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CONTENT

Reports & Concepts

Towards a Pan-European Training Program in Pharmaceutical Medicine

IMI-P16 'PharmaTrain'

by Professor Dr med Dr h.c. Fritz R. Bühler

Almost everything has been addressed to systematically improve the complex and expensive integrated drug development process – but people. People are employed as well-paid experts and they are competent by definition at least in their field of expertise. But what about the understanding of the entire, integrated or holistic drug development process "from molecule to market place"? Where is this being taught or where can it be learned? Yet nobody would deny ▶ page 2

President's Letter

Professor Dr Gerfried Nell, IFAPP President

Dear Colleagues

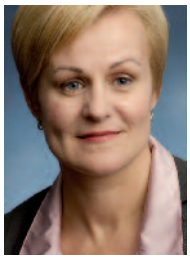
One of the main topics of this 'IFAPP World' issue is the 'PharmaTrain'. What does PharmaTrain stand for? It is the abbreviation of 'Pharmaceutical Medicine Training Programme and Drug Development Sciences', which is one out of fifteen projects that were approved by the European Commission under the 'Innovative Medicine Initiative', IMI. The overall target of IMI is to improve the competitiveness of the European pharmaceutical industry. Eleven of the projects are dedicated to pre-competitive scientific research whereas three of them are aiming at improving education and providing continuous professional development. All of these projects are run by a public-private consortium. The public part of the PharmaTrain consortium is constituted by universities, learned societies and IFAPP, the private part is formed by pharmaceutical companies.

The main objective of the 'PharmaTrain' is to create a new multimodular Diploma / Master Level Program for advanced studies in Pharmaceutical Medicine / Drug Development Sciences based on an updated ▶ page 2

Questions & Answers

Pharmaceutical Medicine in Australia

A Highly Advanced Pharmaceutical Market With a Small but Growing Domestic Pharmaceutical Industry



Dr Leanne Wall, President of the 'Australian Pharmaceutical Physicians Association' (APPA) outlines the position of Pharmaceutical Medicine in Australia in conversation with Eckhard Böttcher-Bühler

According to recently released reports, «Australia is one of the richest pharmaceutical markets in the Asia-Pacific region. The market ranks as the 13th largest in the world, while per capita spending is on a par with European markets such as Sweden or the Netherlands.» «…Australia is considered the third-most attractive pharmaceutical market…highly advanced….The domestic pharmaceutical industry – which includes a large number of multinationals with direct manufacturing presence – is dominated by the producers of generic medicines.

IFAPP WORLD • Dr Wall, Australia is part of the Asia-Pacific region. However, when US or European Pharmaceutical Medicine experts talk about Asia-Pacific, China and India will be likely to cross their minds rather than Australia, which seems relatively invisible with regard to pharmaceutical business. Is there any explanation for this from your perspective as an Australian expert in Pharmaceutical Medicine?

Dr Leanne Wall • It is important to note that although closest to the Asia-Pacific region geographically, Australia is often grouped with other more remote countries. This is because the market here is more comparable with, for instance, that of a medium-sized European country. ▶▶ page 4

President's Letter

◀ page 1 IFAPP syllabus of Pharmaceutical Medicine. Presenting these graduations will hopefully result in facilitating the recognition of Pharmaceutical Medicine as a distinct medical specialty on a European level. Professor Fritz Bühler, who serves as the coordinator of the consortium, is providing firsthand information on the 'PharmaTrain' on page 1 of this 'IFAPP World' issue – it is a huge project and all participants are enthusiastic about it as it provides a great opportunity to improve education in Pharmaceutical Medicine by a quantum leap. Important to say: its achievements will not only boost our discipline in Europe but will prove beneficial on a global level in the end.

In order to warrant a global balance, 'IFAPP World' provides an interview drawing a broad picture of the activities of our Australian colleagues and the 'Australian Pharmaceutical Physicians Association' – APPA. This underlines the global representation of national member societies.

The essential tasks of IFAPP are promoting Pharmaceutical Medicine as our core discipline. To this effect, IFAPP is organizing seminars and congresses. The first highlight of this year was the 10th IFAPP European Conference held in London, UK, on January 30th. This conference was organized together with the 'British Association of Pharmaceutical Physicians' (BrAPP) and the 'British Association of Research Quality Assurance' (BARQA). The seminar provided an excellent overview of "Quality Assurance in Clinical Research" – a report on this conference is presented on page 8.

In this issue you will also find reports on the 'International Conference on Pharmaceutical Medicine' – ICPM 2008 in Amsterdam, The Netherlands, to complete the overview of this excellent congress. The next ICPM in 2010 will draw our attention to the emerging regions in Asia. Therefore, it will be hosted by the 'Chinese Forum of Pharmaceutical Medicine' (CFPM) in Shanghai, China, 7-10 November 2010, jointly organized by the CFPM, the 'Association of Pharmaceutical Physicians' of Singapore (APPS) and IFAPP. Please join us in this important event for Pharmaceutical Medicine and mark this date in your calendar already now.

Last but not least I would like to invite you to share your ideas and proposals and to cooperate with us in developing Pharmaceutical Medicine world-wide.

With kind regards – Professor Dr Gerfried Nell, IFAPP President, Austria ■

Reports & Concepts

◀ page 1 its importance and timeliness: the integrated process still does not deliver more successful New Drug Application (NDA) and over the last few years the 'European Medicines Agency' (EMEA) or the US 'Food and Drug Administration' (FDA) have approved less than 20 NDA per year.

Ever since the first short training course in Pharmaceutical Medicine was founded at the University of Cardiff in 1979 and a second high-throughput course was set up at the University of Basel, at the 'European Center of Pharmaceutical Medicine' (ECPM). Several other courses of this kind and a few new Master-level programs have emerged throughout Europe. In the course of the last 20 years, more than 2,500 integrated drug developers have been trained and examined at the postgraduate level: 12 course providers use the same syllabus of modular training content as initially devised by the 'Faculty of Pharmaceutical Medicine' of the 'Royal Colleges of the United Kingdom' and later adapted by IFAPP, and this led to the accreditation of these courses by IFAPP. Only in Switzerland in 2001 and in the United Kingdom in 2006 did these training efforts with mutually recognized examinations along with work-based training lead to a formal 'Specialist in Pharmaceutical Medicine' as a distinct medical specialty.

