IFAPP WORLD
International Federation of Associations of Pharmaceutical Physicians
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III·2008·DECEMBER

CONTENT

IFAPP's Calendar

Quality Issues in Clinical Research

Tenth IFAPP European Conference in Collaboration with BrAPP and with BARQA – London, Friday 30 January 2009

IFAPP is pleased to announce the 10th European Conference, which will take place in London on Friday 30 January 2009.

This conference will cover a very relevant topic: how to ensure and how to control quality in clinical research. The IFAPP Scientific Committee believes that this issue needs a full day debate, with contributions from all players in clinical development, and from speakers representing EMEA, industry and scientific associations. And it is easy to anticipate that this conference will be very fruitful for all interested parties.

For program details please note page 3 of this IFAPP World issue or visit
www.ifapp.org/home/conferences
Be Sure To Come! ■

Questions & Answers

IFAPP Global Strategy 'Shaping the Future'

IFAPP's new President Professor Gerfried Nell outlines IFAPP's perspective and ambitious aims

In September at the 'International Conference of Pharmaceutical Medicine' (ICPM) 2008 in Amsterdam, the Netherlands, IFAPP presented a poster titled "IFAPP Global Strategy – Shaping the Future" which clearly defined IFAPP's aims and ambitions up to the year 2013. At the same event Professor Gerfried Nell assumed IFAPP's presidency, which means, he will steer IFAPP half way to reach its defined ambitious aims.

IFAPP WORLD • Professor Nell, as the new IFAPP President – do you see room to maneuver in such a pre-fixed program?

Professor Gerfried Nell • Together with my colleagues in the Executive Committee of IFAPP I have been involved in redefining IFAPP's strategy during the last eighteen months. While it is challenging to adapt IFAPP's goals to the changing environment and needs of our members it is an even more demanding task finding the right path to our goals.

IFAPP WORLD • What will you prioritize and focus on and what do you consider the best strategy and tactics in order to approach the defined IFAPP aims?

Professor Gerfried Nell • Our goal is to become recognized as the voice of Pharmaceutical Medicine worldwide. Therefore, we have to increase the awareness of our specialty by publications such as IFAPP World and by sponsoring conferences e.g. the 10th IFAPP EU conference to be held on 30 January 2009 in London, UK, and ICPM 2010 (International Conference on Pharmaceutical Medicine). The awareness of IFAPP and its goals will ▶▶ page 5

President's Letter

Dear Colleagues

Professor Gerfried Nell, IFAPP President

This is my first letter to the IFAPP audience after being elected IFAPP President. It's my pleasure to extend my greetings and best wishes to all of you.

This IFAPP World issue is mainly devoted to news from the International Conference on Pharmaceutical Medicine – ICPM 2008 held in September in Amsterdam, the Netherlands, an open-minded and fascinating city rich in culture and history. It has been a lively conference providing an excellent overview of the state of the art of our discipline – very successful with regard to content, speakers' expertise and social events. I congratulate our Dutch colleagues on their excellent performance in planning and organizing this important event.

Unfortunately, ICPM 2008 did not attract as many attendants as it would have deserved. That's why I am kindly asking you ▶ page 2

President's Letter

◀ page 1 to mark your calendar already now on 7-9 November 2010 with "Attending ICPM 2010".

During ICPM 2008 the IFAPP Executive Committee, the IFAPP House of Delegates and the IFAPP General Assembly held their face-to-face meetings. Past President Luis Collia from Argentina and Stewart Geary from Japan provided an overview of the years 2006 to 2008. This period was characterized by an increase in attendance and activities of the IFAPP Executive Committee.

A Global Strategy Working Party has been formed chaired by Sander Becker from Australia. This group newly defined the goals of IFAPP, presented in a poster at ICPM 2008, which you find at the end of this IFAPP World issue. These goals are already on the way to be implemented.

IFAPP's Council for Education in Pharmaceutical Medicine (CEPM) increased the number of accredited Courses in Pharmaceutical Medicine to 12. Ongoing efforts in organizing national member organizations in Pharmaceutical Medicine have been supported by IFAPP especially in Asia, where the most remarkable event was the First Chinese Conference on Pharmaceutical Medicine in October 2007.

In Europe the most striking development was the foundation of the European Chapter of the CEPM, which facilitated participation in the Innovative Medicines Initiative (IMI) of the European Commission. IMI's goal is to strengthen the competitiveness of the Pharmaceutical Industry in Europe with the rest of our world by launching a program on research, education and training. The partners in this program are universities, learned societies and the companies represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA). Initiated by the European Chapter of CEPM the European Federation of Courses in Pharmaceutical Medicine (EFCPM) was founded and filed an application to IMI for the topic "Pharmaceutical Medicine Training Programme".

Furthermore, IFAPP created the Pharmaceutical Medicine Ethics Council (PMEC), which is available on request for advice on ethical matters relating to Pharmaceutical Medicine. This council also presented a poster at ICPM 2008, which is shown at the end of this IFAPP World issue.

Regarding personnel matters, two new members of the IFAPP Executive Committee were elected in Amsterdam: Ester Freitas from Portugal and Greg Koski from the USA. The officers for the period 2008 to 2010 are Gerfried Nell from Austria (President), Luis Collia from Argentina (Past President), Rudolf van Olden from the Netherlands (President Elect), Stewart Geary from Japan (Secretary), and Herman Lahon from Belgium (Treasurer until the end of 2008) followed by Norbert Clemens from Germany (Treasurer from 2009 onwards).

