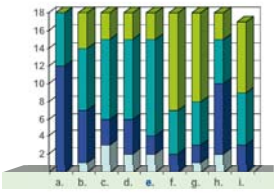
2011 October

IFAPPWORLD

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS

IFAPP'S ETHICS CORNER

IFAPP's Ethics Corner Concept – What is That and Why?



Ten years ago – back in 2001 – IFAPP identified the need to stir the ethics debate amongst health professionals and established an International Working Party on Ethics. Hence the IFAPP International Code of Ethical Conduct for Pharmaceutical Physicians was debated, created, and published in 2003 [current version available ...

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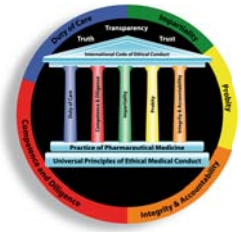
Comments on Ethical Dilemmas Beyond Clinical Trials



Speculating on Study Outcome

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16th 'International Conference on Pharmaceutical Medicine'

14-16 November 2012, Barcelona – Spain

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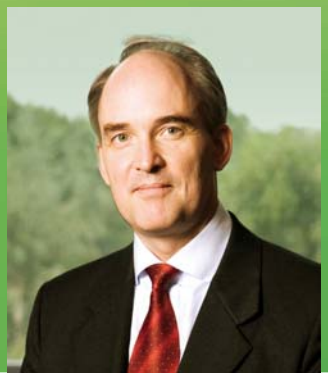
Bild: Fotolia

CONTENT

WWW.IFAPP.ORG

Dr Rudolf van Olden, IFAPP President, The Netherlands:

"Pharmaceutical Medicine is even wider than internal medicine! Like many disciplines in medicine, Pharmaceutical Medicine is not a discipline for physicians only!"



President's Letter

Dear Colleagues

The impressive main lecture hall was still completely empty at eight o'clock in the morning. Several binders had been left in front of some seats. I could still smell the serene learning atmosphere. In fact, over the past three days, more than 150 delegates had got the first in-depth lessons about various topics in the field of Pharmaceutical Medicine. Delegates from all over the world. I picked a binder, opened it and took a look inside: a stack of paper, 12 cm thick, full of presentations and interesting articles of excellent speakers. I put the binder back to its place and looked around.

This is the place in Basel, Switzerland, where 20 years ago the European Centre of Pharmaceutical Medicine – ECPM – was born. I recently traveled to Basel to join the 20th ECPM Anniversary on Thursday, 8 September 2011.

A Commitment to Pharmaceutical Medicine

Currently, the ECPM counts more than 1.200 alumni – an impressive result of a huge commitment to Pharmaceutical Medicine and as well to the pharmaceutical industry. A commitment of a team and a commitment of a particularly active driving force: Professor Dr Fritz Bühler – the founder of ECPM. Well, in Basel you feel the spirit of Pharmaceutical Medicine due to the existence of pharmaceutical industries' headquarters on both sides of the river Rhine with the commitment of the Faculty of Medicine and the ECPM in addition to it.

Contributing to build up Pharmaceutical Medicine as a medical discipline is an important objective of our federation – IFAPP. Working in the field of Pharmaceutical Medicine and drug development, we all are familiar with the questions frequently asked about our roles, responsibilities and specifications of our jobs. How many of our colleagues answer these questions with: "I am a pharmaceutical physician" or "I work as a pharmaceutical scientist"? But how comes that the majority of the physicians worldwide have never heard about Pharmaceutical Medicine? Who are the role models in the field of Pharmaceutical Medicine and do we know them?

Show your identity in Pharmaceutical Medicine!

As individual members of our National Member Associations we all have a responsibility to be crystal clear about the umbrella-discipline of our daily work. As physicians or scientists we work in the field of Pharmaceutical Medicine. Together with all our colleagues in Pharmaceutical Medicine we assume responsibilities for public healthcare in many countries around the globe: in developing vaccines, biopharmaceuticals, small molecules and generics. Creating new health care paradigms. Taking care of the risk management programs for our newly introduced medications. And working on the safety profiles during the life cycles of any pharmaceutical.

Pharmaceutical Medicine is even wider than internal medicine! Like many disciplines in medicine, Pharmaceutical Medicine is not a discipline for physicians only! Working together with all the national member associations of IFAPP on the different aspects of our discipline could contribute to give our profession the right identity. Let's be proud of working together in this front edge of the future in health care! Show your identity in Pharmaceutical Medicine!