Over the last 20 years the interest in integrated postgraduate training in Pharmaceutical Medicine or drug development sciences has significantly increased. More courses – particularly at the Master level – have been started and another seven ones are about to get off the starting blocks. While, by and large, the number of MDs in these courses stays about the same, the fraction of non-MDs has doubled. It makes sense that the same training along the same drug development value chain is given to all people involved in integrated drug development and this is also true for colleagues working at the regulatory authorities and those drug developers working in the small and medium-sized pharma biotech industry - in fact they are the ones who need such integrated competencies most.

Shared Standards for Training in Drug Development

Against this background, several efforts were made to find shared standards for training in drug development including a workshop on 'Pharmaceutical Specialist Education Models' in Basel, Switzerland, in 2002 where the major training organizations, IFAPP, the 'European Federation for Pharmaceutical Sciences' (EUFEPS) and the 'Drug Information Association' (DIA) Europe have tried to find a common ground. Soon afterwards and in the lap of EUFEPS, the 'New Safe Medicines Faster' (NSMF) was born, and during the Danish EU presidency it was pushed to the attention of the European Commission. In 2005, training activities were incorporated into the new 'Innovative Medicines Initiative' (IMI), a joint undertaking by the European Commission with an overall budget of € 1 billion matched by the same contribution 'in kind' by the 'European Federation of Pharmaceutical Industries and Associations' (EFPIA) for over 7 years. There were 18 call topics: 13 for joint public-private research programs and five training programs. Out of 150 applications and following a two-stage competitive evaluation process, 15 projects were granted (€ 127 million per 5 years) which will be started later in 2009. The four training programs (€ 15 million per 5 years) relate to PhD training (EMTrain), ▶ page 3

Celebrating the conferment of the "Master of Science (MSc) in Pharmaceutical Medicine" end of May 2009 at the PME – Institute for Education in Pharmaceutical Medicine, University of Duisburg-Essen, Germany, where this IFAPP accredited study course is the first state-approved Postgraduate Study Course in Pharmaceutical Medicine in Germany.

Reports & Concepts

◀ page 2 postgraduate, second cycle or Master of Advanced Study programs for safety (SafeSCIMET), training in Pharmaceutical Medicine and Drug Development Sciences (our PharmaTrain) as well as in pharmacovigilance and pharmacoepidemiology (Eu2P).

The proposed PharmaTrain provides a comprehensive solution for complex training needs of integrated drug development (sciences) for all professionals involved, including physicians, pharmacists, pharmaceutical scientists, biologists, biometricians, health economists, safety and regulatory scientists from universities, regulatory agencies, large, small and medium-sized pharma-, bio-, med- and nanotech enterprises, and allied companies providing contract research, financial, supply and information services, as well as research ethics committees.

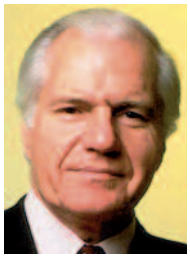
The main objective of PharmaTrain is to create a new multi-modular Diploma / Master Level three-tier Program for Advanced Studies in Pharmaceutical Medicine / Drug Development Sciences, based on the Bologna credit and title system with 60+ ECTS credits (ECTS – European Credit Transfer and Accumulation System) and a new teaching syllabus. This dynamic PharmaTrain program with a preparation, learning, confirmation and sustaining phase will be started de novo in collaboration with six universities, and harmonized with another 12 programs, to form a pan-European, quality management and self-sustaining network. Base Courses (30+ ECTS) will be harmonized at the same quality level with examinations through a unified European system, ensuring that the knowledge requirements will be the basis of the Diploma / Master program. Combined with the documentation of practical work, this will confer a new nation-wide accredited European Specialist in Pharmaceutical Medicine. The modular concept also provides an opportunity for accredited Continuing Professional Development as well as individualized training à la carte.

A PharmaTrain network collaboration is planned between 60 leaders of 26 university training programs and 13 learned societies including three regulatory agencies, DIA Europe and EuropaBio, matched with 20 representatives of 15 EFPIA member companies. PharmaTrain will encourage faculty exchanges between the industry, regulators and academia, and foster distance e-learning capability, and increased flexibility, transferability and mobility. This uniform high-level training in integrated drug development harnesses a new strength in developing new innovative medicines. ■

Personal Snapshot

Promoter of Pharmaceutical Medicine and its Recognition as a Medical Specialty:

Professor Dr med Dr h.c. Fritz R. Bühler



Over the last 20 years, Professor Dr med Dr h.c. Fritz R. Bühler has made a concerted effort to improve the quality of drug development and towards an impactful high-level education and training for all parties involved in the process world-wide.

Fritz R. Bühler is a modern-day medical scientist and a man of business – the type of personality people usually find in a storybook. But above all, he is an expert in Pharmaceutical Medicine, a promoter who has established various programs for education and training in Pharmaceutical Medicine, and he is a protagonist of the idea to make it a recognized medical specialty. In fact, Pharmaceutical Medicine is an officially recognized medical specialty in Switzerland, homeland of Fritz R. Bühler.

Recently, he has promoted the 'Innovative Medicines Initiative' (IMI) Joint Undertaking of the European Commission and EFPIA for the topic 'Pharmaceutical Medicine Training Programme'. He is convinced that this extensive and unique program in a quadrangular collaboration of government and industry with academia and regulators will create a new strength of Europe and a global competitive advantage.

Professional Career

Fritz R. Bühler was born in Basel, Switzerland, where he grew up. He studied medicine and qualified as a Medical Doctor in Internal Medicine at the University of Basel in 1965. He followed on at the Columbia University in New York at the Hypertension Center where he constituted his widely valued research regarding the formation and regulation of arterial hypertension. He introduced the betablockers for treatment of renin-dependent hypertension, an early version of personalized medicine. Back in Switzerland in 1973, he established a hypertension clinic and research center at the University Hospital of Basel. In 1977 he became a Visiting Professor in Cardiology at the Peter Bent Brigham Hospital of the Harvard Medical School in Boston. 1978 he was appointed head physician and 1983 Professor in Cardiology and Internal Medicine at the University of Basel. In 1987 Fritz R. Bühler was appointed Professor of Pathophysiology and Head of Research at the University Hospitals of Basel. He attracted researchers from all over the world who participated in his research unit with a focus on hypertension, arteriosclerosis and heart disease; he and his team were well-known for the contributions to cardiovascular pathophysiology and pharmacotherapy.

In 1991 he took up a new challenge, switched from academia to industry and became Director of World-wide Clinical Research and Development of Hoffmann-La Roche AG in Basel. Fritz R. Bühler is the founder of the 'European Center of Pharmaceutical Medicine' (ECPM) at the Medical Faculty and Pharma Center of the University of Basel where, over the last 20 years, he has established the postgraduate 'European Course in Pharmaceutical Medicine' for physicians and scientists from academia, industry and regulatory authorities. Up to date, far more than 1,200 physicians from all over Europe and beyond have successfully completed this training in integrated drug development.

