2011 April

IFAPPWORLD

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS

PRESIDENT'S LETTER

Dear Colleagues

Professor Dr Gerfried Nell, IFAPP President:

In the last issue of "IFAPP World" we focused on the Asia Pacific region. This issue is highlighting the recent developments in Africa, in particular in the Republic of South Africa. This country has a long-standing tradition in excellent clinical research ...

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1st IFAPP Science2Business Conference

18-19 April 2011, Amsterdam, The Netherlands

Academic-industrial collaboration forms an essential part in the development of new and better medicines. It produces new knowledge, translates into better ways to treat diseases and improve ...

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WWW.IFAPP.ORG

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"The concept of Pharmaceutical Medicine according to the IFAPP standards is well known but has only recently been introduced to academia."

President's Letter

Dear Colleagues

In the last issue of "IFAPP World" we focused on the Asia Pacific region. This issue is highlighting the recent developments in Africa, in particular in the Republic of South Africa. This country has a long-standing tradition in excellent clinical research and high standards of regulatory affairs and is determined to maintain and strengthen its role in these areas. However, it also faces the challenge of fighting diseases like tuberculosis, AIDS and malaria in South Africa and other African countries. Val Beaumont, representing the research based South African pharmaceutical companies, gives a lively picture of achievements and challenges of the pharmaceutical industry in South Africa.

Close to our heart is – in particular – the state of education in Pharmaceutical Medicine, which is different as compared to several European countries. Clinical pharmacologists and pharmacists dominate research and development. For both professions specific graduate programs are available, preparing them for their work in the pharmaceutical industry.

The concept of Pharmaceutical Medicine according to the IFAPP standards is well known but has only recently been introduced to academia. You will see an example described by Professor Dr Bernd Rosenkranz who initiated a Postgraduate Course in Pharmaceutical Medicine based on IFAPP and the UK Faculty of Pharmaceutical Medicine (UK FPM) syllabus at Stellenbosch University in South Africa.

It is anticipated that an increasing demand for effective medicines will result in the need for improvement and extension of education and continuous professional development in drug research, which is exactly what we define as Pharmaceutical Medicine.

Further on in this issue of "IFAPP World", the President-Elect of IFAPP, Dr Rudolf van Olden from Amsterdam, The Netherlands, expands on the 1st IFAPP Science2Business – S2B – Conference which will be co-organized with Science Alliance from April 18th to 19th in Amsterdam, The Netherlands. The agenda deals with academic-industrial collaboration, how to overcome mistrust and institute trustworthy cooperation. Please find an invitational note on page 3 and the detailed program at the end of this issue.

In connection with this S2B conference, the IFAPP committees are going to be newly elected and the agenda for the next two years will be set. My turn as IFAPP President will end and I would like to thank all those who actively participated in IFAPP affairs. It was a great experience working together with you and I would like to thank you from the bottom of my heart for your continuing support. Let us now rally behind the new IFAPP leadership with Rudolf van Olden as elected IFAPP President and help his team to further promote education in Pharmaceutical Medicine thus improving the skills of our colleagues worldwide which will result in the availability of better medicines in the end.

With kind regards

Professor Dr Gerfried Nell,
IFAPP President, Austria

For further information and a detailed program please visit www.s2bc.org

IFAPP's Calendar

1st IFAPP Science2Business Conference

'Academia-Industry Collaboration for New and Better Medicines'
18-19 April 2011, Amsterdam, The Netherlands

Academic-industrial collaboration forms an essential part in the development of new and better medicines. It produces new knowledge, translates into better ways to treat diseases and improve healthcare.

IFAPP is proud to present you the final program of the 1st IFAPP Science2Business (S2B) Conference on Academia-Industry Collaboration for New and Better Medicines.

For further information and a detailed program please visit www.s2bc.org or browse to page 21

The main themes at the S2B conference are "Creating Partnerships" followed by "From Partnership to Trust". We have selected an excellent international speaker faculty, all of whom highly qualified and well-known experts in their field.

Monday 18th April 2011

The Conference will start on Monday 18th April with three plenary key-note lectures about the different perspectives regarding the collaboration between academia and the pharmaceutical industry. In addition, we will continue with four workshops focused on current topics:

- Partners on the Research Agenda: Pitfalls in Partnering – Does the Sponsor Matter?
- Pharmaceutical Medicine: Overcoming Mistrust in the Academia-Industry Collaboration
- Safety Reporting: Ensuring Valid Safety Reporting in Investigator-Sponsored Trials
- Collaboration Models: Trustworthy Collaboration in Clinical Research and Publications

Lise Murphy, Co-Chair of the European Medicines Agency's Patients' and Consumers' Working Party (PCWP):

"The EU Clinical Trials Register increases transparency of medical research and will make it much easier for patients to find information about clinical trials."

Reports and Concepts

EU Clinical Trials Register goes live

Public online register gives access to information on clinical trials

The EU Clinical Trials Register (https://www.clinicaltrials-register.eu) has been launched by the European Medicines Agency (EMA). The online register gives for the first time public access to information on interventional clinical trials for medicines authorized in the 27 EU Member States and Iceland, Liechtenstein and Norway. The database also allows the public to search for information on clinical trials authorized to be carried out outside the EU if these trials are part of a pediatric investigation plan (PIP).

The information contained in the EU Clinical Trials Register is extracted from EudraCT, the EU clinical trials database. It is provided by the sponsor of the clinical trial, and is a component of its application to a national medicines regulatory authority for authorization to conduct a trial. The information from the sponsor is loaded into the EudraCT database by the national medicines regulatory authority. The authority adds to this information the authorization of the clinical trial and the opinion from the relevant ethics committee. Information on third-country trials that are listed in a PIP is provided by the PIP addressee directly, via the EMA, to the system. ■

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1st IFAPP Science2Business Conference

In all the workshops the perspective of both academia and the industry will be presented by excellent speakers.