With kind regards – Dr Rudolf van Olden, IFAPP President, The Netherlands ■

How to stir ethics debate amongst Pharmaceutical Physicians and health professionals – internationally?

IFAPP's Ethics Corner

IFAPP's Ethics Corner Concept – What is That and Why?

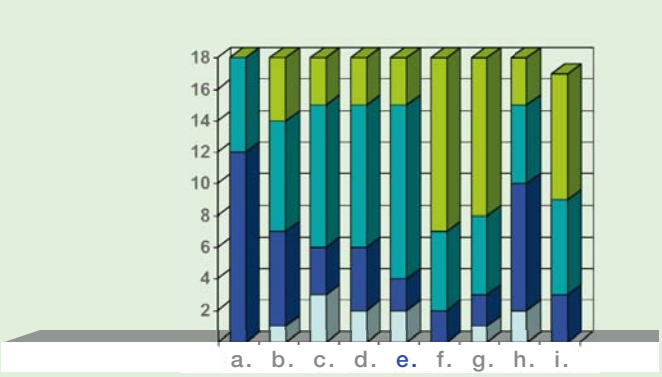
A Rich Tapestry for Real Time Ethics Consideration and Debate is Emerging

Ten years ago – back in 2001 – IFAPP identified the need to stir the ethics debate amongst health professionals and established an International Working Party on Ethics. Hence the IFAPP International Code of Ethical Conduct for Pharmaceutical Physicians was debated, created, and published in 2003 [current version available at www.ifapp.org/home/ethics].

IFAPP WORLD highlighted the importance of IFAPP's Code of Ethical Conduct and published the results of a poll on IFAPP services [IFAPP WORLD II-2006 December, page 11 – available at www.ifapp.org/home/news/ifapp-world] conducted amongst IFAPP's national Member Associations (see figure below).

This poll revealed that whilst 78 percent of the respondents said the Code was working well, several asked "what needs to be addressed and changed?" This showed the need to find workable means and a forum to debate and deliberate ethical issues of particular relevance to pharmaceutical physicians. A global council was the solution – that's why IFAPP's Pharmaceutical Medicine Ethics Council (PMEC) was founded in 2008.

Furthermore, we still needed means to service the ethics needs of our clients – pharmaceutical physicians, IFAPP's national Member Associations and health professionals at large.



Importance of the Ethical Code of Conduct provided as a service by the IFAPP relative to other services – ranking by IFAPP's national Member Associations in 2006.

a. Pharmaceutical and country news
b. International Conference on Pharmaceutical Medicine
c. Conferences involving EMEA
d. Conferences involving FDA
e. Ethical code of conduct
f. Education, accreditation and training in Pharmaceutical Medicine
g. Assistance in establishing courses in pharmaceutical medicine
h. Assistance in establishing member associations
i. Promotion of recognition of pharmaceutical medicine as a medical specialty

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We knew that from an ethics perspective IFAPP was facing worldwide shifts, since major pharmaceutical corporations were reduced through mergers, and communication, media, Facebook, Twitter and YouTube as well as cultural issues had ethical impact and implications.

Engaging and involving our IFAPP Executive Committee provided the answer: During the last IFAPP Executive Committee face-to-face meeting in April 2011, a presentation by Dr Jane Barrett, United Kingdom, and Dr Sander Becker, Australia, Co-chairs of the PMEC, gave an update of the PMEC and the matters PMEC were facing. Dr Johanna Schenk, Germany, reported an ethical problem needing discussion, which was a recent dilemma of certain oncology drugs not being reimbursed in Germany. Others noted the need to convert from a reactive to a proactive mode in thinking about and initiating discussions on ethics. It was suggested that using a social media format for raising and discussing ethical problems might be valuable.

From this, deeper insight and ideas emerged and provided impetus and drivers for IFAPP's Ethics Corner concept to emerge. "Ethical Dilemmas Beyond Clinical Trials – A Case Study – Sponsor Refused Clinical Trial Participation" was duly published in IFAPP WORLD to service our membership need. [IFAPP WORLD 2011 June, page 4 – available at www.ifapp.org/home/news/ifapp-world]

There was limited interest shown by the readership. Given this the PMEC asked the PMEC councilors for a perspective on this case study. This bore fruit highlighting and providing a rich tapestry for real-time pharmaceutical medicine ethics consideration and debate.