Fritz R. Bühler is still ECPM Director and also a member of the Board of the Center for Drug Development Science at UCSF Washington D.C., USA, where he was instrumental in starting the American Course in Drug Development and Regulatory Sciences, ACDRS, both in Washington D.C. and San Francisco; last year the Chinese Course in Drug Development and Regulatory Sciences was set-up at Beijing University. He was a member of the Executive Committee of the 'Swiss Academy of Medical Sciences' and the co-founder of the 'Swiss Society of Pharmaceutical Medicine', and of the trinational BioValley platform at the Upper Rhine. He is engaged as a founder, consultant and investor in various biotechnology enterprises. He received his honorary doctorate 'honoris causa' from the Université de Strasbourg, France, in 1995.

Conductor of the 'PharmaTrain'

With his background, Fritz R. Bühler took on the role of a coordinator of the European 'Innovative Medicines Initiative', IMI, 'PharmaTrain' (detailed information on the PharmaTrain please find on page 1) which is a pan-European work-based program for all those involved in the research and development of medicines to foster their competencies in the process and eventually to help improve overall quality and hopefully to reduce cost. A new European Specialist in Pharmaceutical Medicine and a postgraduate Master in Drug Development Sciences, MDDS or MSc, will emerge.

Eckhard Böttcher-Bühler ■

Questions & Answers

Pharmaceutical Medicine in Australia

◀◀ page 1 The population is substantially of European descent, medical practice is more aligned to Europe, and the pharmaceutical regulatory processes have close links. Furthermore, the pharmaceutical marketing models and controls have close relationships to those of the old mother country, the United Kingdom.

In terms of pharmaceutical markets I am not at all surprised that China and India dominate the stage when our colleagues in the US and Europe talk about the Asia-Pacific. Although I do not profess to be an expert on the pharmaceutical industry in either China or India, what my recent research has shown is that both countries are set to play a significant role in the world's pharmaceutical markets in the near future.

As a starting point, let us compare population sizes of Australia, China and India. The current population estimate for Australia is a mere 21 million while China and India is 1.3 and 1.2 billion respectively. Clearly, Australia in terms of head count is a very 'small fish' in the Asia-Pacific region, however, despite this, the Australian pharmaceutical industry boasts a turnover of US$ 20 billion per annum versus US$ 37 billion in China and only US$ 10.2 billion in India.

IFAPP WORLD • What about Australia's pharmaceutical industry and market from a global perspective and within the Asia-Pacific region?

Dr Leanne Wall • Australia represents a highly advanced pharmaceutical market and comprises 1% of the world pharmaceutical market. The Australian pharmaceuticals industry comprises bio-medical research, biotechnology firms, originator and generic medicines companies and service-related segments including wholesaling and distribution. In 2007-2008, the industry employed over 40,000 people – including 14,000 in manufacturing – and turned over around US$ 16 billion. Exports were approximately US$ 3.1 billion in the 2007-2008 Financial Year, making pharmaceuticals Australia's second largest manufactured export after automobiles and automotive components. In 2006-2007, the industry spent around US$ 688 million on research and development. Sales of complementary medicines in Australia are worth around US$ 0.8 billion a year.

The country has an advanced healthcare system and demand for all types of pharmaceuticals is high. Prices in Australia tend to be low for a developed country, principally due to tight public pricing and reimbursement regulations through the Pharmaceutical Benefits Scheme – PBS –, the government reimbursement scheme.

Now let us look at China and India.

China's pharmaceutical market has shown impressive growth in recent years, in tandem with the country's rapid economic expansion – reaching an estimated US$ 37 billion in 2008 and still growing at near 20% annually. In the past twenty years, China's pharmaceutical market has an averaging of 18 - 20% growth, significantly higher than US and European growth during that period (7 – 9%). However, the industry is still small-scale, with a scattered geographical layout, duplicated production processes, and outdated manufacturing technology and management structure. The pharmaceutical industry also has a lower market concentration and weak international trading competitiveness, coupled with a lack of patented pharmaceuticals developed in-house.

The Indian Pharmaceutical Industry is estimated to be worth over US$ 10.5 billion, growing at about 8 - 9% annually. It ranks very high in the third world, in terms of technology, quality and range of medicines manufactured. From simple headache pills to sophisticated antibiotics and complex cardiac compounds, almost every type of medicine is now made indigenously. The Industry possesses quality producers and many units approved by regulatory authorities in US and UK. International companies associated with this sector have stimulated, assisted and spearheaded this dynamic development in the past 53 years and helped to put India on the pharmaceutical map of the world. The downside, however, is that India is an extremely fragmented market with severe price competition and government price control.

IFAPP WORLD • What types of pharmaceutical companies operate in Australia?

Dr Leanne Wall • Australia has a small but growing domestic pharmaceutical industry, augmented by the presence of many multinational producers.

The market remains heavily reliant on imported drugs; however, local R&D has yet to reach significant proportions, despite continuing government incentives. The majority of pharmaceutical imports are sourced from the European Union.

Low prices for branded products have historically meant that generics are not yet widely used, although this is slowly changing. A number of leading drugs have recently lost patent protection, but price competition tends to be muted for off-patent drugs. The government is, however, currently looking at ways to boost generic consumption in an effort to rein in the overall drugs bill. Reforms to this effect have recently been announced, although they have not met with approval from the generic industry.

There are many different types of pharmaceutical companies operating in Australia. These include international companies with headquarters in the US, UK or Europe, Australian-owned companies, companies which concentrate on a niche market, companies who manufacture products under license for other companies and companies who have entered into co-marketing agreements.

In 2008, the top four companies by sales to pharmacies were Pfizer, AstraZeneca, Sanofi-Aventis and GlaxoSmithKline. The top five companies by hospital sales were Roche, Baxter Healthcare, Amgen, Novartis and Pfizer.

IFAPP WORLD • How many physicians are working in the area of Pharmaceutical Medicine in Australia and how many of them are members of the Australian Pharmaceutical Physicians Association (APPA), which you currently chair as the President?

Dr Leanne Wall • I am not aware of any local data that has been collected that would shed light on the total number of physicians working in the area of Pharmaceutical Medicine. What I can tell you is that APPA currently has 110 members. Most members are from the pharmaceutical industry and post recent mergers, four companies contribute almost half the members – CSL Limited, an Australian-based manufacturer of medical products, Merck Sharp & Dohme, Sanofi-Aventis and Pfizer. We don't have many in APPA from government who work in regulatory or research functions. In terms of our membership, 33% are women, less than 5% reside overseas and we have 19 honorary members who have lifelong membership.