Tuesday 19th April 2011

On Tuesday, the second conference day, we will demonstrate the views of academia, industry, journal editors (British Medical Journal) and health care authorities (European Medicines Agency) about: "Conflicts of Interest in Scientific Journals". Topics such as ghost writing will be discussed in detail.

With the 1st S2B Conference in Amsterdam, IFAPP is starting a new series of S2B conferences around the globe. This will provide you a mental refreshment with regards to credibility of data in commercial and non-commercial trials, the role of independent institutions in the assessment of efficacy and safety, financial incentives and other types of conflicts of interest.

We really hope to welcome you to Amsterdam!

Dr Rudolf W. van Olden, MD, PhD
IFAPP President-Elect, Chairperson of the 1st S2B Conference 2011 in Amsterdam ■

SCIENCE ALLIANCE
Connecting Science and Society

IFAPP

Questions & Answers

Pharmaceutical Medicine in South Africa

A Position Meeting National Particularities and Internationally Accepted Standards

Val Beaumont, Executive Director – Innovative Medicines South Africa (IMSA), expert in Pharmaceutical Industry Affairs, outlines the position of Pharmaceutical Medicine in South Africa in a conversation with Eckhard Böttcher-Bühler from 'IFAPP World'

IFAPP WORLD: The soccer World Cup in 2010 has drawn a clear picture of South Africa's modern and well-organized infrastructure, while the picture regarding South Africa's pharmaceutical industry and policy is vague. Val Beaumont, could you provide a brief description of the respective environment?

Val Beaumont: We find ourselves in a unique position here on the African continent because we have an ambiguous situation. From the commercial and more developed world standpoint, the pharmaceutical industry has been identified as a key area for potential growth and the South African Industrial Policy Action Plan – IPAP – 2010 to 2013 highlights the pharmaceutical industry as one of four priority areas for growth and development in this country. In fact, we do have a fairly well developed pharmaceutical industry.

The Industrial Policy Action Plan looks on domestic production of active pharmaceutical ingredients for key anti-retroviral drugs, of reagents for AIDS and HIV diagnostics under license, of vaccines under license and of biological medicines, e.g., erythropoietin and monoclonal antibodies.

And – what is important – the Action Plan also promises to remove regulatory barriers and constraints to clinical research in South Africa. ▶

Quotation from the South African Industrial Policy Action Plan – February 2010

«Pharmaceuticals sector profile – Manufacturing employment in the pharmaceutical sector was 9,500 in 2007 [0.7%] (down from 16,000 in 1999). It is the fifth largest contributor to South Africa's trade deficit: R14.8 bn in 2008.

While the South African pharmaceutical market is only 0.35% of the global market, it is also the world's largest market for anti-retrovirals (ARVs). Currently, there are 900,000 AIDS patients receiving anti-retroviral treatment (ART) in South Africa, of which 800,000 are in the public sector and 100,000 in the private sector. The cost of ARV procurement by Government in 2009 is estimated at R 2.8 billion, escalating to R 7 billion in 2011. Apart from the economic burden, this poses risks to the security of supply of ARVs.

Imports in 2008 were R 16 billion while exports were R 1.2 billion. The export market has been under significant pressure due to the crisis in Zimbabwe – this market accounted for 50% of South Africa's pharmaceutical exports until 2001 – and competition from exports from India. ▶

Val Beaumont, Executive Director – Innovative Medicines South Africa (IMSA):

”I am a pharmacist, representative of the pharmaceutical industry rather than of pharmaceutical medicine.“

▶ IFAPP WORLD: What does clinical research mean for South Africa?

Val Beaumont: With regard to the statistics: The current clinical research volume in South African rand (R) is 2 billion per year while there is potential for R 4 billion to R 5 billion per year. Overall, about 25% of the investments in clinical research go directly through locally based multinational pharmaceutical companies and the balance through CROs (Contract Research Organizations).

The quality of research for better medicines that we do in South Africa has always been very good. There is a lot of interest to do more clinical research and the infrastructure is well prepared.

South Africa has a high standard of assessment for market authorizations, which is comparable with the most developed countries – all applications for medicines' registration are fully assessed by South African experts. Any product that complies with these standards is registerable here. However, these procedures are slow and inefficient and registration times are excessive for both generic and innovative medicines.

We do have reasonable protection for intellectual property, which is important to encourage engagement in South Africa. This protection is important for the stimulation of development of treatments for the neglected diseases we have over here and also for the development of African traditional medicines.

South Africa is a signatory of the Agreement on Trade-Related Aspects of Intellectual Property Rights – TRIPS – and products must comply with intellectual property legislation although South Africa does have the Bolar provision, allowing generic manufacturers to register their medicines although not sell them ahead of patent expiry. ▶

Key opportunities

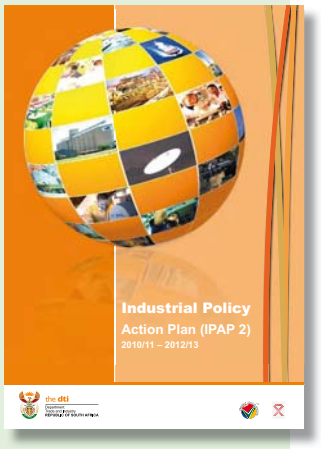
- Domestic production of active pharmaceutical ingredients for key ARVs.
- Local production of reagents for AIDS/HIV diagnostics, under licence.
- Domestic production of vaccines under licence.
- Domestic production of biological medicines such as erythropoietin, monoclonal antibodies and vaccines.
- Removing regulatory barriers and constraints to clinical research in South Africa (current market R 2 billion per year). Potential market size is R 4 billion to R 5 billion per year.

Constraints

- Small size of the South African market (0.35% of global) – the only segment that attracts the attention of foreign investors is the South African ARV market.
- Downward pressure on prices, reducing attractiveness of South Africa to existing and potential investors.