The goals of the IFAPP Executive Committee can be summarized as followed:

- *To increase awareness of Pharmaceutical Medicine*
- *To promote formation of national chapters of Pharmaceutical Medicine*
- *To improve the standards of Education and Continuing Professional Development in Pharmaceutical Medicine*
- *To strengthen the collaboration with other learned societies and associations*
- *To set standards*
- *To organize conferences, which are not only a scientific but also a financial success.*

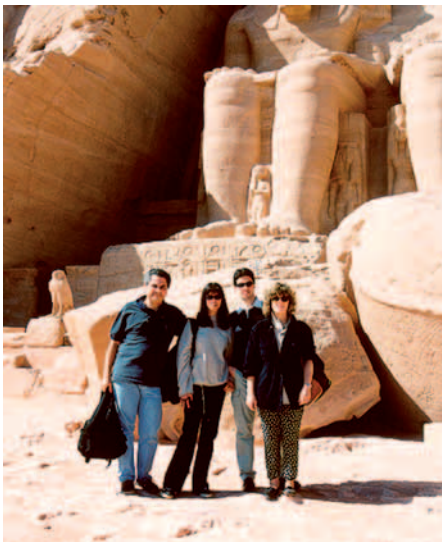
These activities will bring us closer to our goal which is to be recognized as the international voice of Pharmaceutical Medicine.

The IFAPP Executive Committee will keep you updated on its activities. And I kindly invite you all to voice your ideas, proposals, concerns and criticism and to participate in our work.

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

Personal Snapshot

Dr Domenico Criscuolo: Committed to Quality in Clinical Research



"Historical places convey a message of the significant steps mankind made over the centuries" – Domenico Criscuolo, here with his wife Silvana, his son Michele and his daughter Elena, visiting Abu Simbel in Egypt.

Domenico Criscuolo graduated in Medicine in Rome, Italy, in 1973. As a specialist with a Ph.D. degree in hematology and clinical oncology he approached the world of clinical research, where he established his first contact to the pharmaceutical industry. "I just needed one thought only to decide, to join research and development within the pharmaceutical industry professionally," he admits.

Professional Development

This is why in 1975 he moved North from Rome to Milan, where he started an occupation in the clinical research department of Lepetit, in those days the largest pharmaceutical company in Italy, which was taken over by Sanofi Aventis later on. The people of Lepetit successfully developed drugs and the company experienced a tremendous growth. "I attended Lepetit's clinical research department for 10 years – a perfect opportunity to get to know all facets of the profession and to gather lots of valuable experience in clinical development,"

Dr Domenico Criscuolo, CEO of Genovax, Italy, member of the IFAPP Executive Committee: "Those who are involved in clinical research should attend to it with passion committed to the highest achievable standards in quality."

he said. However, in 1985 he changed his employer and accepted a new challenge at Roche Milano, where he had to establish a new department of clinical research, which surprisingly did not exist at that time. "I delight to remember – it was a fantastic time and one of my best experiences: I seized the grand opportunity to set up a group of 40 professionals and took over the international leadership of development projects in oncology and hematology." ▶▶ page 4

Have your tickets ready
and join our "QUALITY ISSUES IN CLINICAL RESEARCH" tour!

(Please visit
www.ifapp.org/home/conferences
for programme details)

THE TENTH IFAPP EUROPEAN CONFERENCE

in collaboration with BrAPP and with BARQA

Quality Issues in Clinical Research

London, Friday 30 January 2009

8.45 am – 17.00 pm · Marriott Hotel West India Quay
Canary Wharf · 22 Hertsmere Road · E14 4ED London, United Kingdom

Introductory Remarks (Domenico Criscuolo – IFAPP)

Looking for a Quality System

GCP Inspections: Role of EMEA (Fergus Sweeney – EMEA)
Role and Activities of National Inspectorates (Katharina Kurpanek – BfArM)
Major Quality Issues in Clinical Research (Jane Winter – BrAPP)
The Role of Audits in the Quality Process (Anna Piccolboni – Zambon Group)
Are Auditors Properly Trained? (David Butler – BARQA)

EU and Quality

EU Focus on Quality (Andrew Fisher – MHRA)
Experiences in Regulatory Inspections (Michael Bean – MHRA)
The Experience of Roche QA (Beat Widler – Roche)
QA and CROs: an Example (Regina Freunscht – Accovion)
Computerized Systems Validation: a Risk-Based Approach (Matthew Jones – BARQA)
Concluding Remarks (Matthew Jones – BARQA, Jane Barrett – BrAPP)

IFAPP
International Federation
of Associations
of Pharmaceutical Physicians
founded 1975

Registration fee:
EUR 800.00

BrAPP & BARQA
members:
EUR 700.00

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BE SURE
TO COME!

Personal Snapshot

◀◀ page 2 Over times the Roche environment changed. Roche had acquired the German company Boehringer Mannheim, and their research group created Novuspharma, a biotech spin-off devoted to oncology where Dr Criscuolo became Head of Global Development. Unfortunately, the key management made this venture to fail.

Dr Criscuolo moved on to the Contract Research Organization (CRO) world and became Vice President of clinical operations at ICON Italy. ICON is an Irish CRO based in Dublin. "I was committed to this job. I hired 50 professionals in less than one year and created a powerful team – however, my heart was still beating for biotech," he said.

He made his way. In 2007 he entered the Biotechnology Park Canavese in the far North of Italy, close to Turin, which promotes and develops research in biotechnologies and life sciences. He became Chief Medical Officer (CMO) of Creabilis, an emerging pharmaceutical company focusing on dermatology. Since March 2008 Dr Criscuolo has been Chief Executive Officer (CEO) of Genovax, a new company, which he founded in collaboration with other immunologists as an academic spin-off from the University of Genoa.

His challenge now is to raise sufficient funds to develop a portfolio of projects, he explains. What he conceals at that point is the excellence and expertise he and his colleagues need first to create ideas, concepts and perspectives for a portfolio, which then might attract investors for funding.

In fact, he passed both steps successfully.

Committed to Quality in Clinical Research

A key of success is quality, which matters most in his work as a clinical researcher, Dr Criscuolo admits and affirms:

"Those who are involved in clinical research should attend to it with passion committed to the highest achievable standards in quality.

He is a good listener – Dr Domenico Criscuolo at the International Conference on Pharmaceutical Medicine – ICPM 2008 in September in Amsterdam.

Quality in clinical research is an issue involving both legal and ethical aspects. And all physicians in Pharmaceutical Medicine, who dedicate their efforts to develop new drugs to cure diseases and improve people's quality of life, should always be careful about the quality of their own work. We definitely owe this to the patients and test persons as our highest priority."

