. 18) approved

on 11 March 2005. There are three principal goals recommended in the paper.

- Medicinal products should be used correctly, both from a medical and economic viewpoint.
- The patients shall be guaranteed access to effective medicinal products, independently of their ability to pay.
- Medicinal products should have the lowest possible price.

Thus, economical considerations have a dominating role in the making of political decisions. Naturally, this has led to a very high rate of use of generic products. The White Paper does not mention much about pharmaceutical industry, but what is written shows little confidence that there will ever be a development of this industry of any sizeable proportion in the future.

However, in recent years, there have been signals from the government side that biotech research and innovation should be appointed as an area of priority, and there are now possibilities for relatively generous government

funding for research-based companies. Thus, several small start-up research-based companies are now emerging, some with promising results from their research. So far, only one of them (Photocure) has reached the market with their own cancer treatment products, of which they now have a considerable export. This company was established in 1997 and carried out the development of their product based on research conducted at the Norwegian Radium Hospital.

The pharmaceutical market in Norway is dominated by imported products, as shown in **Figure 1**. This has, in recent times, been an issue of discussion, since both the number of manufacturing facilities with equipment and the number of personnel with the competence to operate it, is now considered to be approaching a critical low limit should an emergency occur, such as a pandemic.

The most successful Norwegian manufacturing companies have specialised in niche products, and their export figure is high compared

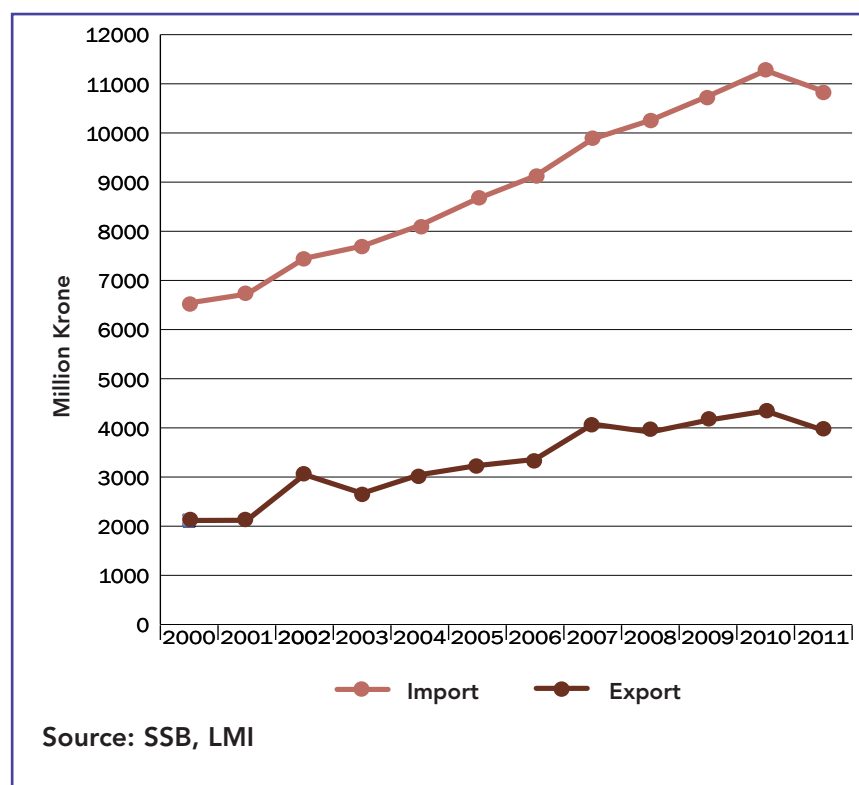


Figure 1: Value in Norwegian Krone of imported and exported pharmaceutical products in Norway during the period 2000–2011⁴.

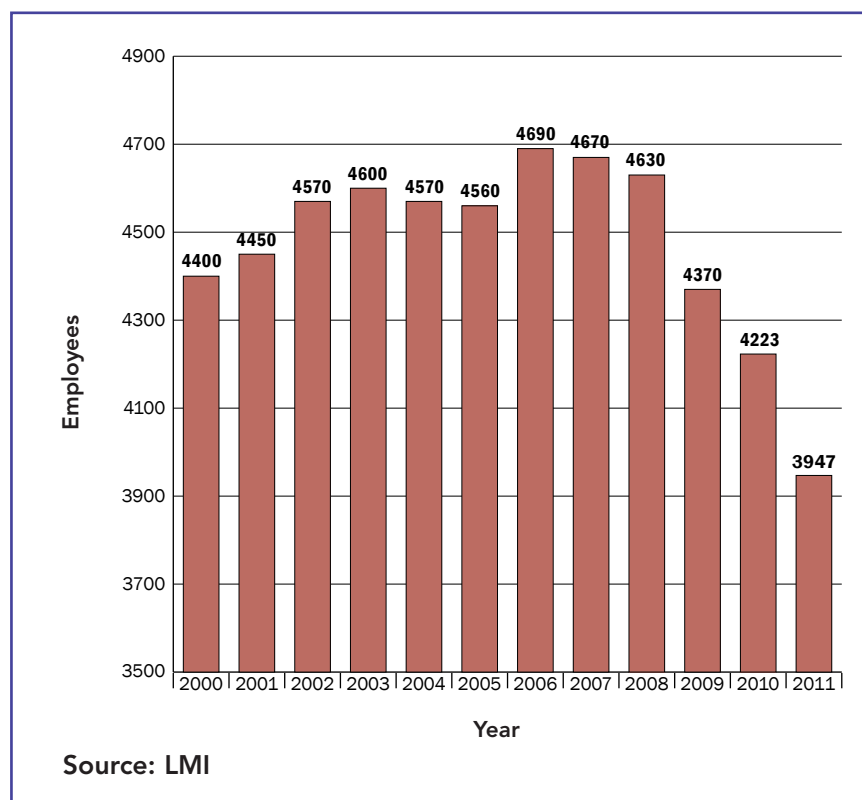


Figure 2: Total numbers of employees in the pharmaceutical industry in Norway during the period 2000–2011⁴.

