◀ tolerant of the local mindset, understand the social system, accept cultural differences and plan everything well in advance.

The third speaker, Frank Fan, focused mainly on China, a country increasingly coming into focus in recent years. The advantages are evident: fast recruitment, huge market, lower costs, and high quality of the work performed. However, due to the fast evolution, there is a shortage of well-trained personnel. The speaker ended his talk by presenting the Clinical Trial Center of the University of Hong Kong as a case study.

Professor Dr Jean-Paul Deslypere, member of IFAPP's Executive Committee, Singapore

Report on the Special Session
Pharmaceutical Medicine in Asia – Today and Tomorrow

Chair: Churl J. Kim (Korea). Speakers: Kenneth Hartigan-Go (Philippines), Kyoko Imamura (Japan), Ahmad Atif Mirza (Pakistan), Paul Jang (Korea), Jean-Paul Deslypere (Singapore), Sunettra Chinnapha (Thailand), Frank Fan, Frank Yuan (China), William Huang (Taiwan)

After an introduction by the new President of IFAPP, Dr Luis Collia, representatives of different Asian countries presented the current status of Pharmaceutical Medicine in their respective countries.

In some countries (Philippines, Japan, Pakistan, Korea, Indonesia) an Association of Pharmaceutical Medicine has existed already for many years, while in other countries it has just been set up (Singapore) or is in the process of being created (Thailand, China, Taiwan).

Importance of Pharmaceutical Medicine increases

The recognition of Pharmaceutical Medicine as a specialty remains a problem in many countries and sometimes there even is no obligation for the pharmaceutical industry to employ a medical doctor. The lack of specific training as a pharmaceutical physician was a concern for many presenters.

In most countries, professionals engaged in clinical research are active in teaching and training, organizing conferences and workshops and enhancing the clinical research quality. Regular interactions with regulatory authorities and academia are seen as equally important.

It was the general consensus of all speakers that pharmaceutical physicians are now playing an increasingly important role in the pharmaceutical industry at many different levels, therefore making the need for appropriate training and certification in Pharmaceutical Medicine more relevant than ever before.

Professor Dr Jean-Paul Deslypere, member of IFAPP's Executive Committee, Singapore

At ICPM 2006 registration desk

Report on Session C
Ethics in Pharmaceutical Medicine

Chair: Sutinder Bindra (AP). Co-Chair: Paul Jang (Korea). Speakers: Jane Barrett (UK): Ethics in Biomedical Research; Pol Vandenbroukke (Japan): Ethics in Pharmaceutical Business Practice; Ock-Joo Kim (Korea): Ethical Issues in Stem Cell Research: Experience in Korea

Ethics in Biomedical Research

Transparency and truth were the themes of this excellent presentation. Within this framework, "informed consent," "free will," "the rights" and "protection" of both the patients and doctors involved in medical experimentation were addressed.

Jane Barrett directed the audience's immediate attention to historical codes relating to medical scientific practice. It was interesting to note that the First Prussian Directive on informed consent preceded the Nuremberg Code of 1947.

Dr Jane Barrett, IFAPP Executive Committee member from The United Kingdom, at Session C

The presenter then mapped out the path for medical researchers and explained its implications – from the Hippocratic oath through to the Declaration of Helsinki, then CIOMS (Council for International Organizations of Medical Sciences), ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use), the WHO (World Health Organization) 'Good Clinical Practice' and the European Union 'Clinical Trial Directive 2001/20/EC'. Jane Barrett explained that patients' rights when taking part in research are also protected under the International Bill of Rights, the International Covenant on Civil and Political Rights – which states that "no one shall be subjected to torture or cruel, inhuman, or degrading treatment or punishment."

An ethical guideline for research involving humans is founded on four principles: beneficence (people can expect that doctors have a duty to do good things to their patients), non-maleficence (patients will not be deliberately harmed by their doctor), autonomy (adults of sound mind have a right to decide what happens to their bodies) and justice (everyone has rights to have medicines tested for them and on them).

The presenter then gave a number of scientific and legal examples that introduced ethical questions, which investigators participating in clinical research need to consider.

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Take home message: The rights of human research protecting the rights of the child, the elderly and the disabled need to be carefully evaluated. *Dr Sander Becker*

Ethics in Pharmaceutical Business Practice

Pol Vanderbroucke provided a brief historical perspective spanning from the 'Hippocratic oath' through the 'Declaration of Helsinki' and 'International Federation of Pharmaceutical Manufacturers' (IFPMA) Promotional Code. The speaker highlighted that most pharmaceutical industry employers are well aware of company business "credo" and "values". However, they are not provided with general business ethics know-how or ethical guidelines. Also "systematic training in ethics" is not provided.