Some interesting facts about APPA – the association has been in existence since 1963. The original association was called the 'Association of Medical Advisors in the Pharmaceutical Industry' and later converted its name to APPA. Members meet four times a year to share best practices within their area of Pharmaceutical Medicine or discuss issues that may be topical at that time, e.g., our meeting to be held in June this year will focus on the swine flu pandemic and the challenges faced in Australia. We have managed to secure an excellent speaker who presented at the recent international flu conference and who consults to the WHO in this area.

APPA is also a member of IFAPP and two of our members are closely involved ▶ page 5

Questions & Answers

◀ page 4 with your association. Dr Sander Becker is founding and instrumental Chairperson of the IFAPP 'Pharmaceutical Medicine Ethics Council' (PMEC) and Chair of IFAPP 'Global Strategy Working Party' and Dr Rob Creek is a member of the IFAPP 'Council for Education in Pharmaceutical Medicine' (CEPM).

IFAPP WORLD • Are all APPA members licensed physicians working in the area of Pharmaceutical Medicine?

Dr Leanne Wall • As a general rule, only medically qualified individuals working as pharmaceutical physicians in the industry are considered for membership of APPA. These physicians fulfill roles such as Medical Director – local and regional –, Medical Advisors and Medical Scientific Specialists. APPA has also created a category of associate membership specifically for those who are usually non-medical heads of departments within the context of pharmaceutical medicine. APPA currently has three such members.

In terms of being licensed, I take it you mean licensed to practice medicine in Australia. Let me first provide some context – in the event that your medical training was undertaken outside Australia and you wish to practice medicine in Australia, you are required to go through a lengthy 're-licensing' process. Australia does not recognize medical qualifications from other countries. Before 1990, Australia accepted medical qualifications from other Commonwealth countries; however, this policy ceased after this time.

In order to 'convert' your qualification, you are required to pass a written, oral and clinical examination, usually spaced a year apart. This is followed by 12 months of supervised training in a public hospital. In total, this process usually takes three years if you are lucky to pass the written and clinical component, which are the toughest.

I am aware of a number of APPA members who immigrated to Australia and chose to work in industry to avoid the lengthy and stressful conversion exams. On the other hand, there are a number of members, such as myself, who, despite having completed the Australian registration exams, chose the industry as their preferred career. All APPA members are registered physicians in at least one country in the world.

It is not a requirement in Australia to have a specialty qualification in Pharmaceutical Medicine in order to work in the industry. This qualification, however, does not allow you to work in clinical practice. Furthermore, APPA have also confirmed that there are no duties undertaken in Pharmaceutical Medicine that require medical registration provided that those duties do not involve the individual management of patients or volunteers in clinical trials.

IFAPP WORLD • So far Pharmaceutical Medicine is not officially recognized as a medical specialty in Australia – does APPA actively aim for the recognition and how could physicians then qualify for it?

Dr Leanne Wall • Since 2006 we have collaborated with the University of New South Wales (UNSW) to create a specific Postgraduate Diploma in Pharmaceutical Medicine available only to physicians.

The syllabus is based on the IFAPP 'Council for Education in Pharmaceutical Medicine' (CEPM) syllabus and the course utilizes some of the existing modules from the Masters in Drug Development program, plus a final module which is designed to round off the course and cover areas not elsewhere included. So far we have nine successful recipients of the Diploma. We anticipate that the course will be accredited when more firmly established.

The University of NSW Postgraduate Program in Drug Development consists of core and elective modules – courses – that lead to three qualifications:

- Graduate Certificate in Drug Development
- Graduate Diploma in Drug Development
- Master of Medical Sciences in Drug Development

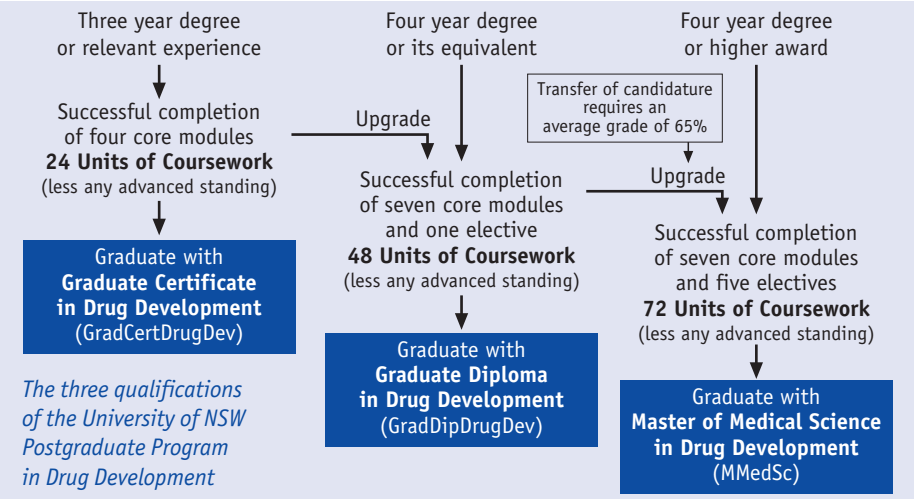
The diagram below illustrates what is required to gain these qualifications.

These post-graduate studies are available to all physicians working in the industry. However, to date we have only had a few APPA members enroll and complete the course. The fact that these studies need to be undertaken in addition to their busy day job, no doubt plays a huge factor in deciding on whether to embark on such a venture.

Unfortunately, none of these post-graduate qualifications are currently recognized in Australia as a medical specialty. In 2002 APPA approached the Royal College of Physicians to discuss the option of having some of these qualifications recognized through the College. This discussion was not successful. However, we hope that as the course becomes more firmly established the College may review their position.

IFAPP WORLD • The 'Association of Regulatory and Clinical Scientists' (ARCS) is a professional development association for people working in the development of therapeutic goods. Do ARCS and APPA compete or cooperate? And what do they do on a national and an international level? What are their aims and objectives?

Dr Leanne Wall • ARCS was founded in 1984. They have approximately 2,500 members who are involved in ▶ page 6



The three qualifications of the University of NSW Postgraduate Program in Drug Development

THE FLAG

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Questions & Answers

◀ page 5 regulatory affairs, clinical research, health economics, medical devices, diagnostics, data management, statistics, medical writing, pharmacovigilance, and the provision of medical information in the Australian pharmaceutical and healthcare industries. ARCS is a not-for-profit company which is governed by an elected Board. Their members are accepted into one of five membership categories: Full, Associate, Student, Retired and Life Membership. All their educational events are open to members and non-members.

