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

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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 National 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 Nolli, 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. Nolli 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 Assobiotec (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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