Lack of key skills in new drug design, pharmaceutical formulation and pharmaceutical biotech. Excessive supply of graduates with conventional skills and knowledge (more suitable for pharmaceutical marketing and sales).»

[Department of Trade and Industry, South Africa: Economic Sectors and Employment Cluster – 2010/11 – 2012/13 Industrial Policy Action Plan. February 2010. Page 61]



The South African Department of Trade and Industry highlights the pharmaceutical industry as one of four priority areas for growth and development.

IFAPP WORLD: You mentioned the Industrial Policy Action Plan – but is the South African industrial policy view congruent with the health care policy perspective?

Val Beaumont: No – indeed – there is a stark contrast. The pharmaceutical market in South Africa is divided into a privately and a state-funded market. According to IMS South Africa data from 2009, the privately funded market represented approximately 15 percent of the 49 million population but was worth around R 20 billion in 2009 while the state-funded pharmaceutical market represented more than 80 percent of the population which was worth around R 5 billion per year.

The South African Department of Health is strongly influenced by a developing world health agenda and environment where generic medicines, lack of funding and challenges in making medicines more affordable and getting them to patients are the order of the day.

The South African Department of Health policy is constantly trying to make medicines more affordable by intervening in the commercial environment and the market place, while the Department of Trade and Industry is trying to attract investments and to grow the local industry.

The South African pharmaceutical industry is operating in this conflicting environment and often faces a lack of harmonization between the different government departments. The challenge for the industry is to elaborate strategies for developing and registering innovative medicines and at the same time making them more affordable and ensure access for all. However, compared to other African countries we are way ahead and have a strong pharmaceutical industry presence.

IFAPP WORLD: What is the pharmaceutical industry point of presence in South Africa?

Val Beaumont: A large number of pharmaceutical companies – some 260 plus – are listed on the IMS data base for South Africa – far more than for other countries in Africa. Many of these are trading units only operating within larger corporations.

However, there are about 25 multinational research-based companies. These companies, together with 20 generic companies, supply most of the medicines in South Africa, with some of the multinational companies now having generic divisions. There also are quite a lot of local manufacturers not only of generics but also of branded originals. They all are organized in trade or industry associations representing different groupings (for details see the paragraphs in the box).

There are about 30 CROs listed. But it seems as though about 23 were actively contracting clinical trials on behalf of pharmaceutical companies and making profit. Most of them are directly working for multinational pharmaceutical companies.

National Association Representing Pharmaceutical Business and Pharmaceutical Medicine in South Africa

NAPM – National Association of Pharmaceutical Manufacturers: NAPM (www.napm.co.za) is a trade organization focusing on the supply of generic medicines, as they state on their website. Generics are frequently imported from India and other countries in the Asia Pacific Region.

PIASA – Pharmaceutical Industry Association of South Africa: PIASA (www.piasa.co.za) is a trade organization with members from research-based multinational pharmaceutical companies operating in South Africa and local manufacturers of pharmaceuticals, especially generics. PIASA is member of the International Federation of Pharmaceutical Manufacturers and Associations – IFPMA (www.ifpma.org).

IFAPP WORLD: What is South Africa's pharmaceutical business value?

Val Beaumont: The pharmaceutical industry contributed 1.17 percent to the Gross Domestic Product of South Africa; it employed over 9.5 thousand employees.

The recently completed Deloitte Report on the high-level financial contribution of the pharmaceutical industry to South Africa found that the revenue of the industry in 2009 was projected to be R 31 billion. Export revenue was about R 1.8 billion in 2009. Most of the exported medicines were exported to other African countries. Medicines imported into South Africa came from Germany (R 1.54 billion), France and the USA (R 1.42 billion each), India (R 1.28 billion) and the United Kingdom (R 1.2 billion).

The pharmaceuticals sold in South Africa were split between prescription medicines (66%), pharmacy only medicines (12%), fast moving consumer pharmaceuticals (12%), and OTC pharmaceuticals (10 %).

In terms of value, more than three quarters of medicines – over 76% – are sold to the private healthcare sector, which represents about 15% of the 50 million population. More than 65% in the private sector were prescription medicines and the generic penetration in the private market was around 58% in 2009. However, in terms of units, two thirds of the medicines are supplied to the public sector.

IMSA – Innovative Medicines South Africa: IMSA (www.imsa.org.za) exclusively representing research-based pharmaceutical companies and also a member of IFPMA.

PHARMISA – Pharmaceuticals Made in South Africa: PHARMISA representing companies with local manufacturing capacity.

SAGMA – Southern African Generic Medicines Association: The member companies of SAGMA (www.sagma.net) are manufacturing generics locally or frequently importing generics from India and alike.

SMASA – Self Medication Association of South Africa: Manufacturers and traders of prescription-free Over-The-Counter (OTC) medicines are represented by SMASA (www.smasa.cc).

SACRA – South African Clinical Research Association: SACRA (www.sacraza.com) is a non-profit organization representing the clinical research industry in South Africa

SAAPP – South African Association of Pharmaceutical Physicians: "SAAPP (www.saapp.org.za) is not as active in industry issues as they were before." [Val Beaumont]

IFAPP WORLD: The people in South Africa and in Africa as a whole are exceedingly challenged by serious diseases, e.g., tuberculosis, AIDS, malaria etc. To combat these diseases South Africa has regulated the procurement of pharmaceutical supplies to ensure that essential drugs are affordable and available. What exactly does that mean for pharma operations and regulatory issues?

Val Beaumont: TB [tuberculosis], HIV/AIDS and malaria are our burden diseases, which are given maximum attention beside maternal health and some other health issues. We are fortunate in having better access to an improved range of very high quality treatments and medicines than our neighbors. Medicines for the public sector are specified by an Essential Drug List – EDL – that is divided into the primary care EDL, the secondary EDL for referred patients and the tertiary EDL, which identifies medicines largely available to specialists only. The country is moving towards an evidence- and cost effectiveness-based approach in order to control the medicines on the Essential Drug Lists.