Words and expression used by our councilors were "most illuminating", "Ethical considerations are seldom easy", "[…] compassionate use programs should […] receive similar image campaigns […]", "The notion that clinical trials provide "treatment" reflects the therapeutic misconception […]."

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Please read the complete quotes on the following pages for a clinical and ethical perspective. We hope exploring our councilors' perspectives will encourage your further interest in ethics and IFAPP's Ethics Corner.

Dear reader, we look forward to your comments, insights and other matters so we can explore ethics together. We trust you will find food-for-thought, a recipe and ingredients to stimulate "ethics passion".

Dr Sander Becker,
Australia, and Dr Jane Barrett, United Kingdom, Co-chairs of IFAPP's Pharmaceutical Medicine Ethics Council ■

CONTINUATION

After publishing "A Case Study – Sponsor Refused Clinical Trial Participation" in the last edition, IFAPP WORLD now presents comments on the ethical dilemma of this particular case.

IFAPP's Ethics Corner

Comments on Ethical Dilemmas Beyond Clinical Trials

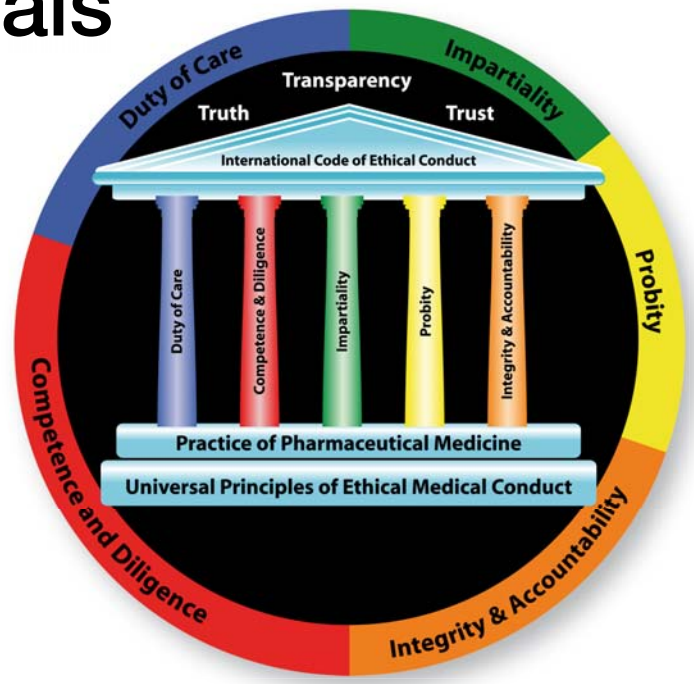
Interested in the underlying article "Ethical Dilemmas Beyond Clinical Trials – A Case Study | Sponsor Refused Clinical Trial Participation"? Read it in IFAPP WORLD 2011 June, page 4 – available at www.ifapp.org/home/news/ifapp-world.

Speculating on Study Outcome

"From the viewpoint of the protocol it is possible that the patient is correctly excluded from the study (although I have some doubts as he meets the requirement of the Karnofsky Performance Scale). However, one of the sponsor's allegations is that the patient's clinical characteristics might influence and worsen the outcome of the study. I think that making a study in this way we risk a result that does not reflect the true efficacy of the drug in real life and is not in line with reality.

From the ethical point of view, I think the patient should have been included because he is young and met the inclusion criteria, but mainly because there is no other treatment available in the country where the study is conducted. The patient should have been included without speculating on the outcome of the study."

Luis Collia, Argentina



Excerpt from "Poster Cancun ICPM 2002 - Dr Sander Becker". Details at www.ifapp.org/home/ethics/code-of-conduct

'Ethics Corner' Most Illuminating

"I found the 'Ethics Corner' most illuminating in that it captures very well the real-world dilemmas we daily face at investigational sites. I suspect that the gravity and urgency of this sort of dilemma may not be well recognised by professionals dealing with clinical development but lacking clinical experience. In other words, this is the sort of perspective that can be best and most appropriately addressed by pharmaceutical physicians.

I look forward to seeing more of these case studies."