to the sales on the domestic market. In addition to the previously mentioned company Photocure, we have one of the world's biggest developer and manufacturer of X-ray contrast media and other imaging agents (formerly Nyegaard & Co., now GE Healthcare), the world's largest manufacturer of omega-3 fatty acids for medicinal use (Pronova BioPharma) and a developer and manufacturer of fish vaccines of considerable importance on the world market (Pharmaq).

Today there are 11 companies with manufacturing licences in Norway. They are mainly situated in the Oslo area, but a few have manufacturing plants in the area surrounding the southern part of the Oslo fjord. GE Healthcare have their large active pharmaceutical ingredient manufacturing plant on the south coast, and Pharmaq have established their plant manufacturing fish vaccines in the area north of Trondheim. The manufacturing companies had approximately 2500 employees in

2010, and there were approximately 1500 employees in the importing companies.

During the last two decades, several Norwegian consultancy companies have been established, and they have been steadily increasing their number of staff and offered attractive positions to academics with suitable background, among them pharmacists. The positions in question are office-based like regulatory affairs, or related to clinical trials. Also, a few pharmacists have been attached to foreign consultancy companies for similar assignments in Norway. The development with regards to employees can be seen in **Figure 2**.

Unfortunately, there are no good recent statistics for the proportion of pharmacists among the total number of employees. The last reliable and accurate figures are from 1998³. In this survey, the total number of pharmacists employed in industry was 322 and 5 employed with clinical research organisations. Approximately 200 of those were

employed in companies with Norwegian ownership and manufacturing in Norway at that time.

Although several employers have carried out considerable downsizing with consequent loss of work places, the emergence of the new research-based start-up companies have been able to absorb the most competent and experienced professionals, to the mutual benefit of both.

Pharmacists occupy a wide range of positions within the industry in Norway. The educational background, in many cases with further specialisation, opens practically any position within research and development, manufacturing, quality control, regulatory affairs, medical affairs, pharmacovigilance, business development and sales. There are, therefore, also many pharmacists at various management levels right up to top management.

The industry thus has a long tradition for being a popular place of work for pharmacists, offering good career possibilities and opportunities for specialisation, in addition to an inspiring cross-professional environment. Those of us who work in the industry hope that a further expansion of this work market will still be seen, at least of a sufficient size to catch up with the number of recently lost positions.

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THE NEW GDP GUIDELINES

by Siegfried Schmitt

On 7 March 2013, the European Commission published the Guidelines on "Good Distribution Practice of Medicinal Products for Human Use" (2013/C 68/01). This new GDP Guideline is a 14-page document that replaces the previous version from 1994. It applies not only to the wholesalers and manufacturers of pharmaceuticals, but also to brokers. The guideline came into force on 8 September 2013.

Siegfried Schmitt is a Principal Consultant in PAREXEL's Strategic Consulting team. His key areas of interest are agile quality systems, competitive compliance and QbD. He has over 20 years' experience in the pharma and medical device industry. He joined PAREXEL in 2007.

The role of the Responsible Person

With this new regulation comes key changes for wholesalers. In particular, the role of the Responsible Person has been defined in much more detail. This is a role comparable to the head of the quality unit. The regulation specifies that the Responsible Person should fulfil their responsibilities personally and should be continuously contactable. The Responsible Person is only allowed to delegate duties, but not responsibilities. Depending on the scale of the wholesale operation, including warehouses and distribution, this may require several Responsible Persons in support of being continuously contactable. Though it is not detailed further in what timeframe and by what means the Responsible Person should be contactable, it is reasonable to assume that this should at the most be within a few hours, e.g. in the case of a recall.

As expected, the Responsible Person should have appropriate competence and experience as well as knowledge of and training in good distribution practice (GDP). In addition, the guideline states that "A degree in pharmacy is desirable". No explanation is given for this peculiar expectation, nor is it made clear what acceptable alternatives may be. There is no obvious reason why a person with a different professional background should not

be capable of performing the duties of a Responsible Person. Persons having wholesale expertise and an understanding of GDP can, in fact, come from any walk of life. Furthermore, few companies employ a pharmacist in the role of the Responsible Person, as wholesale and distribution is not a classical field of expertise for pharmacists. The danger is that we may see a similar diversity in requirements within the European Union (EU) Member States for the professional background of Responsible Persons as is already the case for Qualified Persons.

Wholesalers and brokers

Whereas the 1994 guideline only referred to wholesalers, the new guideline affects both wholesalers and brokers. The difference is that wholesalers must be licenced and brokers must be registered in a Member State of the EU. The regulations go even further, requiring that brokers must have a permanent address and contact details in the Member State where they are registered. It is not clear if statistics are available that would show how widely broker services are used for medicinal products. Thus, the impact of this regulation is not immediately obvious. Nor is it known whether the limitations put on brokers, such as EU residency, will have an impact on drug supplies for the EU. What is, however, clear is that many EU

regulatory agencies are not yet prepared for this change in the regulations. The author's attempts at finding out via the internet how to register as a broker in various EU countries failed miserably. It is questionable whether all agencies have a system for broker registration in place.