Anti-retroviral medications that fight HIV have been licensed by multinational companies to manufacturers in South Africa resulting in very low prices, of a magnitude of the lowest in the world, because we have some very effective licensing agreements. Anti-TB medications are also available throughout the country at very low tender prices. Overall medicines on the Essential Drug Lists are extremely cheap compared to global standards. All this supports the public health sector.

As I already mentioned: The volume of medicines sold to the public health sector is high in terms of units but low by value – compared to the private health sector. And we see ongoing interest by the government to improve the supply of medicines combating burden diseases.

In the private sector, patients can purchase a broad cross section of medicines, provided these medicines are registered by the Medicines Control Council (MCC) of South Africa. Private health insurance covers certain treatments – insurance benefits vary from scheme to scheme.

Notwithstanding registration, the medical schemes tend to restrict reimbursement of innovative medicines on a cost-basis rather than on pharmacoeconomic principles. Hence, while the medicines are available in South Africa, they are not always included in medical scheme formularies.

Overall – we have a good balance of intellectual property protection and of cross licensing to ensure affordable treatments for the burden diseases. And – just to consider – the private health sector creates an environment that ensures that the other new technology medicines are available should people need them.

IFAPP WORLD: Regarding regulatory issues: What is South Africa's position between national particularities and internationally accepted standards, e.g., standards of the International Conference on Harmonization?

Val Beaumont: South Africa by and large follows the ICH standards for clinical research and development and registration. South Africa also is a member of the Pharmaceutical Inspection Convention – PIC.

Our medicines regulations date back to 1965 – when most other industrialized nations implemented controls. Our regulatory authority is well developed and the regulatory system currently being revamped. The quality standards are high with very little difference between South African and ICH policies. Interestingly enough, the assessments of drug applications are totally done by our national experts – in this respect, we are very proud of the expertise and the system we have.

The main challenge that we currently face – and particular as a pharmaceutical manufacturers' organization we see it quite clearly – is to address harmonization between our African neighbors and ourselves. And also to bring some sort of standard of medicines control into broader Africa taking account of the strains of less developed countries and the need to protect patients from sub-standard medicines. It's hard to do it without increasing costs and without creating bureaucracy.

Unfortunately, there are still many African countries procuring medicines wherever they can get them or wherever they can find them with very little quality control or guarantee of

Recently, a Pharmaceutical Business Plan for Southern Africa has been published by the Southern African Development Community – SADC

sustained supply. Our aim should be to ensure a minimum level of protection for all citizens of this continent.

IFAPP WORLD: In this regard – what is the role of South Africa?

Val Beaumont: Recently, a Pharmaceutical Business Plan for Southern Africa has been published by the Southern African Development Community – SADC – with a membership of 15 African states – Angola, Botswana, the Democratic Republic of Congo, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, the United Republic of Tanzania, Zambia and Zimbabwe. It contains an SADC agreement to form an alliance and create common standards and a cooperative arrangement. There are countries, besides South Africa, which have well developed regulatory systems, e.g., Botswana and Namibia.

I would not say that South Africa is necessarily taking a leading role in this process, but we have many Non-Governmental Organizations – NGOs – based in South Africa, which are working throughout the SADC area. These NGOs are creating a discussion around harmonization and regulatory standards, around access to affordable medicines and around manufacturing expertise. There is therefore a lot of work done on the NGO level linking the various health ministries and encouraging harmonization and minimum standards.

IFAPP WORLD: Pharmaceutical operations obviously constitute a very lively scene in South Africa. What about Pharmaceutical Medicine as a discipline involved in clinical research and regulatory issues in SA?

Val Beaumont: That bigger vision of Pharmaceutical Medicine is still in its infancy here.

The bulk of the work is divided between experts in clinical pharmacology as a specialty and quite a senior level of pharmacists with very detailed regulatory training.

A shortage of expertise in clinical research specialists in this country has resulted in more pharmacists and other scientists expanding into this field. We have also seen different medical specialties fulfilling these roles. However, a very high level of expertise satisfies the actual needs of the pharmaceutical industry at the current level of research.

IFAPP WORLD: These professionals – clinical pharmacologists and pharmacists – do they rather cooperate with or compete against each other?

Val Beaumont: They work together very effectively.

A lot of the regulatory work is done, and in fact is dominated by pharmacists, frequently by pharmacists with a specialized post-graduate qualification. We have got a couple of universities, which offer a master degree in industrial pharmacy with a focus on regulatory issues, clinical trial expertise, etc. That's why we have a lot of very strong pharmacists with broader research and regulatory skills.

Then there is the whole world of the pharmaceutical physicians. In the late 1970s they were organized in the South African Association of Pharmaceutical Physicians – SAAPP. However, SAAPP is not as active on industry issues as they were before. Their role seems to have been picked up by the Association of Clinical Research Associates – SACRA. I don't know the reason why the SAAPP is inactive.

In terms of the physician's qualification there is a so-called MPharm-Med Master degree program offered by the University of Pretoria since 1974, which basically is a post-graduate course in clinical pharmacology for physicians holding a Bachelor's degree in medicine and surgery. The MPharm-Med Master does not have all the regulatory issues in it and does not include all the specific qualification for pharmaceutical medicine but it prepares people for the pharmaceutical industry. Most of the medically qualified people in the South African pharmaceutical industry will have the MPharm-Med qualification.

In 2010 a post-graduate diploma course in Pharmaceutical Medicine was also launched at the University of Stellenbosch (for details see page 12).

And there are a few people who are actually fellows of the Faculty of Pharmaceutical Medicine of the Royal College of Physicians of the United Kingdom – FFPM.

IFAPP WORLD: Are you, as a pharmaceutical industry affairs representative, satisfied with the human resources in this field or do you see any further demand for qualified people?

Val Beaumont: Well, I already mentioned the South African Industrial Policy Action Plan, which highlights the pharmaceuticals sector as one of four priority areas for growth and development in this country. If this plan can stimulate an increase in the amount of clinical research that is happening in this country, then we will certainly need a lot more people qualified in pharmaceutical medicine.