Yuji Sato, Japan

CONTINUATION

Well-Being of the Patient versus Study Integrity

"It appears that the patient did not meet the protocol specifications of the study or sufficient criteria for evaluation and, thus, the sponsor was right to deny eligibility. Ethics have to consider both the well-being of the patient and the study integrity. On the part of well-being, a much bigger ethical question is why the patient could not be treated outside of the study if needed. The presentation of the case is inconclusive in this regard but leaves room for speculation about the inefficiency of health care systems or compassionate use regulations or the incapacity of the involved bodies to make use of it. This requires our attention under ethical considerations. A study should not be used as a substitute for such deficiencies." *Hans-Joachim Weber, Germany*

Trial Methodology Closer to Real World Scenario

"There is no clear answer in this case as to what is right or wrong; it depends completely on the aspect of the observer. From a methodological point of view it seems clear that the in/exclusion criteria have to be followed, but in certain diseases where no adequate treatment is available, participation for patients not meeting all in/exclusion criteria could be offered in a compassionate use program. Because sponsors have to consider benefit/risk criteria and issues of insurance I believe they are reluctant to offer such participation at present. Compassionate use programs should be internationally regulated, and receive similar image campaigns such as recently devoted to trials of children and women of childbearing age. This could be a very important task for IFAPP and her societies.

Further to this case, the sponsor could have included the patient despite non-eligibility, risking accusations of methodological mistakes or even non-acceptance of the publication. Compassionate use programs in the past, possibly correctly, have been accused of being pre-marketing measures; borders are somewhat unclear and always leave room for interpretation.

Now the industry is entering an era of highly specific drugs with smaller patient populations and the ability to treat rare diseases. There will be a need to regulate early participation for patients not meeting all in/exclusion criteria. And there is a positive aspect to this, because the criticism of the clinical trial population being a virtual one is well known to all of us. This will require ongoing development of clinical trial methodology closer to the real world scenario, particularly in rare disease populations." *Ilja Fišer, Austria*

Ethical Considerations Are Seldom Easy

"On the face of it, the exclusion of this patient seems unfair. But he had a severe and advanced form of haemophilia and had lost, due to amputation, 50% of the joints that were to be studied. One wonders, therefore, how the study assessments of this patient would be managed in any meaningful way. We are told that he is young, and unable to access any other treatment in his country. So we have his personal dilemma to set against the dilemma of the sponsor. Ethical considerations are seldom easy; in this case science dictates exclusion, human nature longs to treat this unfortunate man. Perhaps, as Dr Weber suggests [in the last quote], compassionate use would be the way to satisfy both sides?" *Jane Barrett, UK*

Clinical Trials Provide 'Treatment' – a Misconception

"The notion that clinical trials provide "treatment" reflects the therapeutic misconception to which both patient-subjects and physician-investigators are subject. Clinical trials generally test the safety and efficacy of a new test article – conditions of equipoise being met, randomization should confer a reasonable balance of risk and benefit. Exposure to a new substance in a trial setting exposes a subject to risks of harm for potential benefits, the likelihood of which no one

CONTINUATION

can be certain. This is very different from being exposed to a known effective therapy.

That said, the principal issue in this case is one of entry and exclusion criteria. These criteria were carefully chosen and evaluated by the research team (sponsor and investigator) and the ethics committee prior to approval and initiation of the trial, and were understood by the potential subject during the informed consent process. While compassion for the individual is understandable and even laudable in this case, inclusion in the trial of an individual who does not meet the eligibility criteria risks undermining the scientific integrity of the trial, and violating guidelines and rules for responsible conduct of clinical research. The investigator followed a proper course of action in seeking broad consultation to ensure that the eligibility criteria were carefully evaluated, and I believe the outcome was appropriate.

Rather than include this individual, consideration of an alternative approach to making the test article accessible is more appropriate. Many sponsors and competent authorities allow for "treatment use of an investigational agent" on a compassionate basis, and this would seem to be the more appropriate course to follow in this case. This approach also satisfies both the scientific and humanitarian concerns raised in this situation."

Greg Koski, USA
Collected by Dr Jane Barrett, United Kingdom, and Dr Sander Becker, Australia, Co-chairs of IFAPP's Pharmaceutical Medicine Ethics Council (PMEC) ■

Dear Reader, IFAPP's Pharmaceutical Medicine Ethics Council (PMEC) invites you to share your ethical considerations and to contribute your opinion, comment, experience or question. Please send a note to IFAPP's PMEC (janebarrett@doctors.org.uk or SanderBecker@aol.com). With your consent it might be published in IFAPP WORLD in full or in part and, if requested, without disclosing your name. Thank you in advance.