The Quality System

The directive requires both wholesalers and brokers to operate a Quality Management System (QMS), which is something new for brokers. As this requirement applies, irrespective of size of the organisation, it will be interesting to see regulatory expectations on how an individual, who operates as a broker, will have to self-audit him- or herself, or how detailed the standard operating procedures will have to be written for the person to understand what they are doing. This is not to say that a QMS is not a necessity, merely that the actual intention of the guideline is not always entirely clear.

Quality Risk Management (QRM) is now a must have element of the QMS. This is certainly a sensible requirement, given the many benefits of QRM, particularly as it helps document rationales and reasons for operational and organisational set-ups. However, it cannot be expected that wholesalers and brokers will have a sound understanding of this requirement, and thus be able to comply with ease. Even the drug substance and drug product manufacturers struggle with the implementation of QRM. All too often, performing a few risk assessments is considered sufficient for achieving compliance. This is, of course, far from adequate.

The directive also brought about some significant changes affecting warehouses, in particular, with regards to storage and segregation, and computerised systems. The standard requirements for restricted access and segregated areas for medicinal products can still be complied with either through physical segregation or by means of a validated computerised system. This is aligned with the good manufacturing practice (GMP)

requirements. In deviation from the GMPs, medicinal products received from a third country, but not intended for the EU market, have to be physically segregated. The same requirement for physical segregation now also applies to expired product. Especially in fully automated warehouses, where product location is randomly assigned by the automated system, and current status (e.g. released) traceability is assured through the validated computerised system, this will potentially require either changes to the program logic plus the associated revalidation activities, or creating a physically segregated solution outside the automated warehouse. In either case, warehouse operators will incur extra cost. This effectively applies dual standards to the acceptability of computerised standards under GMP and GDP.

The directive also addresses Computerised Systems Validation. Computerised systems need to be validated or its fitness for purpose demonstrated through verification studies. What constitutes "appropriate verification studies" though remains a total mystery. It is accepted practice that quality relevant records need to be retained

for certain periods of time. Why the authors of this guideline decided to codify that back-up data (not the records!) are to be retained for a minimum of 5 years at a separate and secure location is another unexplained mystery. Back-ups are generally kept for a week, by which time they have become obsolete. Not even Annex 11 of EudraLex Vol 4 details such requirements. Again, the GDP guideline is not aligned with those for GMP.

Summary

Despite these issues, the guideline certainly strengthens compliance and strengthens supply chain security. For most wholesalers, and possibly the vast majority of brokers, this directive will require them to amend, change or even build from

scratch Quality Systems that meet these requirements. For the pharmaceutical industry's auditors, it means being acutely aware of the subtle, but important, differences between GMP and GDP, and for the regulatory authorities, it means putting in place processes and procedures for the registration of brokers and the inspection of wholesalers and brokers against their licence or registration. For consumers, these tightened regulations may potentially lead to certain drug shortages. Wholesalers and brokers, and ultimately the pharmaceutical industry, will offload the increased cost this directive brings with it onto the consumers, i.e. the patients. Strengthening supply chain security and patient safety comes at a cost.

Editor's comment:

"EIPG, in its responses to consultation documents on the Falsified Medicines Directive and the Commission's GDP Guidelines, has expressed its opinion that failure to establish minimum qualification requirements, responsibilities and professional accountability for the Responsible Person in a manner concordant to those of the Qualified Person, is a major shortcoming of the Directive. In the absence of such provisions, EIPG believes that a pharmacist represents the class of professional whose undergraduate training best encompasses knowledge of the necessary legislation, quality assurance and quality management principles, and an understanding of medicinal products at such a level as to be able to implement the conditions necessary for their safe transport and storage."

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COMPETENCES FOR INDUSTRIAL PHARMACY PRACTICE IN BIOTECHNOLOGY – THE PHAR-IN PROJECT

by Jeffery Atkinson, Jane Nicholson, Bart Rombaut

The PHAR-IN consortium (538252-LLP-1-2013-1-BE-ERASMUS-EKA) consists of pharmacy faculties and industrial partners from countries of the European Higher Education Area (EHEA), members of the European Association of Faculties of Pharmacy (EAFP; www.eafponline.eu/), together with a professional organisation representing industrial pharmacists, the European Industrial Pharmacists' Group (EIPG; www.eipg.eu/). PHAR-IN is funded by the European Commission (EC) via its Education, Audio-visual and Culture Agency (EACEA; http://eacea.ec.europa.eu/index_en.php).

Jeffrey Atkinson is Emeritus Professor at Lorraine University and Executive Director, Pharmacolor Consultants Nancy (pcn-consultants), Villers, France.
Jane Nicholson is Executive Director of the EIPG, Paris, France.
Bart Rombaut is President of the EAFP and Head of the Department of Pharmaceutical Biotechnology and Molecular Biology, Faculty of Medicine and Pharmacy, Vrije Universiteit Brussels, Brussels, Belgium.