ARCS and APPA have worked closely together for over 20 years. This close collaboration has focused on bringing education to those in the pharmaceutical industry. ARCS also assist APPA on the administrative side of the association, i.e., membership and website management, bulletin broadcasts, meeting organizers, etc. Recently, APPA was approached to assist ARCS in identifying key opinion leaders within the medical community who would be interested in providing medical education to their members. The ARCS 2009 conference just held in Sydney the first three days of June was the first conference that included a session organized and chaired by APPA.

IFAPP WORLD • What about regulatory issues – is Australia following the idea of harmonization of the main pharmaceutical markets?

Dr Leanne Wall • Australia's regulatory authority – the 'Therapeutic Goods Administration' TGA – is an active participant in the global harmonization initiatives and is in close and regular communication with the other major regulatory agencies such as FDA and EMEA. It has regular video conferences with these agencies, and more when specific issues arise. One factor of geographic location is that at times the TGA is able to assist with the training and development of other national drug regulatory agencies in the Asia-Pacific region.

IFAPP WORLD • With regard to the structure of the Australian pharma business and to Australia's geographical position in the Asia-Pacific region with fast emerging huge markets in the neighborhood – in your opinion, what are the main challenges for Australia's Pharmaceutical Medicine and, all in all, for Australia's pharma business?

Dr Leanne Wall • Three specific challenges come to mind for the Australian pharmaceutical business but really these issues are global and not unique to Australia.

Firstly, government controls on medicines' costs, which has long been a concern here and is getting worse. An increasing, aged population is placing a strain on current healthcare systems in Australia, in particular the provision of pharmaceutical medicines. In turn, the government is placing increasing pressure on the industry to reduce the cost of drugs in order to control the government budget blow out on the PBS reimbursement scheme. As a result, generic companies are being looked upon more favorably by the government in hope of cost savings down the line. Other strategies such as mandatory price reductions within certain therapeutic classes have already been included in government legislation. As an example, when the first generic drug enters a particular therapeutic class reimbursed through the PBS, all drugs within that class, regardless of whether they are still on patent, have to take a mandatory 12.5% price reduction.

Secondly, opening up of clinical research opportunities in other much more populace countries – with much improving quality and quality assurance – is a direct business competition. This has resulted in a number of major changes we have seen recently in Australia. Research and Development is increasingly being outsourced to CROs, Pfizer being a recent example when they closed down their Australian research facility, retrenching around 52 clinical research trained employees, in favor of local CROs. Conducting trials in Australia is also expensive and long delays for Ethics Approval are frequently encountered. Furthermore, with a small population of 21 million, Australia is being overlooked for the larger countries with vast numbers of potentially drug naive patients such as can be found in China and India. Despite research in Australia being sound and data generated of very high quality, we are being overlooked by global pharmaceutical companies who find it easier to approach the larger countries in Asia-Pacific who have extraordinary recruitment potential.

Thirdly, closer scrutiny of marketing activities and of doctor-industry relationships is very much on the radar in Australia, with media fuelling the debate. I have been part of the Medicines Australia Code of Conduct Review Panel for our new Code and as part of the updating of the Code we sought stakeholder feedback from healthcare professional organizations, consumers and the industry and attempted to address their concerns in the new Code. We also reviewed a number of overseas Codes, including that of the US, UK and South Africa to gain a sense of where the global industry is going. I am confident that the new updated version of the Code, to become effective hopefully in January 2010, will provide clarity on many aspects of the doctor-industry interaction and hopefully in so doing, will silence the critics in the future.

IFAPP WORLD • Dr Wall, thank you very much for your openness and detailedness.

References available upon request ■

Notes from the Editor

Subscriptions to 'IFAPP World' and 'News Alerts'

Interested in being alerted about the 'Latest News' on the IFAPP website, 'IFAPP World' releases and news regarding the 'International Conference on Pharmaceutical Medicine' – ICPM 2010 – in Shanghai, China, 7-10 November 2010?

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Upon entering your e-mail address into the personal subscriptions database, you will get an e-mail with a hyperlink to the newsletter 'IFAPP World' and to the latest IFAPP news upon availability.

IFAPP News

New IFAPP Treasurer

Dr med Norbert Clemens is the new IFAPP Treasurer who was inaugurated on 1 January 2009. He succeeds in his respective responsibility Dr Herman Lahon, IFAPP's first-ever president 1975-1978 and the only Honorary Life President of the federation who retired from the Executive Committee member after 33 years of services. After gaining his MD and his PhD in Germany, Dr Clemens pursued a successful academic career holding a number of positions. His introduction into the pharmaceutical industry occurred as a project manager first, then as Medical Director, General Manager and Head Global Clinical Trial Services with a broad exposure to world-wide clinical research, project management and drug safety. He is now Head of Clinical Development with a Contract Research Organization.

Dr Clemens maintains a visible presence in European pharmaceutical circles: he was a board member of the R&D Committee of the 'German Pharmaceutical Industry Association' (BPI) for several years and he is a member of the drug safety and educational commissions and Past President of the 'German Society of Pharmaceutical Medicine' (DGPharMed). ■

IFAPP's Regional Update

Japanese Association of Pharmaceutical Medicine Holds Annual Meeting

by Dr Stewart Geary, Japan, member of the IFAPP Executive Committee and of JAPhMed

The 'Japanese Association of Pharmaceutical Medicine' (JAPhMed – http://japhmed.jp) held its annual meeting on 14-15 March 2009 in Kobe, Japan, where the members confirmed several important new decisions for the organization. JAPhMed has recently grown to over 220 physician members from industry, academia and regulatory authorities and over 50 per cent of the members were represented at the annual meeting, either in person or by voting proxy.

At the meeting the members confirmed JAPhMed to become a non-profit foundation ('Zaidanhoujin') in order to formalize its status as a non-profit organization. Dr Kyoko Imamura was confirmed as the new President of the organization, succeeding Dr Kihito Takahashi. Other officers as well as the auditor were also formally confirmed. In addition, the members agreed to purchase access to the 'eCLIN online training course' on the conduct of clinical trials in order to further augment the educational opportunities for physician members of JAPhMed.