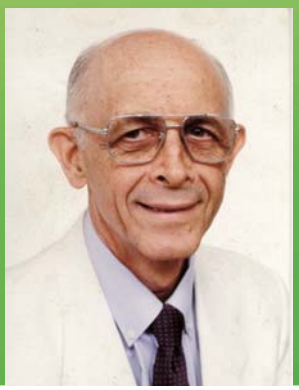
IFAPP News

New IFAPP Member: Bangladesh Association of Pharamceutical Physicians

IFAPP welcomes the Bangladesh Association of Pharamceutical Physicians (BAPP) as a new member – the 30th IFAPP member association. This is a great opportunity for a fruitful collaboration in the field of Pharmaceutical Medicine with other experts and collegial associations all over the world.

BAPP was founded in 2007 with an office in Dhaka, Bangladesh. Founder and active President is Dr Hasan Mahmood, MBBS, MBA (International Business & Marketing).

BAPP currently counts 25 members, who basically work in the field of marketing as there is very little clinical research and development activity in Bangladesh to date. However, according to the BAPP President, multinational pharmaceutical corporations are about to start with clinical research. BAPP supports them with providing information on resources and business prospects and invites all members of IFAPP to visit Bangladesh. Dr Hasan Mahmood: "We have 160 million people and different diseases. This is a major opportunity for contract research organizations (CROs) and BAPP aims to help establishing CROs here in this ambitious and beautiful country." ■



Dr Paulo Aligieri, Executive Secretary of the Brazilian Society of Pharmaceutical Medicine (SBMF) reports from an SBMF event.

Reports and Concepts

SBMF Meeting Provides Updated Information on Biomarkers

The Brazilian Society of Pharmaceutical Medicine (SBMF) has always invested in updating and training SBMF members and other health professionals in different aspects of Pharmaceutical Medicine. Continued education opportunities are included in meetings, conferences and courses. Since the SBMF Office could not host large meetings, conference rooms were rented in hotels, in conference venues, or sponsored by third parties, especially by the pharmaceutical industry. A great number of meetings had been held in the Nycomed conference room for about three years.

In 2006, a partnership between SBMF Directors and the Trade Association of the Pharmaceutical Industries of the State of São Paulo, Brazil – Sindusfarma – marked the creation of new opportunities.

Sindusfarma is a highly respected and well-known trade association in the State of São Paulo and nearby states. In 2006, Sindusfarma did not only sponsor a number of educational projects, but also made available a large conference room with a capacity for 110 people, as well as an extensive list with the electronic contact details of industry professionals, and an experienced team that SBMF could use at almost no cost.

In recent years, SBMF has hosted a lot of meetings that filled the Sindusfarma conference room. Most of these meetings focused on clinical research, pharmaceutical industry careers, health product regulations, pharmacovigilance, generic drugs, and other important issues in Pharmaceutical Medicine.

Roundtable on "Advances in Research and in the Practical Use of Biomarkers": Moderator Dr Carlos Kiffer from GC-2 Pharmaceutical Research and Development, Llc, São Paulo, Brazil (in the center). Seated beside are Dr Gustavo Campana (Formato Clínico and CG-2) and biologist Estela Barão (Thomson Reuters).

Part of the audience listening to the lectures of the session "Advances in Research and in the Practical Use of Biomarkers".

On 26 May 2011 SBMF again played a key role in disseminating new medical and pharmaceutical knowledge relevant for the effective and safe practice of Pharmaceutical Medicine. SBMF also shared innovative knowledge relevant for scientific evolution and practice. A prestigious audience, including people responsible for strategic decisions in the ▶

pharmaceutical industry and representatives of universities and other areas, participated in the meeting titled "Biomarkers: Use in Research, Clinics and Regulatory Affairs" held in the Sindusfarma conference room. A computer terminal in the lobby also demonstrated how to explore large scientific databases.

Dr Paulo Aligieri,
SBMF Executive Secretary, São Paulo, Brazil

Professor Dr Paulo Andrade Lotufo, University Hospital of the University of São Paulo, (in the center) listens to an explanation by Martin Roca (left) and biologist Estela Barão (right), both from Thomson Reuters.

IFAPP News

New Presidents of IFAPP's Member Associations

The IFAPP notes several changes within the IFAPP Member Associations. New Presidents were elected within the following organizations (in alphabetical order):

Australia: New President of the Australian Pharmaceutical Physicians Association (APPA) is Dr Beata Niechoda. APPI Delegate to IFAPP is Dr Eugene Goh.