The aim of the project is to recruit a panel of industrialists and educationalists that will propose a list of competences and outcomes required for education in biotechnology for future and current employees in the pharmaceutical industry. These will then be ranked using Delphi methodology in importance by a wider panel of industrialists and academics (drawn in a first stage from EIPG and EAFP membership with a snowballing effect for recruitment of others). Using several rounds of the Delphi process, a consensual, hierarchal list of competences and outcomes will be produced and possible factoid competences removed. The list will then be used to adapt the education and training in biotechnology given at higher education institutions (HEIs).

All information will be freely

available, with no copyright or ownership issues involved, to other European organisations, professional associations, HEIs, big pharma, etc. wishing to produce similar courses. Through its European network of Member Associations, the EIPG will advertise the results of the project to employees of the pharmaceutical industry. The EAFP and the PHARMINE network will ensure dissemination to academics. In all cases, dissemination will be through classical channels: websites, conference presentations, email newsletters and journal articles.

This project will have a substantial impact on employees of the drug industry, providing them with the skills they need in a fast-changing world. It will also improve the ability of the European industry to compete in the global pharmaceutical world. Ultimately,

the project will impact on the well-being of the European population through research and development (R&D) and production of safer, more effective, modern-day medicines.

The work programmes (WPs)

PHAR-IN is divided into five WPs. WP1 management (MNGT) will be run jointly by P1/VUB (Vrije Universiteit Brussels; www.vub.ac.be/en/?via=accept-language) and P2/PCN (Pharmacolor Consultants Nancy (pcn-consultants); <http://pcn-consultants.com/>). Basecamp (<https://basecamp.com/>) software will be used. This is a web-based project management and collaboration tool with to-dos, files, messages, schedules and milestones.

WP2 implementation (IMP) will be run by P2/PCN. This will constitute the core of the project and will consist of the following.

- Production of a list of topics for a curriculum in present day pharmaceutical biotechnology using a Delphi process. The Delphi method is a structured communication technique which relies on a panel of experts (members of EIPG and EAFP, and industrial pharmacists). The latter answer questionnaires – in this case, the ranking of topics for a pharmaceutical biotechnology course (PBC) – in two or more rounds. After each round, a facilitator (P2/PCN) provides an anonymous summary of the experts' forecasts from the previous and experts are encouraged to revise their earlier answers in the light of the replies of other members of their panel. It is believed that, during this process, the range of answers will decrease and the group will converge towards the "correct" answer. Ranking will be done using Likert scales that are used in questionnaires to obtain participant's preferences or degree of agreement with a statement or set of statements.
- Production, running and evaluation of the course at King's College, London (KCL) and the University of Catania (UniCt; www.unict.it/en/rectors-welcome).

WP3 quality plan (QPLN) will be centred on the evaluation of the work of the consortium. It will be run by P2/PCN. WP4 dissemination (DISS) will be run by P2/PCN and will concern the dissemination of the consortium's work and results to all potential stakeholders starting with members of EIPG and EAFP. WP5 exploitation (EXP), run by P2/PCN, will promote the survival of the project once the 2-year period of EC/EACEA funding is over.

The partners

P1, the VUB will act as administrator of the PHAR-IN project. VUB is an offshoot of the French-speaking Université Libre de Bruxelles that was founded in 1834. In 1970, the two universities became separate legal, administrative and scientific entities. VUB has a medical and pharmacy faculty. The latter is at the forefront of modern developments in pharmacy education and training

in community, hospital and industrial pharmacy practice. VUB has run many EU-funded and other types of projects in the fields of pharmacy education, training and research – mostly recently the PHARMINE ("PHARMAcy education IN Europe") project (www.pharmine.org) that dealt with pharmacy education and training in the EU, and the on-going EACEA-funded programme PHAR-QA that deals with Quality Assurance in European Pharmacy Education and Training (www.phar-qa.eu/).

The key activities of P1/VUB include pharmacy education and training (PET) for community, hospital and industrial pharmacy practice, scientific research in four areas (molecular virology, analytical chemistry, neurosciences, molecular toxicology), and research in PET: "gaming", problem-based learning, project learning and line projects.

The managerial tasks at VUB will

be assumed by Bart Rombaut. Bart Rombaut has a Pharmacy and PhD degrees from VUB and has been professor there since 1991 and Dean of the School of Pharmacy since 2005. He was also guest professor at the University of Nijmegen (Netherlands), received the International Prize Princess Josephine-Charlotte for outstanding work in the field of Neuro-virology, and is a member of the Real Academia Nacional de Farmacia (Spain). He is on the board of the important pharmaceutical and biomedical organisations in Europe and the world. He was project leader of "PHARMINE", 2008. His wide-ranging research interests include molecular virology, vaccines and antiviral products; he has an "h" index of 14 (<http://thomsonreuters.com/web-of-science/>).

P2, PCN, will act as executive director. pcn-consultants offers consultancy for projects in the biomedical/pharmaceutical sciences at the European level from preparation through coordination to report writing and dissemination. Documents can be prepared in English or French according to EU or other guidelines. pcn-consultants evolved from "Pharmacolor", an SME that was started in 1986. Pharmacolor, based in the Pharmacological Laboratory of the Pharmacy Faculty in Nancy, was involved in the preclinical development of many anti-hypertensive agents such as the calcium entry blockers darodipine, nifedipine and isradipine, the ACE inhibitors captopril, perindopril and ramipril, and the AT1 antagonist telmisartan. Pharmacolor was also involved in the preclinical evaluation of melatonin derivatives. Pharmacolor also developed several degree courses, such as a masters in preclinical drug evaluation, as well as the "European Summer School in Pharmacology".