An Activist for Pharmaceutical Medicine

Dr Criscuolo elaborates his idea of quality in clinical research as an active member of the Italian Association of Pharmaceutical Medicine (SSFA) and of IFAPP. "Offer some of your free time to our associations in Pharmaceutical Medicine – either on a national or an international level. It is a very important task which will certainly provide you great satisfaction," he said.

In 1978 he became a member of SSFA and was immediately elected Treasurer, next Secretary, then President to the SSFA Council. He was the only SSFA President elected for four terms consecutively. During his 10-year presidency he boosted SSFA's visibility and scientific reputation by organizing several events and resuming the National Conference, which had been suspended for about 20 years.

In 1994 SSFA organized the International Conference of Pharmaceutical Medicine (ICPM) in Rome with Dr Criscuolo as SSFA President. Afterwards he joined the IFAPP Executive Committee and was elected President from 2002 to 2004. "This offered to me a unique opportunity to establish important and long-lasting collaborations with colleagues all over the world. I still devote a significant part of my free time to IFAPP, which in return has offered me significant gratifications, both as a professional and a private person."

Years ago IFAPP arranged a first scientific meeting in collaboration with European Medicines Agency (EMEA) officers. The event proved to be successful and beneficial to the participants as a unique opportunity to directly interact with the authorities. That's why the conference has been repeated year-by-year, attracting pharmaceutical professionals from all over Europe and from the US.

Dr Criscuolo has headed the organizing committee for several years, maintaining this important IFAPP tradition and setting high standards. The next conference, which as usual will be hosted in London (for details see page 3), will deal with "Quality in Clinical Research" – an issue that particularly lies at Dr Criscuolo's heart.

Eckhard Boettcher-Buehler ■

IFAPP's Calendar

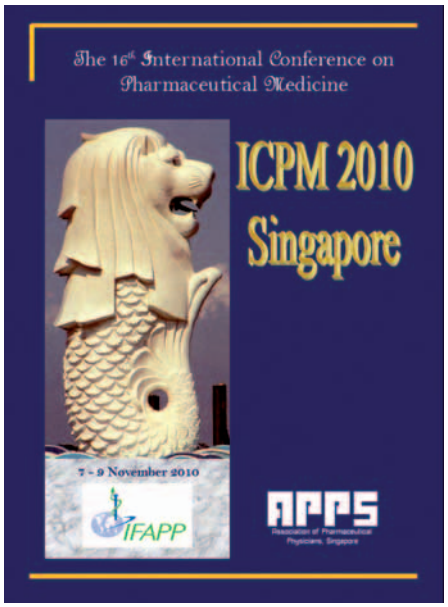
ICPM 2010 in Singapore

16th International Conference on Pharmaceutical Medicine

The "International Conference on Pharmaceutical Medicine" (ICPM) is an important venue for an update on latest trends in Pharmaceutical Medicine, the discipline concerned with the discovery, development, evaluation, registration, monitoring and with marketing aspects of medicines for the benefit of patients and the health of the community.

The 16th "International Conference on Pharmaceutical Medicine" – ICPM 2010 – will be held in Singapore, a place that has rapidly developed core capabilities from drug discovery to clinical applications. Singapore has chosen the biomedical industry to be its fourth economic pillar and worked hard to be the hub of biomedical research in Asia.

Make sure to come and attend ICPM 2010. Mark your calendar by now on 7-9 November 2010 with "Attending ICPM 2010 in Singapore". For further details please check www.ifapp.org in the menu "conferences" at intervals. ■



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."

Questions & Answers

IFAPP Global Strategy – 'Shaping the Future'

◀◀ page 1 also be increased in partnership with other learned societies. We have to promote the formation of national chapters especially in Africa, Asia, Eastern Europe and Latin America. We will further improve and promote the standards of continuing medical education (CME) and continuing professional development (CPD) and provide accreditation in Pharmaceutical Medicine and related areas especially Clinical Research for clinical investigators.

IFAPP WORLD • IFAPP's 'Global Strategy Working Party' – did it just shape the ideas for IFAPP's future or will it be involved to implement it?

Professor Gerfried Nell • The primary goal of the Global Strategy Working Party is defining the goals for the IFAPP's future. The implementation will be the task of several working groups of the IFAPP Executive Committee. Some of these groups represent a success story, e.g., accreditation of academic courses in Pharmaceutical Medicine by the IFAPP Council on Education in Pharmaceutical Medicine (CEPM) worldwide. The responsibility of the CEPM is providing metrics for the implementation and advising the IFAPP Executive Committee in case of new developments.

IFAPP WORLD • All in all – what are your suggestions and desires with regard to the IFAPP Executive Committee's part and portion in achieving IFAPP's goals? And what about the other IFAPP Working Groups?

Professor Gerfried Nell • I am convinced that not only the members of the Executive Committee but also the interested colleagues of national Member Associations (nMAs) have to join forces in order to reach the goals. We have to set up an infrastructure for channeling the enthusiasm and efforts of our colleagues in the most efficient way.

We have envisaged nine working groups in order to implement our strategy. Besides the Gobal Strategy Working Party, we can build on previous work, e.g., the already mentioned CEPM headed by Jean-Paul Deslypere from Singapore. The task of this group is to define standards in Pharmaceutical Medicine and provide accreditation of courses and other educational offerings in this field. Another working group chaired by Domenico Criscuolo from Italy is in charge of organizing congresses. The Pharmaceutical Medicine Ethics Council (PMEC), chairperson Jane Barrett from the United Kingdom, is concerned with ethics in Pharmaceutical Medicine. A communication network has already been established by means of two media: IFAPP World with the editors Johanna Schenk from Germany, Stewart Geary from Japan and Jean-Paul Deslypere from Singapore and the IFAPP Website is taken care of by John Lee from Sweden.

However, communication has to be defined as the means to disseminate our message to the outside world and we need a unified approach established by another working group. Furthermore, we will be setting up a working group looking at our relationship with other organizations, e.g., the World Medical Association and the World Health Organization (WHO) led by Mirela Barbu from Switzerland. The working group national Member Associations headed by Montse Barcelo from Spain will focus on the needs and expectations of our members.