The speaker posed a provocative question: "Do we need ethical guidelines?" He believed that they are as important as company culture, business performance, industry and company regulations and legal advice. Clinical research ethics codes are developed and continue to evolve, while business ethics and other aspects of the pharmaceutical industry are less well developed.

Take home message: Business needs to take responsibility for training their employees by establishing ethical guidelines or business codes will need to be introduced.

Dr Sander Becker

Ethical Issues in Stem Cell Research: Experience in Korea

Detailing the Huang Woo-Suk cloning stem cell scandal that rocked the world's scientific community, Ock-Joo Kim of Seoul National University, Korea, gave a fascinating presentation. Huang's paper had been hailed as a breakthrough, opening the possibility of degenerative diseases cures. He was hailed as a hero until it became evident that the so-called stem cell colonies had been faked.

The speaker impressed the audience with her candor. She gave the background on when the fraud being first suspected and then proven, including the investigations that had taken place in the research center, outlining her involvement in the process. Ock-Joo Kim spoke of the furious South Korean media debate initiated by the revelations and of her anger that a respected scientist published work he knew to be false.

The speaker said that the controversy is still raging in the Korean scientific community, with some feeling that it was unpatriotic to challenge someone who had given the country a lead in such a promising new area. Indeed, some companies withdrew advertisements from the television station that first revealed the problems with Huang's work.

Take home message: All scientific breakthroughs must be rigorously tested and reproduced before they can be considered true advances. In this respect nobody is above the law or above suspicion. Science must also be ethical and truthful. *Dr Jane Barrett*

Report on Session D
How to Improve Access to Medicine

Chair: Bong-Min Yang (Korea). Co-Chair: Stephen Phua (Singapore). Speakers: Zili Li (USA): Improve Access to Medicine – What We Can Learn From US FDA Clinical Review Practice; Criscuolo Domenico (Italy): Pricing and Reimbursement; Johanna Schenk (Germany): Informed Patients

Access to medicines depends on market availability and affordable cost. In countries with a socialized health care system the drug reimbursement reduces the patients' co-payment.

Three presentations considered access to medicines, each from a different angle. Zili Li highlighted that recently a US Food and Drug Administration (FDA) clinical review practice attempted to bring effective and safe drugs sooner to the general public. Regulatory agencies in other regions have to find out if these good review practices are applicable in their markets. The second speaker, Criscuolo Domenico, discussed pricing and reimbursement, which is still regulated by national health services in most countries of the European Union (EU), while in Japan and the US there is a free market approach. Hence prices and reimbursement in the EU are based on a cost-effectiveness evaluation and reference price system, comparing individual price of any new drug against the prices of similar drugs within the same class that are already available for the same indication.

Informed patients

Experts expect increasing price pressure on new 'expensive' drugs, unless these new drugs are seen as truly 'innovative' or orphan drugs. This economic pressure will be a barrier to new drugs access. In her presentation on 'informed patients,' Johanna Schenk outlined that drug information is shifting away from paternalism to partnership. However, although not all patients can be reached, the majority should benefit when well informed.

Well-informed patients are less anxious, start their treatment earlier, follow their doctor's advice more closely, and are capable of self-management and more efficient in searching for adequate resources. Better-informed patients also avoid or minimize the risk of adverse reactions and interactions. This may result in a drop in health care costs.

Additionally, patients can provide a unique perspective on the importance of innovative drugs and state with authority the balance that should be struck between benefits and risks. To facilitate this, pharmaceutical professionals and physicians have a vital role in a concerted action together with prescribing physicians, clinical investigators, regulators and patient organizations.

Dr Henri Pintens, Belgium

Report on Session E
Pharmaceutical Medicine

Chair: Henri Pintens (Belgium). Co-Chair: Churl J. Kim (Korea). Peter Stonier (UK): Pharmaceutical Medicine as a Specialized Discipline of Medicine; Madeleine Billeter (Switzerland): Pharmaceutical Medicine Specialization in Europe: Is the Model Exportable Elsewhere? Kyoko Imamura (Japan): Development Pharmaceutical Medicine Specialty in Asia

Dr Churl J Kim, Korea, and Dr Henri Pintens, Belgium, co-chairing Session E