The managerial tasks at pcn-consultants will be assumed by Jeffrey Atkinson. Jeffrey Atkinson was educated at Cambridge University, England and taught

A summary of the project

| WP | Milestone | Measurable indicators of progress |
|------|--|---|
| MNGT | Setting-up of Basecamp website. Posting of information and its discussion. | Basecamp website exists and is functional. |
| MNGT | Three consortium meetings at VUB in Brussels: kick-off, intermediate and final. | Meetings are held, well-attended and all relevant matters are dealt with. |
| MNGT | Production of intermediate and final reports, and financial tables by VUB and PCN, approved by consortium. | Reports and financial tables are accepted by EACEA. |
| IMP | Drawing up of first list of competences and modalities for PBC, Delphi through committee, drawing up of second and future lists, Delphi through EIPG, EAFP and industrialists. | Lists are produced; consensus Delphi process is performed; a final consensus framework of topics for the PBC is produced. |
| IMP | Establish PBC and advertise. | PBC is produced. Advertising is carried out satisfactorily: all target groups are contacted. |
| IMP | Run and evaluate PBC. | PBC successfully carried out and evaluated. |
| QPLN | Ensure quality assurance (QA) and monitoring of the project. | QA is successfully ensured and the project successfully monitored. |
| DISS | Ensure production and dissemination of information on the project to potential stakeholders. | All stakeholders are successfully contacted. |
| EXP | Post-funding period: maintenance of Delphi tool, track changes in competences, develop PBC according to changes in competences. Adapt to areas other than biotechnology. | Post funding exploitation is successfully carried out. |

cardiovascular pharmacology and therapeutics at the University of California, Davis, California, USA, the "Mario Negri" Pharmacology Institute, Milan, Italy, the Medical Faculty of Lausanne University, Switzerland, and the Pharmacy Faculty of Nancy University, France. Twenty years ago he created a masters degree course in preclinical drug evaluation/safety pharmacology in collaboration with the European pharmaceutical industry; many of the graduates of this course now work in the pharmaceutical and related industries. He also directed preclinical research at the Nestlé Research Laboratories, Lausanne, Switzerland and Rhône-Poulenc Santé, Paris, France. Whilst working at Nancy University, he collaborated extensively with European and American drug companies on the development of several antihypertensive drugs. He sat on the board of many industrial and government research committees in Europe, US and Asia. His seminal work includes over 200 publications with a global "h" index of 24. Jeffrey Atkinson has been working as an expert and evaluator for the EU for over 15 years. He is Emeritus Professor of Pharmacology at Lorraine University, France.

P3, the EIPG, will be an essential element of implementation WP and together with EAFP will lead WP5 exploitation. EIPG will also provide invaluable advice on the regulatory aspects of any recommendations and other issues coming out of PHAR-IN. EIPG is a European association representing the national, professional organisations of pharmacists employed in the pharmaceutical and allied industries of the Member States of the EU. Its foundation dates back to 1966 and, over the years, it has progressed its activities in line with the evolution of the EU. As a European association having its official seal with the French Order of Pharmacists, EIPG is registered at the Prefecture of Police in Paris. Today, EIPG represents about 12,000 pharmacists working in the

European industry.

The managerial tasks at P3 will be assumed by Luigi Martini who is Professor of Pharmaceutical Innovation at KCL and Director of Rainbow Medical Engineering; KCL is Europe's largest centre of health education, with world renowned clinical services and research in physical and mental health. Professor Martini has occupied many roles in industry from Senior Director of Preclinical and Pharmaceutical Development for Emerging Markets and Asia Pacific at GlaxoSmithKline to the development of dosage forms and the design and successful implementation of technological platforms, e.g. the DiffCORE and MyDOSE technologies. Professor Martini was made visiting Professor at John Moores University of Liverpool in 2006 and designated a Fellow of the Royal Pharmaceutical Society in 2008. He was appointed a member of the REF2014 sub-panel for Pharmacy, Dentistry, Nursing and Allied Healthcare Professionals in 2011. His research interests include the use of ultrasonic processing technology to fabricate medical devices and pharmaceutical dosage forms, the design of dosage form concepts for delivering personalised medicines and the development of biopharmaceuticals.

EIPG/KCL will also be represented by Brian Gennery who will develop a distance learning course based on the results of the PHAR-IN Delphi survey.

P4, UniCt, will play a major role in WP2 implementation. UniCt has been a focal point in culture and learning since its founding in 1434. Today, it offers an attractive portfolio of academic titles and is engaged in creating a "laboratory" in which the ancient knowledge of the Mediterranean culture meets the new technologies in order to offer an original and advanced training experience. UniCt is also a very attractive proposition for companies with an interest in the transfer of technology from the university departments, institutes and research centres. The Faculty of Pharmacy

has updated its formative offer fitting in line with the strategy of the EHEA and the EU Directive for the profession of pharmacist. UniCt also has specialist courses of Pharmaceutical Chemistry and Technology and Pharmacy.

The managerial tasks at UniCt will be assumed by Giuseppe Ronsisvalle who is Vice-President of the Organisation for Economic Co-operation and Development (OECD) Programme on Institutional Management in Higher Education (IMHE, www.oecd.org/edu/imhe/). He recently participated as a member of the evaluation team in the analysis of the Lombardy within the OECD reviews of higher education in regional and city development. Professor Ronsisvalle is coordinator of the Internal Quality Office (Presidio della Qualità) of the UniCt. He is also former president of the Italian Conference of Deans of Pharmacy, and Vice-President of the EAFP. He is the Italian representative in the Steering Committee for Education Policy and Practice (CDPPE) of the Council of Europe. He was a member of UniCt team for the EUA-CRE evaluation and collaboration with OECD in the programme on higher education in regional and city development. He is a member of the Italian Chemical Society and the Accademia Gioenia of Natural Sciences. Giuseppe Ronsisvalle's main interests are R&D of neuro-protection drugs and new central analgesics, as well as the study of mechanisms of neurodegenerative disease.