However, at the moment politicians of South Africa are not doing anything visible to make it easier for companies to bring clinical research to this country. In fact, it can be quite difficult here to get a trial approved.

At the same time, other countries have facilitated clinical research and built up centers of excellence where companies get their clinical trials approved more quickly. The investments follow these smarter regulatory processes. That's why we are losing trials to other countries. And we also notice that the number of companies doing such research is diminishing by mergers and acquisitions.

We would be happy if the regulatory process here in South Africa became more efficient. We also hope that the Department of Science and Technology pursues its policy of stimulating research in South Africa.

IFAPP WORLD: In your opinion, what are the main challenges for South Africa's Pharmaceutical Medicine and, all in all, for South Africa's pharmaceutical business?

Val Beaumont: The main challenge for the South African healthcare environment altogether and for the pharmaceutical industry in particular is to make innovative medicines accessible to the broader population. If we look at the split between public and private sector and the access to healthcare at the moment there is a lot of work to be done. We have to find ways to make it happen.

The success will depend on cooperation and trust between the pharmaceutical industry and the South African government. The interests are quite different. For instance, the Department of Health is constantly making interventions, which reduce the viability of the industry in the country.

The interests need to be well balanced – this is the challenge.

IFAPP WORLD: Thank you very much for your openness and detailedness. ■

Reports and Concepts

South Africa Pushes Postgraduate Education in Pharmaceutical Medicine

Could IMI PharmaTrain Open its Activities to Non-EU Regions?

Planning and execution of research and development programs for novel drugs, preparation of regulatory documents for marketing authorization, pharmacovigilance and post-marketing activities – topics constituting the medical specialty Pharmaceutical Medicine – have become increasingly complex. Highly specialized experts in Pharmaceutical Medicine are required to oversee these activities.

Recognizing the urgent need for training in Pharmaceutical Medicine, numerous training programs have been developed over the past 20 years or are under development by universities or other faculties in Europe, America and Asia.

The websites for instance of IFAPP (www.ifapp.org/home/education) and Innovative Medicines Initiative (IMI) PharmaTrain (www.pharmatrain.eu) provide a glance of these trainings and other educational activities.

In South Africa, physicians working in the pharmaceutical industry were organized in the South African Association of Pharmaceutical Physicians (SAAPP – www.saapp.org.za) ▶

Prof Dr Bernd Rosenkranz, Stellenbosh University, Republic of South Africa:

He strongly believes it would be useful to open the IMI PharmaTrain activities to non-EU regions, such as South Africa.

with 83 members in 2005, although this organization has not been active during the past few years. No efforts have been made to recognize Pharmaceutical Medicine as medical specialty. Instead, clinical pharmacology has been accredited as medical specialty by the Health Professions Council of South Africa (HPCSA –www.hpcsa.co.za) Postgraduate Education and Training Subcommittee and the Medical and Dental Professions Board and Council in 2009. Final gazetting by HPCSA is pending. Clinical pharmacology is represented by The College of Clinical Pharmacologists (CCP), a member of the Colleges of Medicine of South Africa (CMSA – www.collegemedsa.ac.za, equivalent of the UK Royal College of Physicians – UK RCP).

South Africa's Diploma in Pharmaceutical Medicine

In 2010, the Pharmacology Division at Stellenbosch University together with Tiervlei Trial Centre (TTC) launched a 2-year, part time postgraduate diploma course in Pharmaceutical Medicine, the first of its kind in South Africa. The syllabus of this course is based on those proposed by the UK Faculty of Pharmaceutical Medicine (UK FPM) and by IFAPP to ensure harmony with other existing programs. The course has been accredited as Postgraduate Diploma in Pharmaceutical Medicine (PGDip Pharm Med) by the Stellenbosch University and by the South African Department of Education.

As of April 2010, the University also offers the individual modules of the program as four separate short courses. Successful participants are awarded Continuing Professional Development (CPD) points and a certificate of competence. Applicants with a medical, dental or pharmacist degree can be admitted to the program on the basis of the degree, whilst those with a nursing, biomedical or other relevant science degree need to have had two years of experience in pharmaceutical medicine prior to participation.

Module Outline of the Post Graduate Diploma in PM in South Africa

The program consists of the following four modules, as well as of a research project:

Module I: Introduction to Pharmaceutical Medicine: Principles of Drug Discovery and Clinical Pharmacology
- Discovery of New Medicines
- Principles of Clinical Pharmacology

Module II: Non-Clinical Development of Medicines: Safety Pharmacology, Legal, Ethical and Regulatory Issues
- Pharmaceutical Development
- Non-clinical Safety Pharmacology & Toxicology
- Legal, Ethical and Regulatory Issues

Module III: Clinical Development of Medicines: Epidemiology, Statistics and Data Management
- Clinical Development
- Statistics & Data Management
- Principles of Clinical Epidemiology and Pharmacoepidemiology

Module IV: Pharmacovigilance, Pharmaceutical Marketing and Economics of Health Care
- Safety of Medicines and Pharmacovigilance
- Pharmaceutical Marketing
- Economics of Health Care and Pharmacoeconomics

The program is managed by a team of four (three from the University and one from Tiervlei Trial Centre), augmented with a small group of local lecturers. The South African pharmaceutical industry has expressed an interest in the program but there is no external funding commitment at this time. Instead, the development of the program

and management of the course are funded by student fees at present; however, it also uses the infrastructure of the Stellenbosch University.

Could IMI PharmaTrain expand its program from Europe to non-European regions?

In Europe, the IMI PharmaTrain has been established in order to set, maintain and constantly improve the standards and quality management of the training schemes in the European Union. In 2010 this initiative prepared an integrated European Training Syllabus (www.pharmatrain.eu in the menu under "Syllabus"), which is being submitted for approval and incorporation by all stakeholders in Europe, including the UK FPM. Since there will be an increasing demand for capacity development in Pharmaceutical Medicine also in the rest of the world, the author strongly believes it would be useful to open these activities to non-EU regions, such as South Africa.