As evidenced by the decision on the eCLIN course, training in Pharmaceutical Medicine has become an increasing focus of JAPhMed in recent years. JAPhMed's monthly meetings include two hours of lectures on Pharmaceutical Medicine, and the organization has organized a thorough course covering all the modules in the syllabus recommended by the IFAPP 'Council on Education in Pharmaceutical Medicine' (CEPM). Dr Hideo Shibata, who heads the Education Committee for JAPhMed, noted, "We have developed a rigorous requirement for training contact hours and last October, we completed the first certification of physicians in Pharmaceutical Medicine after implementing written and oral examinations for demonstrating competency in the subject."

In keeping with previous annual meetings, the bulk of the JAPhMed annual meeting consisted of lectures on select topics in Pharmaceutical Medicine including pharmacovigilance, risk management, the recent revision in the Declaration of Helsinki, the use of large databases for pharmacoepidemiologic research, development of vaccines in Japan and epidemiologic research using pharmacogenomics. The majority of lecturers at the meeting were from academia, illustrating the strong contacts between industry and academia in Japan. One of the highlights of the meeting was a panel discussion on issues in supporting and funding independent pharmaceutical research in universities.

Commenting on the accomplishments of the previous year Dr Takahashi noted, "We can look back on a year of growth for JAPhMed membership and active support by our organization of several conferences on Pharmaceutical Medicine and public health both in Japan and elsewhere in Asia. With our recent progress in establishing training and certification programs in Pharmaceutical Medicine, I feel we have increased the awareness of the importance of this field."

Looking ahead to the coming year, Dr Imamura noted, "My goal for JAPhMed's immediate future is to grow and be exposed to a variety of opportunities as the expert organization in Pharmaceutical Medicine. To reach this target we need to motivate ourselves and encourage subcommittee activities to work on issues where our medical and pharmaceutical knowledge are best utilized."

As described in its vision statement, JAPhMed looks forward to continuing to "promote Pharmaceutical Medicine by enhancing the knowledge, expertise and skill of pharmaceutical physicians, thus leading to the availability and appropriate use of medicines for the benefit both of patients and the society." ■

2009 JAPhMed annual meeting: Panelists discuss funding for pharmaceutical research at academic medical centers in Japan – far right side: Dr Kyoko Imamura, new JAPhMed President

News and Views from IFAPP's Member Associations

Hungary • The Hungarian member association 'Clinical Trial Management Society Hungary' (CTMS) – virtually 'Magyarországi Klinikai Vizsgálatszervezök Társasága' (MKVT) – has re-elected Dr Gábor Szepesi as President. A new secretary, Dr Otto Skoran, was nominated.

The CTMS/MKVT has recently moved to: Üllöi út 55, H-1091 Budapest. The website address has also been changed – www.mkvt.hu

Germany • The 'German Society of Pharmaceutical Medicine' (Deutsche Gesellschaft für Pharmazeutische Medizin – DGPharMed) held its elections of the board at the annual meeting in March. Dr Reinhard Hönig is the new President of DGPharMed. He is the successor of Dr Norbert Clemens, who will remain in the DGPharMed board as Past President and German delegate to IFAPP.

Argentina • The 'Argentine Society of Pharmaceutical Medicine' – 'Sociedad Argentina de Medicina Farmacéutica' (SAMEFA) – has a new board constituted in December 2008: Dr Juan Carlos Groppa was elected new President for the period from 2008 to 2010. Other Executive Committee members elected are Dr Hugo Cohen Sabban (Secretary) and Dr Eduardo de la Puente (Treasurer). Standing members: Dr Luis Collia (IFAPP Past President), Dr Pablo Viard, Dr Luis Pliego, Dr Daniel Mazzolenis, and Dr Liliana Lemme.

Three international meetings on Pharmaceutical Medicine were successfully held in Buenos Aires, Argentina, in 2008, in which SAMEFA participated or provided support: In March 2008 it was the first 'Latin American Congress of Rare Disease and Orphan Drugs', in October 2008 the '8th International Society of Pharmacovigilance (ISoP) Conference', and in November 2008 the '5th Annual Latin American Congress on Clinical Research', co-hosted by SAMEFA and the 'Drug Information Association' (DIA). Details about the three conferences are available on the IFAPP website www.ifapp.org (following the menu "news", "latest news", "archive" and "January 23-01").

France and Turkey • Until recently, IFAPP used to grow to a membership of 30 national member organizations. At the end of last year, however, the French 'Association of Physicians in the Healthcare Industry' – 'Association des Médecins des Industries des Produits de Santé' (AMIPS) – decided to withdraw membership for 2009 due to local priorities. The Turkish organization discontinued its activities. ▶ page 8

IFAPP's Regional Update

◀ page 7 As IFAPP President Professor Dr Gerfried Nell stated in his monthly message of May 2009, "The French temporary withdrawal stimulated IFAPP as the international umbrella organization to strive even harder for showing its value for the national member organizations because that is the only purpose of it. The case of the Turkish society demonstrates the necessity to assist newly founded organizations to overcome the hurdles of the beginning. I am sure that we will see a revival of the Turkish association. Clearly, the way to move forward for IFAPP is increasing its cooperation with the national societies.

New Regions • Fortunately, there is also an upside. The IFAPP Executive Committee has set up a working group called "New Member Associations" led by Dr Luis Collia, Past President of IFAPP, providing assistance and advice. IFAPP is making strong headway for instance in Asia.

In China the 'Chinese Forum of Pharmaceutical Medicine' (CFPM) has been established and is in the process of becoming a member of IFAPP. The CFPM will host the 'International Conference on Pharmaceutical Medicine 2010' – ICPM 2010 – in Shanghai, China, 7-10 November 2010, jointly organized by the CFPM, the 'Association of Pharmaceutical Physicians' of Singapore (APPS) and IFAPP.

Societies for Pharmaceutical Medicine also exist in India and Bangladesh or are being founded, e.g., in Malaysia. IFAPP is on its way to become a really global organization." Please read the entire monthly message at www.ifapp.org following the menu "news", "latest news", "archive" and "May 25-05". ■

Reports & Concepts

Quality Issues in Clinical Research

Report of the 10th IFAPP European Conference in London, January 2009

The IFAPP European Conference coming off in London, United Kingdom, in January has become a regular meeting date for IFAPP members and all interested parties. The 10th IFAPP European Conference on 30 January 2009, devoted to "Quality Issues in Clinical Research", was organized by IFAPP in collaboration with the 'British Association of Pharmaceutical Physicians' (BrAPP) and with the 'British Association of Research Quality Assurance' (BARQA). In the opening speech, Domenico Criscuolo, President and CEO, Genovax, Italy, underlined the importance of reaching the 10th annual event and stressed quality as a critical issue in Pharmaceutical Medicine, as the pharmaceutical industry altogether is dealing with ill people.