P5, Genzyme (www.genzyme.be/default.asp), will play a key role in WP2 implementation. Genzyme is a particularly interested party in this education project, as education resources are hard to find. To date, Genzyme has invested substantial time and resources to educate and train their personnel. This project will enable Genzyme to have readily educated industrial pharmacists available to support their current operations and the expansion project.

In October 2001, Genzyme Corporation acquired the Belgian

part of Pharming N.V. in Geel, Belgium to develop Genzyme's first bio-therapeutics manufacturing facility in Europe. The manufacturing facility comprises a continuous production line for the manufacturing of enzymes for enzyme replacement therapies and a fed-batch production line for the manufacturing of therapeutic monoclonal antibodies. The first product is enzyme replacement therapy for Pompe disease, a rare, often fatal, genetic disease of the muscle. Regulatory approval for commercial production of this enzyme was received in 2009–2010 for the EU, Japan, Canada, US and Brazil. The monoclonal antibody produced in Geel was for the treatment of B-CLL leukaemia, and approval of its manufacturing for the EU and US was received in 2009 and 2010. This monoclonal antibody is also being evaluated in a number of clinical trials for treatment of other cancers and multiple sclerosis.

The managerial tasks at Genzyme will be assumed by Gunther Pauwels who currently holds the position of Senior Director of Quality Affairs at Genzyme, Geel, Belgium. Gunther Pauwels has worldwide experience and expertise (>15 years) in the design, start-up, qualification and validation of multiple Pharma and Biotech production units. His specialised education as an Industrial Pharmacist has enabled him to absorb solid and pragmatic expertise in the various elements within the Pharmaceutical Quality arena. Gunther Pauwels believes in systems, organisation and governance; 'Quality is not a silly coincidence, but a result of careful planning and meticulous execution'.

Gunther Pauwels is an active member and speaker within recognised industry associations, such as VAPI, ISPE, PDA and ASQ; and is a certified (ASQ) Quality Auditor.

P6, Areta International (www.aretaint.com/), will play a key role in WP2 implementation. Areta International is a biotech company dedicated to the contract development and manufacturing of biotechnology products and cell-based medicines. The company was founded in 1999 and is located in the Insubrias Biopark, 30km northwest of Milan. Areta is organised in two divisions: Areta services (GMP and R&D) and Areta research (research and co-development of bio-drugs). The GMP unit is focused on manufacturing of bio-drugs for advanced therapies. Stem cells for tissue regeneration, tumour treatment using cells or recombinant proteins, antibodies for therapy or for therapeutic cells selection and DNA as vaccines are examples of projects being performed by Areta. In the R&D field, Areta has developed more than 300 projects of customised monoclonal antibodies specific to different antigens. The company also has a unique skill in setting up immunological and cell-based tests for characterisation and quality control of different products.

The managerial tasks at Areta will be assumed by Maria Luisa Nalli, the founder and Chief Executive Officer of Areta International. She holds a degree in Biological Sciences from the University of Pavia and a PhD from the Université Libre de Bruxelles. Dr. Nalli has more than

20 years' industrial experience as a scientist and group leader in cell biology and immunology working at the Lepetit Research Center, part of the multinational group of Dow Pharma (Merrell Dow, Marion Merrell Dow and Hoechst Marion Roussel). Since 2007, she has been Chief Executive Officer of HO.p.e. s.r.l, a spin-off of the State University of Milan, with Areta International, for the development of an innovative universal kit to ascertain growth hormone abuse for anti-doping purposes as well as biomedical applications. She is a member of the Executive Committee of Assobiotech (the Italian biotechnology industry association), Board Member at EuropaBio (the European Association for Bio-industries) and Member of the European Federation of Biotechnology. She is author and coauthor of more than 30 papers and 11 patents and she obtained "The Piazza Mercanti Award" 5th edition (2007) given by the Chamber of Commerce of Milan, and the "Rosa Camuna Prize" from Regione Lombardia (2012). She is also one of the 100 profiles of the volume dedicated to the city of Milan of the series entitled "The women protagonist" (2010).

Conclusion

The PHAR-IN consortium that involves academia and industry will produce a Delphi-based, rapid analysis tool for the identification of the most up-to-date requirements for pre- and post-graduate education in competences for industrial pharmacy practice in biotechnology. It will then go on to develop the courses required for such education.

Erratum

Industrial Pharmacy advises that within the content of the article titled "Generics uptake in Europe – the impact of pricing and reimbursement policies", published in *Industrial Pharmacy*, March 2013, Issue 37, the phrase 'price referencing' should be replaced with 'pricing and reimbursement' throughout the article. Furthermore, this article was abstracted based on the original paper published in *GaBI Journal*: Vogler S. The impact of pharmaceutical pricing and reimbursement policies on generics uptake: implementation of policy options on generics in 29 European countries—an overview. *Generics and Biosimilars Initiative Journal (GaBI Journal)* 2012;1(2):93–100. doi:10.5639/gabij.2012.0102.020.