Stellenbosch University, Matieland, 7602, Stellenbosch, South Africa

IMI PharmaTrain with Worldwide Impact

«First-year achievements include a standardised Syllabus with a worldwide impact since it is foreseen to be adopted by the International Federation of Associations in Pharmaceutical Medicine (IFAPP) and the Faculty of Pharmaceutical Medicine (FPM), Royal College, UK, […]» [IMI PharmaTrain – First Annual Work Progress and Financial Report – 25 October 2010 – www.pharmatrain.eu in the menu under "News" and "First Annual Report"]

Meanwhile the UK FPM, public partner of IMI PharmaTrain, and its International Committee (IC) are striving to promote Pharmaceutical Medicine outside the UK, taking into account the principles established by the Faculty. Towards this goal, potential synergies between the UK FPM, its international members and other organizations are explored to improve implementation of new training programs. In order to assess the situation regarding new courses on Pharmaceutical Medicine outside the UK including South Africa, a working group of the IC has assessed standardized materials used for teaching and/or exams, e-learning, budgets and sponsoring opportunities in 2010.

Prof Dr Bernd Rosenkranz, FFPM, Head Division of Pharmacology, Department of Medicine, University of Stellenbosch, Republic of South Africa.

Contact: rosenkranz@sun.ac.za

Dr Michel Goldman, Executive Director of IMI:

"It is clear that IMI is performing a vital role in working towards finding better solutions for patients across Europe."

Reports and Concepts

New Projects to Boost Drug Innovation in Europe

Innovative Medicines Initiative (IMI) has Launched its Second Wave of Research Projects

The European Innovative Medicines Initiative (IMI), currently the largest public-private partnership in the biopharmaceutical sector, has launched its second wave of research projects at the 8th March 2011, which address key areas including cancer, immune-mediated diseases, infectious disorders and electronic health. With 23 projects now up and running, over Euro 450 million is now committed by the European Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA) on a uniquely large scale.

A Two Billion Euro Research Program

IMI runs a Euro 2 billion research program aiming to speed up the discovery and development of safer and more effective drugs for patients and to reinvigorate the biopharmaceutical sector in Europe. The main goal of this innovative funding scheme is to focus on collaborative research efforts, which will produce new solutions to some of the most relevant health issues facing Europe today.

In the 23 IMI projects 225 different research groups from 23 major pharmaceutical companies affiliated to EFPIA are collaborating with 298 academic teams drawn from across Europe. The partnerships include 47 small and medium-sized enterprises (SMEs) and 11 patient organizations and the European Medicines Agency (EMA).

European Countries with ongoing IMI projects

Working Smarter for Real Results

According to an IMI communication, the partners within the project consortia cross traditional industry and geographical boundaries, co-operating to deliver real results through "working smarter" to offer concrete solutions to solving health problems across a range of diseases and disorders. The diversity of European expertise is evident across the 23 projects – most European member states are represented, demonstrating Europe's ability to act together to move towards a future of innovation excellence. ▶

The first wave of 15 projects have already produced output

The **IMI NEWMEDS** project include the biggest database ever compiled on schizophrenia – with more than 10,000 patients included - and pioneer mechanistic studies combining genetic and imaging approaches through the participation of 9 pharmaceutical companies, 7 academic teams and SMEs.

The **IMI U-BIOPRED** project, which has 35 participants drawn from across 13 European member states, has developed an international consensus statement on the classification of patients with severe asthma and produced a new algorithm for use in clinical research.

IMI Education and Training Programs have now successfully launched new European standards for graduate and post-graduate courses in medicines research through the extensive collaboration of 85 public and private partners, including 4 regulatory authorities. These include:

- **PharmaTrain** (Pharmaceutical Medicines Training Programme – www.pharmatrain.eu)
- **EMTRAIN** (European Medicines Research Training Network – www.emtrain.eu)
- **Eu2P** (European Programme in Pharmacovigilance and Pharmacoepidemiology – www.eu2p.org)
- **SafeSciMET** (European Modular Education and Training Programme in Safety Science for Medicines – www.safescimet.eu)

IMI also provides a new forum for a balanced dialog with the regulatory agencies and patients' organizations, seen in practice in the **IMI PROTECT** project where the EMA coordinates efforts to develop innovative pharmacovigilance tools based on patient-reported outcomes. The **IMI SAFE-T** project has already initiated a dialog with the U.S. Food & Drugs Administration (FDA) and the EMA about the strategy to be followed to qualify biomarkers for drug safety in clinical trials.

IMI's Third Wave Coming Closer

IMI's third wave of projects which are under construction will cover key areas for the development of innovative medicines including autism, tuberculosis, diabetes and safety of drugs and vaccines. More information on the Call 3 topics is available on the IMI website.

Detailed information is available at www.imi.europa.eu

EBB ■

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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." ■

IFAPP's Calendar

1st IFAPP Science2Business Conference

'Academia-Industry Collaboration for New and Better Medicines'

18-19 April 2011 • Amsterdam – The Netherlands

The interaction between academia and industry lies at the heart of any drug development process. With controversy around these interactions, this conference aims to focus on reappraisal of the relationship between industry and academia. How can we define these partnerships whilst respecting the different approaches of both stakeholders?

IFAPP is proud to present you the final program of the 1st IFAPP Science2Business (S2B) Conference on Academia-Industry Collaboration for New and Better Medicines.

A detailed program is available at www.s2bc.org and at the end of this IFAPP World issue. ■

ICPM 2012

IFAPP's 16th 'International Conference on Pharmaceutical Medicine'

2012 • Barcelona – Spain

IFAPP is glad to announce that the next International Conference on Pharmaceutical Medicine will be held in 2012 in the beautiful city of Barcelona, Spain. Barcelona is known for its hospitality. It is a perfect venue for scientific forums and productive discussions on the pharmaceutical industry's hot topics, as well as a cozy and friendly place for sightseeing.