Fergus Sweeney from the 'European Medicines Agency' (EMEA) was co-chair of the morning session and the first speaker. In his presentation he underlined the quality program in place at the EMEA and provided indications of the EMEA-FDA (US 'Food and Drug Administration') collaboration to harmonize quality requirements. He also indicated the quality program in place at EMEA related to Third World countries, as some clinical data are generated in these regions of the world. Katharina Kurpanek, Good Clinical Practice (GCP) Inspector from the German 'Bundesinstitut für Arzneimittel und Medizinprodukte' (BfArM), presented a detailed overview of the quality programs in place in Germany. Jane Winter, expert in quality assurance (QA) at Pharma Business Solutions Ltd, member of BrAPP, United Kingdom, reported her experience with the implementation of study oversight in order to prevent quality issues. As Ms. Winter stated, companies, which rely heavily on outsourcing to achieve their development requirements, must pay particular attention to ensure an auditable oversight process is in place to demonstrate their accountability for patient safety and scientific integrity of the data. Although study oversight is key to ensuring appropriate clinical trial conduct, there is growing concern about the costs to meet the expectations of the Regulatory Authorities.

The morning session was then completed by Anna Piccolboni, Preclinical & Clinical QA Manager at Zambon SpA, Italy, who reported on her experience in auditing studies to keep quality under surveillance, and by David Butler, Quotient Bioresearch Ltd and member of BARQA Education and Training Committee, United Kingdom, who stressed the importance of proper education and training for personnel responsible for quality.

Andrew Fisher, representative of the 'Medicines and Healthcare products Regulatory Agency' (MHRA), United Kingdom, opened the afternoon session with an overview of his experience as a GCP inspector. Mr. Fisher reported that the majority of findings were related to the investigational medicinal product (IMP), to contracts and to the quality oversight of the study. He concluded that sponsors and CROs did have similar levels of findings from inspections.

Michael Bean, Johnson & Johnson, member of BARQA, United Kingdom, started in pharma, then spent a few years at EMEA quality program, and is now back in pharma. Bean stressed the importance of close collaborations between different parties, as this approach would be instrumental to produce the desired level of quality. Michael Britt, Roche AG, Switzerland, reported on Roche's quality system, which was continuously improved, last but not least as a result of a collaboration with regulators. The secret lies with the early detection of high risk situation, and having quality experts as regular members of project teams, he concluded. Regina Freunscht, a QA expert at Accovion GmbH, Germany, presented an oversight of the quality system in place in this contract research organization (CRO). Ms. Freunscht reported on the high level of attention to quality, as CROs are under a double scrutiny: from sponsors and from regulatory authorities. Finally, Matt Jones from BARQA, United Kingdom, talked about quality issues in the IT environment as an area of paramount importance, as we are now entirely dependent on the software and hardware worlds.

Jane Barrett, President of BrAPP and The Barrett Consultancy, United Kingdom, closed the event and reiterated the success of IFAPP European Conferences, which every year address a different topic of interest to regulators, pharmaceutical companies and CROs. Quality is and will remain a top priority area, bearing in mind that professionals in Pharmaceutical Medicine are developing drugs to help patients. Hence, quality in drug development is not just a must, it is an ethical duty.

Dr Domenico Criscuolo, Italy, member of the IFAPP Executive Committee ■

Abridged Reports from ICPM 2008

Developing Pharmaceutical Care – Medicines After the Blockbuster Era

Amsterdam, The Netherlands, 7-10 September 2008

"State of the Art in Trial Design Technology"

Chairs: Professor Dr Gerfried Nell, General Manager, NPC Nell Pharma Connect, Austria; Dr Paul de Koning, Vice President, Astellas Pharma Europe R&D, The Netherlands. Speakers: Professor Dr Paul Rolan, Professor of Clinical Pharmacology, University of Adelaide, Australia; Dr Kevin Cheeseman, Early Development Group Director, AstraZeneca, United Kingdom; Dr Kit Roes, Vice President, Organon part of Schering Plough, The Netherlands.

Validity of Biomarkers and Surrogate Endpoints

Professor Dr Paul Rolan reported on "Validity of Biomarkers and Surrogate Endpoints". He started with definitions differentiating between clinical endpoints (how a patient feels, functions or survives), biomarkers (any physiological measurement which may be a measure of a baseline state, a pathological process, or a response to a drug) and surrogate markers (this is a very small subset of biomarkers which substitute for a clinical endpoint, e.g., blood pressure, cholesterol).

The predictive value of biomarkers is not at first a question of the reliability of its measurement, which is assumed to be sufficient, but it depends on four aspects of validity.

- "Criterion validity": How does the test compare to a gold standard, i.e., a clinical endpoint.
- "Construct validity": Is there an accepted theory ("construct") available to link the test and the drug effect sought?
- "Face validity": Does the test appear to be a plausible measure of the drug effect sought?
- "Content validity": Do the test panels cover the range of intervention effects?

Professor Dr Rolan went on to explain that two types of biomarkers should be distinguished. Type 1 is drug-specific and relates to the initial pharmacological effect, e.g., the effect of an opioid on pupil size. Type 2 describes the subsequent effect on disease mechanism and is regarded as a systemic property. In the opioid example, this would be an effect in a pain model, e.g., cold pain model.

Regulatory authorities are showing an increasing interest in defining new biomarkers for assessing drug safety. In this regard, Professor Dr Rolan presented an example for new biomarkers predicting renal safety. In summary he stated that biomarkers have come of age and are part of the essential tool kit. Whereas "validity" is a reasonable term for the numerical precision aspect, "predictive utility/qualification" may be better for the interpretation aspect. However, the scientific world is getting more sceptical about surrogates.

Pharmacogenetics in Clinical Trial Design

Dr Kevin Cheeseman talked on "Pharmacogenetics in Clinical Trial Design". He explained that the last ten years have seen a surge in research into the genetic basis of drug response due to the hope that pharmacogenetic investigations may address major health needs, e.g., reducing adverse drug reactions. Pharmacogenetics may also help to improve the productivity of drug research and development. And last but not least, it may have the potential to improve treatments for chronic diseases, which pose the greatest disease and cost burdens in all developed countries.