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regulatory review

The current review period has seen a number of changes in the regulation of medicines and regulatory guidance in the EU, International markets and the USA.

United States of America

Pre-launch activities importation requests

This draft guidance describes the US Food and Drug Administration's (FDA's) policy regarding requests for the importation of unapproved finished dosage form drug products by applicants preparing products for market launch based on anticipated approval of a pending new drug application, an abbreviated new drug application or a biologics licensing application.

Monitoring crude heparin for quality

This final Guidance for Industry clarifies FDA's expectations and recommendations and includes references to a recently-developed assay for detecting ruminant contamination of crude heparin.

Draft guidance documents issued before 2010; withdrawal of guidances

FDA is withdrawing draft guidances that are no longer up-to-date, and is also actively reviewing the draft guidances to determine which ones to either revise or finalise.

Europe

First conclusions of parallel assessment of quality-by-design applications

The European Medicines Agency and US FDA have published a joint Q&A that outlines the conclusions of their first parallel assessment of quality-by-design elements of marketing authorisation (MA) applications.

Concept paper revision of the note for guidance on manufacture of the finished dosage form

The objective of the guideline which is open for comment until

31 December 2013, is to underline all aspects of manufacture that are important both for applicant and regulator. Information which falls under GMP should not be part of the MA file and only product-specific issues need to be described. A need to incorporate holding times and conditions as well as shipping/transportation conditions will be discussed.

Concept paper on development of product-specific guidance on demonstration of bioequivalence

This draft concept paper has been released for a 2-month public consultation.

Importation of active substances (Heads of Medicines agencies)

Active substances (ASs) intended for the manufacture of medicinal products may arrive at the European Economic Area (EEA) from countries that are not listed as being GMP equivalent to EU and without the required written confirmation. The process map in this document describes the actions that, if taken by an importer under these circumstances, may facilitate the avoidance of problems at the point of importation, or later in the supply chain.

EU GMP Guide Chapter 2: personnel

Changes have been made in order to integrate the principles of "Pharmaceutical Quality System as described in the ICH Q10. A section has been added on consultants. The existence in certain circumstances of a Head of Quality Assurance or head of the Quality Unit is introduced. The revision comes into operation on 16 February 2014.

MHRA

ASs imported into the EEA

The MHRA will not control AS import at the border and will instead control at inspection of manufacturers and, where there is a risk trigger, at inspection of AS importers and distributors.

Requirements for Change of Ownership submissions

Applicants will now be required to declare the Marketing Status of the product when the transfer of licence has been applied for.

International

ICH Q3D Guideline for Elemental Impurities

This new guideline has reached Step 2b of the ICH Process and now enters the consultation period (Step 3). It is open for comment until 31 December 2013.

WHO

Two documents marked as restricted in terms of the readership to which they have been issued for comment are summarised below.

General guidance for inspectors on "hold-time" studies

Indicates that maximum allowable hold-time should be established to ensure that in-process and bulk product can be held, pending the next processing step, without any adverse effect to the quality of the material. These time periods must be supported by adequate data.

Proposed updated text for GMP for pharmaceutical products: main principles

The paragraphs that need to be updated have been identified as being in the following sections:

- Section 1 – Quality Assurance/Quality System
- Section 2 – GMP for pharmaceutical products
- Section 7 – Contract production and analysis
- Section 17 – Good practices in quality control

For further information on these and other topics we suggest you refer to the websites of relevant regulatory bodies and to current and past editions of "GMP Review News" published by Euromed Communications. To subscribe to this monthly news service contact info@euromedcommunications.com

Education

In June, after some last minute proposals for amendments to the revision of Directive 36/2005/EC, agreement was reached between the Irish Presidency of the Council and the European Parliament representatives on the text of the Professional Qualifications Directive. The text has been circulated to our national delegates.

The application to review and update the competencies needed for the biotechnology component of the pharmacy course (PHAR-IND) has been approved for funding by the European Commission under the Erasmus programme. Industrial partners involved are EIPG, Genzyme (Belgium) and Areta International (Italy), along with the Vrije University, Brussels, the University of Nancy (Pharmacolor

Consultancy) and the University of Catania.

Good Manufacturing Practice

EIPG comments on the European Union Commission's revised chapters 3 (Premises and Equipment), 5 (Production) and 6 (Quality Control) and Exposure Limits in Shared Facilities were submitted to the European Medicines Agency (EMA) and Directorate-General for Health and Consumers (SANCO). As a result, we have been invited to send a representative to a workshop at the EMA next month on dedicated facilities.

US Pharmacopeial Convention

A representative of the US Pharmacopeia (USP) office in Basel and a member of the Headquarters

staff from Rockville met with our President and Treasurer at the Ordre de Pharmaciens to discuss areas of potential collaboration. The USP is looking for experts to join their panels on drug classification, drug shortages and diagnostics.

European Pharmacy Students' Association

The new President of the European Pharmacy Students' Association (EPSA) is Tiia Metiäinen (Finland) and the EPSA Vice-President of External Affairs is Gabriela Valentova (Czech Republic). They can be contacted via their executive positions epsa.president@epsa-online.org and vp.ea@epsa-online.org

Jane Nicholson, Executive Director EIPG, jane@nicholj.plus.com

Message from Tiia Metiäinen, President of the European Pharmaceutical Students' Association

I am currently finalising my pharmacy studies at the University of Helsinki. I became involved in student association work right from the beginning – and got hooked. After being active locally, it felt natural to move to national level and I got involved in the European Pharmaceutical Students' Association (EPSA), first as a representative of Finnish pharmacy students and later as a member of the EPSA Team as Training Coordinator, Vice President of Education and now President.