Last but not least, we need to improve our system of fundraising and a group, chaired by me, will be looking at the necessary infrastructure to run the activities mentioned above.

IFAPP WORLD • The IFAPP Executive Committee members represent IFAPP's national Member Associations. But otherwise, how can IFAPP attract direct attention of these national associations and their memberships?

Professor Gerfried Nell • The keyword is communication. Reporting each of the activities of IFAPP to the nMAs is one of the main tasks of the EC members who represent 17 out of 30 nMAs. We use our communication tools like IFAPP World and our Website. The president provides a Monthly Message to all nMAs. The CEPM is conducting a survey on the composition of the membership of the national chapters in order to better define their needs. The newly founded working group on national Member Associations is planning to collect more information about the needs and wishes of nMAs.

IFAPP WORLD • The already mentioned poster 'Shaping the Future' boldly states right in its center "IFAPP needs your help" and specified essential needs. Who is addressed and what shall they do?

Professor Gerfried Nell • Firstly, the IFAPP EC needs the enthusiasm and dedication of all of its members. Our goals can be achieved by teamwork only. We need to maintain close contact to the nMAs because the purpose of our work is to serve their needs. IFAPP is not operating detached from the surrounding world of political and professional organizations, academic bodies, regulatory authorities and international organizations engaged in clinical research and related fields. We have to establish and maintain contacts with these parties in order to reach our goal.

Professor Gerfried Nell (left), IFAPP's new President and CEO of NPC Nell Pharma Connect Ltd., Vienna, Austria, beside IFAPP's Past President Dr Luis F Collia, Merck Chemical Argentina, Buenos Aires, Argentina, attending a conference.

IFAPP WORLD • Fostering education and training in Pharmaceutical Medicine (PM) is a main objective in IFAPP's global strategy. What is the status quo and how do the next steps look like?

Professor Gerfried Nell • Presently, Pharmaceutical Medicine is recognized as a medical specialty in its own right in Argentina, Mexico, the Republic of Ireland, Switzerland and the United Kingdom only. Efforts to spread the acknowledgement of our discipline are ongoing worldwide. These intentions are supported by the CEPM by setting standards in our specialty for continuing medical education (CME) and continuing professional development (CPD) and providing accreditation of courses in Pharmaceutical Medicine. We will focus during the next five years on the European Union (EU), which is rolling out the Innovative Medicines Initiative (IMI). IMI includes as a pivotal component a Pharmaceutical Medicine Training Program. In order to get organized for participation in IMI, a European Federation of Courses in Pharmaceutical Medicine (EFCPM) has been established already. We hope that this will boost the recognition of Pharmaceutical Medicine in the European Union.

IFAPP WORLD • What about Pharmaceutical Medicine education in the US, in Latin America, in the Asia Pacific region, etc.?

Professor Gerfried Nell • There are clearly differences in the recognition of Pharmaceutical Medicine regionally. In Latin America Pharmaceutical Medicine is already recognized in two countries ▶ page 6

Questions & Answers

◀ page 5 (Argentina and Mexico) and others, e.g., Brazil, moving forward strongly towards this goal. In Asia one can feel the spirit of exploring the new area of Pharmaceutical Medicine especially in the countries of the Pacific Rim. They are in the process of creating national associations as a first step. In Central and Eastern Europe colleagues are more focused on clinical research and they will certainly embrace the concept of Pharmaceutical Medicine at a later stage. In the US Pharmaceutical Medicine was developed in close connection with another professional organization engaged in clinical research, the Association of Clinical Research Professionals (ACRP). This relation offers a strong alliance of professionals involved in clinical research but may delay the evolution of Pharmaceutical Medicine as a distinct medical discipline.

IFAPP WORLD • Ethics in Pharmaceutical Medicine is another IFAPP objective and at ICPM 2008 in Amsterdam IFAPP's Pharmaceutical Medicine Ethics Council presented a poster claiming "Truth, Transparency, Trust". What does IFAPP do to enhance ethical excellence in clinical research?

Professor Gerfried Nell • IFAPP issued an International Code of Ethical Conduct for Pharmaceutical Physicians six years ago. It serves as a guideline for controversial "ethical" decisions in pharmaceutical development. Now, IFAPP created the Pharmaceutical Medicine Ethics Council (PMEC) whose task is to provide independent medical, scientific and ethical advice to the IFAPP EC on the safety, quality and performance of pharmaceutical development of drugs and devices. Since pharmaceutical development and marketing of drugs and devices is fraught with ethical issues, building trust based on truth and transparency is essential for every pharmaceutical physician and professional.

IFAPP WORLD • Of course, ethics is an essential element of quality in clinical research. Is quality in clinical research a next focus for IFAPP, especially as 'Quality in Clinical Research' is the principal theme of the 10th IFAPP European Conference, which will be held in London in January 2009?

Professor Gerfried Nell • The main purpose of IFAPP is to set up and monitor standards in all aspects of Pharmaceutical Medicine. Monitoring quality is crucial in achieving reliable results in clinical research. Therefore, we chose the topic "Quality in Clinical Research" for our next IFAPP EU Conference scheduled for 30 January 2009 in London, UK. We appointed a panel of excellent speakers and are hoping for a large audience.

IFAPP WORLD • Will IFAPP be strong enough to sufficiently afford this ambitious 'Shaping the Future' program?

Professor Gerfried Nell • You touched a crucial point. Besides a part time secretary, all work is done by volunteers. Because of financial limitations we cannot afford a bigger professional infrastructure which would greatly help achieving our goals. Thus, the order will be, firstly, increase income and then, secondly, step up our infrastructure.

IFAPP WORLD • Assuming Pharmaceutical Medicine is accredited as a medical specialty in the majority of countries – would your answers above have been different?

Professor Gerfried Nell • Having achieved acknowledgement of Pharmaceutical Medicine as a distinct medical specialty is our primary goal to which we have still a long way to go. However, this is the first step only. Most of my answers would not be different because IFAPP would have to develop further our discipline and adapt standards for education and accreditation and foster its international visibility. ■

Reports & Concepts

Review of the Declaration of Helsinki

WMA Reaffirms Primacy of Patients in Medical Research

A revised version of the Declaration of Helsinki has been adopted by the World Medical Association (WMA) in October 2008. Some also call it the "Bible" of medical research involving human subjects, which in fact sets out ethical research principles.

