## 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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## 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.