The Asociación de Medicina de la Industria Farmaceutica Española (AMIFE) will take care of the organization of ICPM 2012 and will count on the vast experience and recommendations of colleagues from other national associations.

Shortly, the exact date and a first program draft will be provided. Looking forward to welcoming you to Barcelona in 2012. ■

EACPT 2011

10th Congress of the European Association for Clinical Pharmacology and Therapeutics

26-29 June 2011 • Budapest – Hungary

IFAPP is going to participate in the EACPT 2011 in Budapest, Hungary, by sponsoring a symposium titled "The role of IFAPP in Pharmaceutical Medicine education programs" on 27 June 2011 from 5 – 7 p.m.

A detailed program is available at www.eacpt2011.org ■

Prof Dr Henk Jan Out, President of Dutch Association of Pharmaceutical Medicine:

"The NVFG Presidency is a great opportunity for me to further strengthen the role of Pharmaceutical Medicine in The Netherlands."

IFAPP's Regional Update

The Netherlands: New President for the Dutch Association of Pharmaceutical Medicine

The board of the Dutch Association of Pharmaceutical Medicine (NVFG – Nederlandse Vereniging voor Farmaceutische Geneeskunde) changed during the General Assembly in Zoetermeer, The Netherlands, in November 2010.

Chairman Dr Rudolf van Olden, IFAPP President-Elect, resigned as NVFG President and transferred his chairmanship to Professor Dr Henk Jan Out. Dr van Olden led the NVFG for six years. He is President-Elect of IFAPP and will take over the role of IFAPP President from Professor Dr Gerfried Nell in April 2011. ■

Germany: Relaunch of the German Society of Pharmaceutical Medicine's Journal

The German Society of Pharmaceutical Medicine (Deutsche Gesellschaft für Pharmazeutische Medizin e.V.– DGPharMed) has re-launched and re-named its quarterly released journal – now entitled "pharmazeutische medizin".

The DGPharMed journal was first launched in 1985 under the name "Pharma Arzt" (Pharmaceutical Physician).

The journal "pharmazeutische medizin" reflects the specialty of Pharmaceutical Medicine in its entirety and is addressed to approx. 1,400 DGPharMed members and members of the Austrian Society of Pharmaceutical Medicine. It will soon be offered for purchase to non-members. ■

Dr Reinhard Hönig, Daniel Sehrt (left to right)

Germany: New Board of the German Society of Pharmaceutical Medicine

The German Society of Pharmaceutical Medicine (Deutsche Gesellschaft für Pharmazeutische Medizin e.V. – DGPharMed) held its elections of the board at the 27th Annual Meeting in March in Cologne, Germany. Daniel Sehrt is the new President of DGPharMed. He is the successor of Dr Reinhard Hönig, who will remain in the DGPharMed board as Immediate Past President. Dr Norbert Clemens is re-elected DGPharMed Delegate to IFAPP; Dr Clemens is also the IFAPP Treasurer. ■

Dr Gustavo Kesselring, Vice-President of the Brazilian Society of Pharmaceutical Medicine:

"I would like to share with you a personal achievement that I understand is the result of the work we have developed with several other colleagues from IFAPP."

IFAPP's Regional Update

Brazil: Honorary Lifetime Membership Award for Dr Gustavo Kesselring – Congratulations!

Dr Gustavo Kesselring, Vice-President of the Brazilian Society of Pharmaceutical Medicine (SBMF – Sociedade Brasileira de Medicina Farmacêutica), will be honored for his contributions to Pharmaceutical Medicine with the 2011 Honorary Lifetime Membership Award of the Academy of Pharmaceutical Physicians and Investigators (APPI).

This honor is granted each year to an individual recognized for having made an outstanding contribution to research and/or Pharmaceutical Medicine. ■

Mexico: High Level Pharmaceutical Medicine

«Pharmaceutical Medicine in Mexico has reached a level of development that must be reinforced and perfected for maintaining regional and global leadership. Mexico's current level of development can be measured by the new empowerment of undergraduate and specialist educational programs for those interested in Pharmaceutical Medicine at both public and private universities. Mexico is the first country in Latin America to obtain official recognition and support by one of two most renowned upper education and postgraduate institutions in the country.»

This is a description by a group of Pharmaceutical Medicine specialists from Mexico, two of them representatives of the Association of Medical Specialists in the Pharmaceutical Industry (Asociación de Médicos Especialistas en la Industria Farmacéutica, A.C. – AMEIFAC), an IFAPP member association – President Dr Vanessa Cohen and Vice-President Dr Marlene Llópiz-Avilés.

The authors provide a detailed description on how Pharmaceutical Medicine in Mexico has developed over the past few decades. They also provide an insight in education and training, the roles and the various responsibilities of Pharmaceutical Physicians in Mexico. They will follow on: «[…] local associations, such as […] AMEIFAC, have become major drivers for the development and growth of Pharmaceutical Medicine in Mexico by performing multiple activities of relevance to the discipline.» [Cohen-Muñoz V et al.; Pharmaceutical Medicine 2010; 24:211-218] ■

The Flag

IFAPP World is a publication of the

International Federation of Associations of Pharmaceutical Physicians (IFAPP)

IFAPP, founded in 1975, is a non-profit organization with 28 national member associations worldwide.

IFAPP acts as an international forum for all pharmaceutical physicians' organizations worldwide by dealing with matters brought to its attention through national member associations.

Editorial Board Representatives:

Dr Johanna Schenk, FFPM (johanna.schenk@pharmaprojekthaus.com), Frankfurt/Main, Germany

Professor Dr Jean-Paul Deslypere (jpaul@signet.com.sg), Singapore

Dr Stewart Geary (s2-geary@hhc.eisai.co.jp), Tokyo, Japan

Editor in Chief:

Eckhard Böttcher-Bühler (www.boebue.de), Eckental, Germany

Design & Layout:

Dipl. Designer Bruno Schwarz FH (www.brunoschwarz-design.de) Oberasbach, Germany

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IFAPP is in search of further Gold and Silver Sponsors.