The Declaration of Helsinki is a guideline for signatory countries and was issued in 1964 as a response to the abuses of human subjects by Nazi scientists. Since then, the document has undergone five revisions, the most recent one in 2000. Furthermore, the latest notes of clarification were added in 2004. All this is the product of extensive consultation with national medical associations, researchers, governments and industry worldwide. In the latest revision process Brazil, Germany, Japan, South Africa and Sweden have been appointed as members of the technical review working group.

Contentious issues such as the use of placebos and safeguarding access to treatment for all study participants were discussed.

Discussion of the Draft Revision

The latest semi-public discussion of the draft revision was held in São Paulo, Brazil, in August 2008 with individually invited stakeholder representatives. The round of debates regarded important alterations, e.g. the involvement of children in drug trials. And the agenda included contentious issues such as the use of placebos and safeguarding access to treatment for all study participants. Dr Gustavo Kesselring, Clinical Research Director of the Hospital Alemão Oswaldo Cruz in São Paulo, Brazil, President of the Brazilian Society of Pharmaceutical Medicine and member of the IFAPP Executive Committee, attended this review discussion as an accredited expert and summarized the essentials as follows:

Children as Trial Subjects

Drug testing in children was an important issue in the discussions, emphasizing the drug dose used in children is frequently estimated based on extrapolations of the dose used in adults, which is not risk-free at all. ▶ page 7

Attendees of the semi-public discussion of the draft revision of the Declaration of Helsinki in São Paulo, Brazil: Dr Eva Bågenholm, who chaired the WMA Ethics Committee sitting in the center first line. Next left to right: Dr José Luiz Gomes do Amaral, President of the Brazilian Medical Association, and Dr Otmar Kloiber, Secretary General WMA.

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As a not-for-profit organization IFAPP appreciates the support it receives from institutions with a passion for enhancing the knowledge, expertise and skills of pharmaceutical physicians worldwide. Information on sponsorship opportunities is available at www.ifapp.org, section sponsors.

Reports & Concepts

◀ page 6 *This is why the inclusion of children and women in medical research has gained international attention and some support: Brazil, Europe and the US have already issued respective regulations and require the inclusion of these patient groups in clinical trials.*

Placebo in Clinical Research

The discussions regarding an increase of the use of placebo have been controversial: some stakeholders wanted to ban the use of placebo, while others call for careful use of them, and others again argued that placebo should be used in a larger number of trials.

Earlier in August 2008, the Brazilian National Health Council, an agency in charge of social control of the unified health systems in Brazil, passed a resolution that permits the use of placebo in the absence of approved treatments exclusively – however, at the time of the discussion, this resolution was not a decision officially enacted by the Brazilian Health Minister.

The Brazilian National Health Council also sustained that all research subjects should have access to the best trial-tested therapeutic resources when the trial finished. The discussion about access to trial-tested products has been dragging on for ten years, and some opposition groups uphold that access should be given according to local circumstances.

At that point, participants of the discussion in São Paulo sharply criticized "approaches, which combine interests of the industry with the desperation of the poor", as someone stated. This was practiced, for instance, in an African country, where a company tested, if patients suffering from AIDS responded to a low-cost, hence low-dose anti-AIDS cocktail, which had been tested successfully in a higher, thus more efficient dose before. The company argued that the respective country could not afford the expensive treatment and therefore accepted to participate in the research assuming it might be better to enroll patients in that trial rather than offering nothing at all.

The Final WMA Revisions

The WMA, at its annual General Assembly in October 2008 in Seoul, South Korea, reaffirmed its controversial position against practices that open the door to exploitation of research subjects, particularly in developing countries – "refusing to bow to pressure from industry and government regulatory agencies," as the WMA stated in a release.

On the practice of comparing new experimental treatments to placebos rather than existing treatments, the revised Declaration specifies that this may be done only under very limited circumstances where patients who are given placebos will not suffer any serious or irreversible harm.

The revised Declaration also reaffirms the right of research subjects to share in any benefits that might result from the research, for example, the access to interventions identified as beneficial in the study.

New paragraphs of the revised Declaration deal with the consent on the research on human material, such as blood, tissues, and DNA, and human data and require clinical trials to be registered in a publicly accessible database.

Dr Eva Bågenholm, a physician from Sweden, who chaired the five-country working group that wrote the draft revision, said the consultation showed that the strict provisions of the Declaration for protecting research subjects were sound and firm. "The WMA now looks to other stakeholders, especially governments, to raise their standards to the Declaration's level", she added. ■

Dates & Deadlines

30 January 2009 • London, United Kingdom

The Tenth IFAPP European Conference – Quality Issues in Clinical Research

The International Federation of Associations of Pharmaceutical Physicians (IFAPP) in collaboration with the British Association of Pharmaceutical Physicians (BrAPP) and with the British Association of the Research Quality Assurance (BARQA) • For details see page 3.

24-28 April 2009 • Denver, Colorado, USA

ACRP 2009 Global Conference & Exhibition

The Association of Clinical Research Professionals (ACRP) assembly of educational resources and inspirational personalities devoted to the drug, biologic, and device research industry in collaboration with the Academy of Pharmaceutical Physicians and Investigators (APPI) Physicians Program

17-23 July 2010 • Copenhagen, Denmark

16th World Congress on Basic and Clinical Pharmacology 2010

International Union of Basic and Clinical Pharmacology (IUPHAR), Danish Society of Pharmacology and Toxicology, Danish Society of Clinical Pharmacology • www.worldpharma2010.org

7-9 November 2010 • Singapore

ICPM 2010 – 16th International Conference on Pharmaceutical Medicine

The event will be of interest to anyone who is working or studying within the various fields / disciplines related to Pharmaceutical Medicine, drug regulation, clinical pharmacology, pharmacotherapy and health economics.

For further details please check www.ifapp.org in the menu "conferences" at intervals.