Pharmacogenetic testing has become increasingly common in drug development aiming to better understand variability in efficacy and safety and eventually resulting in so-called "personalized medicine". Looking at the status of personalized medicine, it is obvious that there is an increase in the number of drugs which have to be indicated in accordance with the results from specific diagnostic testing. However, almost all of the examples of diagnostic testing for specific drug treatments are derived either from oncology (e.g., Herceptin, a treatment for breast cancer, requires testing of HER2) or infectious diseases (e.g., Maraviroc to treat HIV/AIDS requires testing of CCR 5 tropism).

These are examples showing how genetic variations in the target need to be characterized for accurate drug selection and proper indication. This is an area where scientific understanding meets regulatory requirements and commercial opportunities, and it illustrates, that molecular diagnostic is becoming an evermore important part of standard clinical practice.

As Dr Cheeseman summarized, using pharmacogenetics throughout R&D is already impacting program designs, study designs, internal decision-making, external product approvals and treatment decisions. While the pace of change is slow in some areas, the impact is already high in others.

Developing pharmaceutical care in a non-competitive atmosphere – ICPM 2008

Adaptive Clinical Trial Design

Dr Kit Roes expanded on "Adaptive Clinical Trial Design". These are multistage study designs using accumulating data to decide how to modify aspects of the study without undermining the validity and integrity of the trial design or, in simple words: We can learn as we go, change the design while going and still ending up with a valid clinical trial with a higher success probability. Classically, an adaptive design is used with single rising dose studies to establish a safe dose range. The new aspect is the adaptive interim design, which, for instance, allows dropping ineffective doses during the progress of the trial.

Although the underlying statistical principles are well accepted, there are few examples only in which new drugs have obtained approval by authoritative bodies based on the results of trials with adaptive interim designs.

Adaptive trial designs raise challenging questions for clinical trial management and logistics and increase the risk of bias by information and adaptive decisions. The regulatory attitude has been characterized by a cautionary approach, particularly in the confirmatory setting, while at the same time the potential of this new tool is highly recognized. Health authorities want to see that adaptive designs produce scientifically better answers on efficacy and safety and are not only a way for "faster" and "more efficient" R & D. ▶ page 10

IFAPP's Vision Statement

"By 2011, IFAPP is recognized and accepted as an authoritative voice on the medical aspects of the pharmaceutical industry and education and standards within pharmaceutical medicine by governmental and regulatory authorities, pharmaceutical industry bodies, the public, healthcare providers, healthcare professionals, academic bodies and the media."

Abridged Reports from ICPM 2008

◀ page 9 All in all, biomarkers, pharmacogenetics and adaptive trial designs are gradually transforming and improving research and development of new drugs, but it is an evolution rather than a revolution which takes more time than optimistic observers might have anticipated.

Professor Dr Gerfried Nell, Austria, IFAPP President

"Modern Clinical Development – Outsourcing Strategies"

Chairs: Dr Domenico Criscuolo, President and CEO, Genovax, Italy; Dr Philippa Smit-Marshall, Vice President, PharmaNet, The Netherlands. Speakers: Jeffrey McMullen, President and CEO, PharmaNet, USA; René Sluijter, Head Global Alliance Management, Solvay Pharmaceuticals BV, The Netherlands; Dr Gillian Langford, Product Development Manager, Alizyme Ltd, United Kingdom.

Clinical Development is a crucial step in the long-lasting path from drug discovery to marketing – ICPM 2008 devoted two sessions to this topic. The author of this report had the opportunity to co-chair one of these session on "Outsourcing Strategies". There were three speakers, wisely selected to represent three different environments: Contract Research Organizations (CROs), big pharma and small biotechs.

Models for Outsourcing

Jeffrey McCullen expressed the opinion that the role of CROs has dramatically evolved in the last 20 years. The initial scope, limited to full or functional service providers, has changed into more adaptable models, which take clients' needs and expectations into account. As the clinical phase has become ever more important in drug development, clients are keen to utilize more accurate tools to build up reliable partnerships with CROs with the aim to speed up the entire research and development process while improving outcomes. In conclusion, the modern paradigm for outsourcing is increasingly based on strong and long-lasting partnership.

Partnering with CROs

René Sluijter confirmed these trends. In fact, he was able to report his personal experience as he managed to establish and consolidate a specific alliance with a CRO. He also reported about the evolution in the client-CRO relationship. CROs, which originally were only assumed as additional resources, have got a more important role in the process of drug development over time. Solvay, for instance, decided to adopt an "alliance" model with the selected CRO, based not only on a complete disclosure of plans and objectives, but also on sharing project goals and related benefits.

Outsourcing Needs of Biotech versus those of Pharma

Dr Gillian Langford presented an interesting comparison between outsourcing models in big pharma and in small biotechs. Biotech companies are usually driven by the need to meet ambitious milestones and whilst pharmaceutical companies also work to similar timelines, there is an element of risk mitigation, which may affect the way in which they outsource projects. Pharmaceutical companies "as a rule" prefer to outsource repetitive non-core tasks, which would require additional staff within the company, while biotech companies outsource a much wider variety of tasks and often even entire projects.

One of the major differences between pharma and biotech is the level of internal expertise. In many biotech companies projects are managed by a small team or even by a single project manager, who may be responsible for outsourcing all aspects of a project. In contrast, pharmaceutical companies have internal resources and expertise for many aspects of the project, and outsourcing is a matter of tactics rather than a strategy.

Conclusion

In conclusion, this ICPM 2008 session was an interesting update of outsourcing management: it is noteworthy to underline the significant changes which occurred in approximately 20 years. When outsourcing was invented in the early '80s, it was conceived for limited use of additional external resources. Over times, outsourcing has become a strategic tool, used by companies to move from fixed to variable costs, and also to gain in flexibility and competitive pricing. Now most big pharma are moving into a strategic alliance with one or two preferred CROs, and some of them are implementing shared objectives and bonuses to both internal and external staff. A very interesting change, which may raise a naïve question: "If internal and external staff share goals and bonuses in order to create a very strong team spirit, is the outsourcing strategy still a valid model?" The author's personal opinion is that this strategy is certainly cost-effective in biotechs and small pharma as they have an erratic need of resources. But in big pharma, where the demand for resources is relatively stable, I am honestly very puzzled!

Dr Domenico Criscuolo, Italy, member of the IFAPP Executive Committee ■

IFAPP's Calendar

ICPM 2010

'International Conference on Pharmaceutical Medicine'

Shanghai, China, 7-10 November 2010

Please join us at this important event for Pharmaceutical Medicine and mark this date in your calendar already now. Detailed information on ICPM 2010 will be available soon on IFAPP's website www.ifapp.org or subscribe to IFAPP's 'News Alert' under www.ifapp.org/subscribe – looking forward to seeing you in Shanghai! ■

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