Detailed information on sponsorship opportunities is available at www.ifapp.org, section "sponsors" in the menu.

1st IFAPP Science2Business Conference
18 – 19 April 2011Amsterdam, The Netherlands

Monday 18 April 2011

Chair: Prof. Silvio Garattini, Pharmacologic Research Institute 'Mario Negri', Italy

THEME I: CREATING PARTNERSHIPS

08:30 Welcome with coffee and tea

09:00 Opening remarks from the Chair

09:05 Introduction IFAPP Science2Business Conference
Rudolf van Olden, President-Elect IFAPP, Director Medical and Regulatory Affairs, GlaxoSmithKline, The Netherlands

09:20 Snapshot public professional perception on the collaboration between industry and academia
David Vulcano, AVP and Responsible Executive for Clinical Research for Hospital Corporation of America, Former chair at Association of Clinical Research Profession (ACRP) Board of Trustees, USA

09:50 How to manage conflicts of interest
Robert Steinbrook, National correspondent New England Journal of Medicine (NEJM) and Adjunct Associate Professor of Medicine and of Community and Family Medicine, Dartmouth Medical School, USA

10:20 Best Practices for Academic Industrial Relations
Marie Claire Pickaert, Deputy Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA), Belgium

10:50 Questions and answers

11:00 Coffee/Tea

11:30 Breakout sessions part I: The value of strategic partnerships in conducting trials

PARTNERS IN RESEARCH AGENDA

Pitfalls in Partnering Does the Sponsor Matter?

Chair: Norbert Clemens, Head of Clinical Development, CRS Clinical Research Services, Germany

Academia: Prof. Adam Cohen, Director Centre for Human Drug Research, The Netherlands

Industry: Erik Tambuyzer, Senior VP Public Policy, Genzyme, Belgium

PHARMACEUTICAL MEDICINE

Overcoming Mistrust in the Academia-Industry Collaboration

Chair: Gustavo Kesselring, Director Clinical Operations, Hospital Alemao Oswaldo Cruz, Brasil

Academia: Prof. Fritz R. Bühler, Coordinator IMI, PharmaTrain, University of Basel, Switzerland

Industry: Mike Hardman, VP Science Policy, EMTRAIN coordinator, AstraZeneca, UK

12:45 Lunch

1st IFAPP Science2Business Conference
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Monday 18 April 2011

Chair: Prof. Silvio Garattini, Pharmacologic Research Institute 'Mario Negri', Italy

13:45 Breakout sessions part II: How to set-up and maintain strategic partnerships

SAFETY REPORTING

Ensuring Valid Safety Reporting in Investigator-Sponsored Trials

Chair: Prof. Bert Leufkens, Chair CBG-MEB and member of EMA Pharmacovigilance WP, The Netherlands

Academia: Marcel Kenter, Executive Director, CCMO (Dutch Competent Authority), The Netherlands

Industry: Mariska Kooijmans-Coutinho, VP Drug Safety & Risk, Management International, Biogen Idec, UK

COLLABORATION MODELS

Trustworthy Collaboration in Clinical Research and Publications

Chair: Prof. Jacques Demotes-Mainard, Program coordinator, ECRIN, France

Academia: Prof. Sander van Deventer, Translational Gastroenterology at Leiden University MC, The Netherlands

Industry: Armin Szegedi, Head Psychiatry, Neuroscience Clinical Research, Merck, USA

15:00 Coffee/Tea

15:30 Report Breakout Sessions

16:00 Debate: "The Future of Clinical Trials: Reappraisal of Academia-Industry Partnerships"
Chair: Prof. Henk-Jan Out, VP Clinical Research, Women's Health & Endocrine, Merck, The Netherlands
Participants: selection of speakers

17:00 Closing of the day and reception

19:00 Conference dinner, separate registration on the conference website

1st IFAPP Science2Business Conference
18 – 19 April 2011Amsterdam, The Netherlands

Tuesday 19 April 2011

Chair: Domenico Criscuolo, CEO, Genovax, Italy

THEME II: FROM PARTNERSHIP TO TRUST

08:00 Welcome with coffee and tea

08:30 Opening remarks from the Chair

08:40 Reflection and comments from the floor concerning day 1
Domenico Criscuolo, CEO, Genovax, Italy

09:10 Which country performs the best in Clinical Trials: measured by looking at scientific output
Prof. Dick de Zeeuw, Chair of the Department of Clinical Pharmacology, University Medical Center Groningen, The Netherlands

09:40 Perspective Journal Editor; "Conflicts of Interest in Scientific Journals"
Trish Groves, Deputy Editor, BMJ and Editor-in-Chief, BMJ Open, UK

10:10 Perspective Pharmaceutical Industry
Jack Watters, Global Vice-President for External Medical Affairs, Pfizer, UK

10:40 Perspective European Medicines Agency
Fergus Sweeney, Head of Compliance and Inspections, EMA, UK

11:10 Coffee/Tea

11:30 Debate: "The Future of Clinical Trials: Reappraisal of Academia-Industry Publications"
Chair: Peter Klöpel, Executive Board Member of the German Society of Pharmaceutical Medicine, Germany
Participants: Pharmaceutical Industry, Journal Editors, EMA and academia

12:45 Concluding remarks: Recommendations for Trustworthy Partnerships
Rudolf van Olden, President-Elect IFAPP, Director Medical and Regulatory Affairs, GlaxoSmithKline, The Netherlands

13:00 Closing of the day and Lunch

14:00 IFAPP: General Assembly, closed session and ending at 15:00

14:00 Round table meeting: "Public and private challenges for global standardization in GCP expertise and education", separate registration on the conference website

17:00 Closing of the post-conference Round table meeting