Reports & Concepts

Boosting Education, Training and Professional Development in Pharmaceutical Medicine in Europe

IFAPP with the Winning Team for an "Expression of Interest"

By Professor Gerfried Nell, IFAPP President

"Innovative Medicines Initiative" – What it is All About

On the 20 December 2007 the European Commission issued the Council Regulation (EC) No 73/2008 setting up the "Joint Undertaking for the implementation of the Joint Technology Initiative on Innovative Medicines", in brief called Innovative Medicines Initiative (IMI). IMI is a public-private partnership (PPP) involving the pharmaceutical industry represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the European Commission. IMI's overall goal is to make Europe again a world leader in pharmaceutical research. To address this challenge, IMI will harness the know-how and expertise available across Europe's biopharmaceutical sector, by pooling competencies and resources from the public and the private domain. The research activities, to be supported under IMI, will be open to all research actors, provided that they are performed within Europe.

The total financial volume of the project to be extended over 5 years from 2009 to 2013 amounts to 2 billion euros, with 50% originating in cash from the EU Commission and the other 50% contributed "in kind" by the member companies of EFPIA.

On the 30 April 2008 the calls for IMI, i.e., the topics of the whole project, were published. In total, 18 calls had been formulated. Six calls related to research in safety, seven to efficacy and five to education and training.

The Applicant Consortium Formed by EFCPM and IFAPP

Already in 2007 the IFAPP Council for Education in Pharmaceutical Medicine (CEPM) created a European Chapter headed by Dr Juan Lahuerta from Spain in order to grasp the opportunity of participation in IMI with the aim to promote Pharmaceutical Medicine within the European Union (EU).

Firstly, the European Chapter approached the providers of academic courses in Pharmaceutical Medicine within the EU and associated countries. In 2008 the European Federation of Courses in Pharmaceutical Medicine (EFCPM) was formed under the chairmanship of Professor Fritz Buehler, Director of the European Center of Pharmaceutical Medicine (ECPM) in Basel, Switzerland. Together with IFAPP, represented by the European Chapter of the CEPM, a legal entity was created according to Swiss law – EFCPM and IFAPP formed the applicant consortium with the Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom (FPM) assuming observer status.

"Pharmaceutical Medicine Training Programme"

The applicant consortium drafted an Expression of Interest (EoI) for topic 16 (Pharmaceutical Medicine Training Programme – IMI Pillar 16, shortly IMI-P 16). Its main goals are providing a comprehensive solution for the complex needs of integrated drug development for all professionals involved from universities, regulatory agencies, pharmaceutical enterprises and allied companies as well as research ethics committees. To address these needs, a pan-European comprehensive multi-modular training program at the master level – Master of Advanced Studies in Pharmaceutical Medicine / Drug Development Sciences – and other programs will be targeted for specialists within this IMI program. The program will comply with the Bologna credit and title system and will be underpinned by a quality management system. Eight working packages have been defined in order to accomplish these goals. IFAPP members are involved in all working packages.

On the 15 July 2008 the EoI was submitted for the first stage evaluation. Altogether, 134 EoIs have been filed for all eighteen topics of IMI, out of which 4 for IMI's call 16. Almost 1,300 teams participated. These teams came from nearly all member states of the EU and associated countries but also from the US, Australia and Russia.

The Winning Team for IMI-P 16 First Step

The evaluation was performed by external experts and coordinators of EFPIA. At the end of September 2008, the EU announced that our applicant consortium is the winning team for call 16. Presently, we are joining with representatives of EFPIA in order to form a full consortium, which then will compile the Full Project Proposal (FPP), which is a 100-page document to be submitted on the 20 January 2009. This document will undergo a second peer review until the end of March 2009. We hope to get approval also in the second step. The Grant Agreement and the Project Agreement will then follow in the second quarter of 2009.

At this point in time we are in the middle of a hectic working period. However, if successful, what we are all struggling for, this program will offer a great opportunity to update, improve and harmonize continuing medical education (CME) and continuing professional development (CPD) in Pharmaceutical Medicine in Europe and to establish our discipline as a masters program for all pharmaceutical professionals in several European universities. This will also greatly improve the chance of obtaining official recognition of Pharmaceutical Medicine as a medical specialty in the EU countries. ■

THE FLAG

IFAPP World is a publication of the

International Federation of Associations of Pharmaceutical Physicians (IFAPP)
The Federation, founded in 1975, is a non-profit organization with 30 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.

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Abridged Reports from ICPM 2008

Developing Pharmaceutical Care – Medicines After the Blockbuster Era

Amsterdam, The Netherlands, 7-10 September 2008

"Modern Clinical Development – Trends in Clinical Development"

Chairs: Dr Johanna Schenk, Senior Partner & Managing Director, PharmaProjekthaus GmbH & Co. KG, Germany; Tanja Hoffman, Senior Director, Product Specialist, Quintiles Corp., The Netherlands. Speakers: Dr Richard Tiner, Medical Director, Association of the British Pharmaceutical Industry (ABPI), United Kingdom; Tom Ruane, Senior Director, Patient Recruitment, Quintiles Limited, United Kingdom; Dr Annalisa Rubino, Director, Outcome, United Kingdom.

Stimulating Innovation: Conditional and Accelerated Approach

The session started with a presentation on conditional and accelerated drug approval, provided by Dr Richard Tiner. In case companies manage to demonstrate an unmet medical need or the new product represents a significant improvement, the European Committee for Medicinal Products for Human Use (CHMP) would accelerate approval within 150 days. The conditional authorization applies to products, which treat, prevent or diagnose seriously debilitating or life-threatening diseases, to orphan medicines or to products to be used in emergency situations in response to public threats. Scientific advice from the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom may increase the likelihood that clinical trials and other research activities during development will meet evidence requirements for clinical decisions based on cost-effectiveness, thus providing access for patients through positive appraisal.

Patient Recruitment Strategies: Differences between Phase II/III and IV

Tom Ruane continued with patient recruitment strategies and differences between phase II/III and phase IV trials. A patient-centered recruitment strategy, which matches the protocol to the patient has been developed successfully by Quintiles, he said. Patient retention, compliance and motivation is managed by site staff using different tools, such as study calendars with key information and appointment dates, SMS text messaging, "Thank You" and "Happy Birthday" cards, appropriate recognition awards. Patient referrals to sites

Tom Ruane, United Kingdom

can be increased by combining advertising with partner sites and by patient awareness and education programs.