What attracted me to EPSA was the open and constructive atmosphere, as well as the international environment. Being active in a student organisation on a European level offers so many opportunities to learn about your profession, different cultures and European health policy making. As students, we represent potential for all the sectors of pharmacy and, therefore, an organisation like EPSA provides a completely unique panoramic view of European

pharmacy as a whole.

As President, my tasks divide between internal and external functions, such as leading a team of over 20 students from around Europe, chairing our General Assembly and representing EPSA to our members as well as external people. My goals for this mandate include finding the right balance between these two aspects of my position. I would like to bring a touch of Nordic efficiency to the functioning of the association, encouraging an outcome-oriented approach in our work as well as aiming to boost EPSA's visibility to pharmacy students and professional bodies alike.

Advocacy is one of our key areas of work and we are currently refining our processes, making them more transparent and representative through an advocacy platform for European pharmacy students created last mandate. Tightly linked to this is supporting our member associations in promoting collaboration between

pharmacy students locally as well as encouraging student advocacy on a national level. It is important that students get engaged and interested in the future of their profession if we want to improve European pharmacy in the future.

Collaboration with professional organisations forms a cornerstone for EPSA, as maintaining a dialogue between the student and professional worlds is important so students are aware of hot topics in pharmacy, and can voice their opinions on issues that they might be required to find solutions to in the near future. A good example of EPSA's professional collaboration is our work with EIPG on the upcoming EPSA careers website that provides information on different opportunities for European pharmacy students in the pharmaceutical industry.

*Tiia Metiäinen
EPSA*

events

NOVEMBER

4–8 November 2013 – Basel, Switzerland

The Universe of Pre-filled Syringes and Injection Devices
www.pda.org

6–7 November 2013 – Istanbul, Turkey
Biological Production Strategies in Turkey and MENA
www.informa-ls.com/biotechmena

20–21 November 2013 – Oxford, UK
21st Annual Microbiology Conference
www.pharmig.org.uk

25–27 November 2013 – London, UK
Tableting Technology for the Pharmaceutical Industry
www.jpag.org

25–27 November 2013 – Budapest, Hungary
Pharma Packaging 2013
www.gmp-compliance.org

27–29 November 2013 – Lisbon, Portugal
8th QP Association Forum
www.gmp-compliance.org

DECEMBER

2–4 December 2013 – London, UK
GMP and GDP Symposium
www.mhra.gov.uk

10–11 December 2013 – Barcelona, Spain
Rapid Microbiological Methods Conference
www.gmp-compliance.org

11 December 2013 – Edinburgh, UK
Half-day Symposium
"Dissolution of inhaled products: in vitro developments, in vivo relevance and the potential impact on regulatory thinking"
www.jpag.org

12–13 December 2013 – Heidelberg, Germany
The Responsible Person for Good Distribution Practices
www.gmp-compliance.org

JANUARY

21–23 January 2014 – Frankfurt, Germany
Clinical Supply Chain
www.pharma-iq.com

28–29 January 2014 – Berlin, Germany
Protective Packaging Solutions for Pharmaceutical Product Stability
www.gmp-compliance.org

28–29 January 2014 – London, UK
Joint Regulators/Industry QbD Workshop
www.pda.org

FEBRUARY

6th February 2014 – London, UK
Developments in Analysis of Orally Inhaled and Nasal Drug Products
www.jpag.org

11 February 2014 – Manchester, UK
Good Clinical Practice Symposium
www.mhra.gov.uk

18–19 February 2014 – Brussels, Belgium
6th Annual Disposable Solutions for Biomanufacturing
www.pharma-iq.com

18–19 February 2014 – Berlin, Germany
Pharmaceutical Microbiology
www.pda.org

18–20 February 2014 – Munich, Germany
6th Disposable Solutions for Biomanufacturing Summit
www.disposablebiomanufacturing.com

24–25 February 2014 – Washington DC, USA
2014 Aseptic Annual Conference
www.ispe.org

24–27 February 2014 – Montreal, Canada
12th Annual Cold Chain GDP & Temperature Management Logistics Summit
www.coldchainpharm.com

25–26 February 2014 – Barnard Castle, UK
Cleaning Validation
www.honeyman.co.uk

MARCH

4–5 March 2014 – London, UK
Clinical Outsourcing & Partnership World 2014
www.healthnetworkcommunications.com

11–12 March – Brussels, Belgium
Parenteral Packaging
www.pda.org

13 March 2014 – London, UK
The Pharma Summit 2014 Reinventing Business Models and Markets
www.economistconferences.co.uk

14 March 2014 – London, UK
Good Clinical Practice Symposium 2014
www.mhra.gov.uk

24–26 March 2014 – Heidelberg, Germany
ICH Q7 Compliance for APIs Manufactured by Chemical Synthesis
www.gmp-compliance.org

25–26 March 2014 – Lyon, France
Modern Biopharmaceutical Manufacturing
www.pda.org

26–28 March 2014 – Barcelona, Spain
19th Congress of the EAHP: The Innovative Hospital Pharmacist – Imagination, Skills and Organisation
www.eahp.eu/congresses

31 March–3 April 2014 – Lisbon, Portugal
9th Pharmaceuticals, Biopharmaceutics and Pharmaceutical Technology World Meeting
www.apv-mainz.de