Accelerating patient recruitment for Phase IV studies is not considered appropriate, as it would blur the naturalistic approach.

The future of patient-recruitment strategies goes towards increased involvement of patient advocacy groups, also towards the move from expensive conventional advertising to more focused Internet based strategies and self involving patient registries, e.g., iGUARD. The Clinical Research Associate (CRA) will evolve towards a patient recruitment specialist and its role more and more become a "Relationship Manager".

Post-Marketing Surveillance: Registries and Other Techniques

The session topped off with a presentation by Dr Annalisa Rubino; Director of Epidemiology with Outcome on Post-marketing surveillance. Modern approaches to monitoring safety call for using a wide range of tools, including longitudinal observational studies with direct patient access, patient registries, risk minimization action plans, controlled distribution programs in order to provide real-world

Rijksmuseum Amsterdam, The Netherlands: ICPM 2008 Opening Ceremony – a reset of the "Night Watch", the most famous opus of the Dutch painter Rembrandt (1606-1669), displayed in the Rijksmuseum.

Dr Annalisa Rubino, United Kingdom

data and minimize the risk of harm from medical products after approval. Patient registries are based on an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves predetermined scientific, clinical, or policy purposes. Patient registries are not Good Clinical Practice (GCP) interventional trials: the treatment is assigned at doctors' discretion, there is observation without intervention, data are collected from patients seeking care with broad enrollment criteria. Compared to clinical trials, registries are often larger, include a diverse group of prescribing physicians, have a longer follow-up and more clinically relevant outcome measures.

There is increasing recognition that an active surveillance approach is an important adjunct to passive event detection for understanding product safety after launch. By providing a system for reporting adverse events and the context for estimating the rates of occurrence, registries can help both to quantify risk and to provide important information about clinical correlates. Registries can be mandated by regulatory bodies for products approved under an accelerated review process, approval contingent on conducting post-marketing surveillance studies, monitoring by safety signals and possible birth defects. More information on registries is available at www.effectivehealthcare.ahrq.gov on the internet.

Dr Mirela Barbu, Switzerland, member of the IFAPP Executive Committee

▶ page 10

Abridged Reports from ICPM 2008

"Any End of the Blockbuster Mindset"

Chairs: Dr Stewart Geary, Vice President, Eisai Co. Ltd., Japan; Dr Henk Jan Out, Senior Vice President Clinical R&D, N.V. Organon, The Netherlands. Speakers: Professor Daan Crommelin, Scientific Director, Top Institute Pharma, The Netherlands; Dr Erik Tambuyzer, Senior Vice President, Genzyme, Belgium; Martin Eijgenhuijsen, Senior Portfolio Manager Global Healthcare, APG Investments, The Netherlands.

R&D Philosophy: Public-Private Partnerships

The final day of the ICPM2008 Conference opened with an examination of the transition from the blockbuster business model in the session "Any End of the Blockbuster Mindset." Dr Daan Crommelin opened the session with a description of "Public-Private Partnerships, PPPs: a new paradigm for successful drug discovery and development?" Driven by increasing costs, concerns about pharmaceutical development productivity, and a realization that the pharmaceutical industry produces very high-added economic value per Full Time Equivalent, partnerships between government, academia and pharmaceutical industry are a product of mutual interest and need.

Professor Crommelin presented the Top Institute Pharma in the Netherlands as an example to illustrate how these partnerships can work. This partnership is a virtual institute funded in part by industry, academia and government, and setting up projects between universities in the Netherlands and local and global pharmaceutical companies to perform precompetitive research, and education and training programs. It focuses on critical areas of medical need and priority medicines as opposed to lifestyle drugs. The international character of Top Institute Pharma is illustrated by the fact that one third of the researchers involved come from outside the Netherlands. Closer collaboration between industry and academia holds promise in improving the efficiency and productivity of drug development.

Targeted Therapies: a Sustainable New Business Model?

Dr Erik Tambuyzer then presented on "Targeted Therapies: a Sustainable New Business Model?" encouraging the audience to move beyond the concept of blockbusters to the one of sustainable business models. He discussed the model of treatments for orphan diseases as just one of many possible models for these new developments. Many orphan drugs, by definition limited to very small patient populations with a high unmet medical need, are based on a direct link between diagnosis and therapy, for instance, with disease diagnosis of a congenital enzyme deficiency linked to a therapeutic replacement of that enzyme. Such products can produce a higher and more reliable benefit for affected patients which, together with the small number of patients treated, justifies their frequently higher prices.

Dr Tambuyzer compared the old paradigm of "trial and error" medicine, where in many therapeutic classes only a certain percentage of patients proves to benefit from their therapy, to a new paradigm of personalized medicine where testing links the disease diagnosis and therapeutic action, resulting in better compliance and eliminating side effects. Following on points raised by Professor Crommelin, Dr Tambuyzer noted that partnership is the key to this sustainable future, including partnership with patient groups and physicians.

Dr Tambuyzer also noted the common problem the industry faces when the actions of a few cause the image of the entire industry to suffer. The pharmaceutical industry's reputation and recognition of its positive contributions to society is a matter that we all need to work on to strengthen and improve.

Drivers Behind Science: Role of Financial Investor

Martin Eijgenhuijsen rounded out the session by providing an investor's perspective in his presentation – "Drivers Behind Science: Role of Financial Investor." He noted that there has long been recognition that the industry faces a "patent cliff" over 2010-2013 as a large number of blockbusters go off patent and that each year the list of major structural issues facing the pharmaceutical sector has grown.

It is now clear that the industry will not be in a position to repeat its current blockbuster business model after that period and that we stand at a crossroad for diversification. One illustration of how serious this challenge is for the industry is the stagnation in investment returns for pharmaceutical company investors since the year 2000 and the substantial decrease in the value the market places on pharmaceutical company earnings as evidenced by the halving of the price-to-earning ratios since then.

Eijgenhuijsen called on the industry to launch multiple new business models in parallel as a medium-term solution, moving from pure products to products and services, to consider selling the outcome rather than just the pharmaceutical, and to move to new customers. In the longer term the industry might either choose for geographic diversification by entering new countries – often the currently developing countries outside the US, EU and Japan – with new or different products at new price points or using new pricing models or therapeutic specialization including biotechnology products and personalized medicine as described by Dr Tambuyzer. A key message was that long-term business model differentiation will be necessary.

Caroline van Bruggen, IFAPP secretary (right), and her colleague Miranda Meulstee at the IFAPP both.

The core message of the session was that new business models, beyond the blockbuster, are both necessary and possible with academic and other partners standing ready to lend expertise and resources. Some companies are already presenting examples of sustainable business models based on the treatment of very small groups of patients.

Dr Stewart Geary, Japan, member of the IFAPP Executive Committee ■

The next two pages:

The Particular Poster Session

At the "International Conference on Pharmaceutical Medicine" – ICPM 2008, held the 7-10 September 2008 in Amsterdam, the Netherlands – IFAPP presented two particular posters which are displayed on the next two pages:

Page 11: "IFAPP's International Code of Ethical Conduct for Pharmaceutical Physicians" produced by the IFAPP Pharmaceutical Medicine Ethics Council (PMEC), which is available on request for advice on ethical matters relating to Pharmaceutical Medicine.

Page 12: "IFAPP Global Strategy – Shaping the Future", made to order of the IFAPP Executive Committee by the IFAPP Global Strategy Working Party.

IFAPP's International Code of Ethical Conduct for Pharmaceutical Physicians – 6 years later

Authors: Dr Sander Becker MB.BCh, FFPM, Dip. Bus Admin and Dr Jane Barrett MB BS, FFPM, LLM [Co-chairs] – IFAPP Executive

IFAPP's Pharmaceutical Medicine Ethics Council

AIMS

- Provide guidelines
- Continually re-evaluate ethics behavior in our contemporary global society

CONSTITUTIONALISE

Working Party of Ethics [WPE] 2001

↓

Pharmaceutical Medicine Ethics Council [PMEC] 2008

WHAT HAS WPE ACHIEVED ?

1. "IFAPP's Code of Ethical Conduct" was published April 2003 – see: Website
2. IFAPP World – 2 publications
   a – "High importance of IFAPP's Code of ethical Conduct" – Dec 2006
   b – "Exercise in ethical conduct decision making" – Dec 2007

CONTROVERSIAL "ETHICAL" DECISIONS

- Washington Post "Body-hunters" series
- Thalidomide 1960s - "requestion world authorities' thinking"
- Vioxx voluntary – "withdrawal ensuing Cox 2 fallout" [2004]
- Monoclonal antibody Phase 1 potential disaster [2006]

TRUTH, TRANSPARENCY, TRUST

FUTURE ADVANCES IN PHARMACEUTICAL MEDICINE ETHICS

- Poverty
- Global bioethics
- Biobanking – Stem cells
- Culture shift / Geographic boundaries
- E – Clinical trials
- Errors, Accountability, Evidence-based informed decisions

IFAPP

IFAPP GLOBAL STRATEGY
'Shaping the Future'

RATE OUR AIMS

2008

1.	Act as international forum of and for Pharmaceutical Physicians	55%
2.	Foster Pharmaceutical Medicine as a specialty	40%
3.	Develop pharmaceutical medicine education	60%
4.	Promote National Member Associations relationship between medical, allied professions, regulatory authorities (FDA, ...), international organisations (WHO, ...)	40%
5.	Disseminate Pharmaceutical Medicine information to Health Professionals worldwide	44%
6.	Organise Pharmaceutical Medicine conferences and other meetings	65%

CAN WE DELIVER 90 - 100 % ?

2013

1.	Act as international forum of and for Pharmaceutical Physicians	90%
2.	Foster Pharmaceutical Medicine as a specialty	90%
3.	Develop pharmaceutical medicine education	100%
4.	Promote National Member Associations relationship between medical, allied professions, regulatory authorities (FDA, ...), international organisations (WHO, ...)	90%
5.	Disseminate Pharmaceutical Medicine information to Health Professionals worldwide	90%
6.	Organise Pharmaceutical Medicine conferences and other meetings	100%

CHALLENGES

- Value -
- Visibility -
- Viability -
- Validity -
- Versatility -
- Volume -

THIS IS YOUR FEDERATION

IFAPP needs your help.

- Collaboration
- Cooperation
- Communication

Engagement + Involvement

INITIATIVES

- **REVISIT**
  - Vision
  - Aims
  - Metrics
- **IFAPP INFRASTRUCTURE**
  - Leadership
  - Working parties
  - Sub-committees
  - Expand volunteers...
- **NATIONAL MEMBERSHIP ASSOCIATION**
  - Demographics
  - Needs analysis
- **EDUCATION**
  - Targeting pharmaceutical medicine
  - Syllabus update
- **IMAGE, VALUE & VISIBILITY**
  - Pharmaceutical Physician
  - Pharmaceutical Medicine
  - IFAPP vs ICPM

  Action : Public Relations Branding
- **RELATIONSHIPS WITH**
  - Medical & allied professionals
  - Regulatory authorities
  - International organisations
- **BUSINESS PLAN**

  FUNDRAISING
- **NEW REGIONAL & CHAPTERS**
  - China, India...
  - South America etc
- **IFAPP WORLD**
  - Distribution
  - Activation

  WEBSITE

IFAPP GLOBAL STRATEGY WORKING PARTY

ROLE: Process and System driven – trends, utilities, define and defend issues and solve problems.

BRIEF: To assist IFAPP explore options, debate issues, think through implications, track metrics, identify possible solutions.

MEMBERSHIP: 5 core, plus 20 associate members (if needed).

Authors: Dr Sander Becker Australia **[Chairperson], Dr Chris Allen** USA, **Dr Johanna Schenk** Germany, **Dr Norbert Clemens** Germany **and IFAPP Executive colleagues.**

IFAPP