Austria: Dr Dagmar Doby is the new President of the Austrian Society for Pharmaceutical Medicine (Gesellschaft für Pharmazeutische Medizin e.V. – GPMed – www.gpmed.at). GPMed Delegate to IFAPP is Professor Dr Gerfried Nell, Past President of IFAPP.

Hungary: The Hungarian member association Clinical Trial Management Society Hungary (CTMS – MKVT – www.mkvt.hu) elected Dr Judit Tarnai for the next term of presidency. CTMS delegate to IFAPP is Professor Dr Sandor Kerpel-Fronius.

Indonesia: Dr Budhy Widjojo was elected as new President of the Indonesian Association of Pharmaceutical Physicians (PEDFI – Perhimpunan Dokter Farmaseutika Indonesia). PEDFI Delegate to IFAPP is Dr Rosalina Sutadi.

Mexico: The General Assembly of the Mexican Pharmaceutical Physicians Association (AMEIFAC – www.ameifac.org.mx) elected Dr Marlene Llopiz new President. She also is AMEIFAC delegate to IFAPP and Secretary of IFAPP's Executive Committee.

Pakistan: The Pakistan Association of Pharmaceutical Physicians (PAPP) has recently elected Dr Shehla Naseem their President.

IFAPP congratulates the new Presidents of IFAPP Member Associations and also would like to thank the former Presidents for their contributions to IFAPP. IFAPP is looking forward to continuing the fruitful co-operations.

† Professor Dr Jean-Marc Husson, former IFAPP President (1998-2000)

Obituary

Professor Dr Jean-Marc Husson, Former IFAPP President, Dies

IFAPP sadly has to announce that Professor Dr Jean-Marc Husson, former IFAPP President (1998-2000), passed away in Paris, France, on 6 June 2011. The members of the IFAPP Executive Committee commemorate him as a popular partner and colleague and express their feelings of deepest sympathy and condolence to the family.

Jean-Marc Husson was a co-founder of Eudipharm, a provider of European courses leading to a European Diploma in Pharmaceutical Medicine based at the Université Claude Bernard in Lyon, France. He was also a co-founder of PharmaTrain and a member of the PharmaTrain Executive Board. And he was a member of the Ethics Committee of the Royal College of Medicine in the United Kingdom.

Jean-Marc Husson has continuously pushed the idea of Pharmaceutical Medicine forward from various positions within the pharmaceutical industry, regulatory organizations and pharma associations. The following details regarding his career are quoted from a summary provided by Eudipharm on www.eudipharm.net/claroline141/HUSSON/:

"He worked for the Hoechst-Roussel group for 25 years and was Roussel-Uclaf's International Medical Director from 1979 to 1987. Later he worked for Regulatory Affairs and Pharma Policy. He was deeply involved in EFPIA, SNIP / LEEM & French Ministries WP. He was President of IFAPP (1998-2000). He has participated in ICH (1990-1997) and was directly involved in the development of the E1, E5, E6, E7, E8, M3 guidelines and the coordination of other efficacy texts as EFPIA Task Force Leader for Efficacy.

He left industry in 1996 to become a consultant for the pharmaceutical industry and emerging small and middle size companies. Dr Husson was a specialist in pharmaceutical medicine (Switzerland) from 2002 until his death. He was a specialist in internal medicine (hepato-gastroenterology and vascular diseases/HTA). He was also Professor for Industry at the University of Montpellier and also trained at INSEAD (AMP programme)." ■

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 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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IFAPP's Calendar

16th 'International Conference on Pharmaceutical Medicine'

14-16 November 2012, Barcelona – Spain

ICPM 2012

On behalf of the organizing committee the Presidents of IFAPP and of the Spanish Association of Pharmaceutical Medicine (AMIFE) are please to inform you about the upcoming 16th 'International Conference on Pharmaceutical Medicine' – ICPM 2012 – to be held in Barcelona, Spain, from Wednesday through Friday 14th-16th November 2012. ICPM 2012 is jointly organized by IFAPP and AMIFE.

ICPM 2012 will ensure a top-level scientific program with experts' presentations on well-differentiated and important dimensions of our professional endeavors, with additional debates, discussions, an interchange of ideas and sharing of information and good practices. You will enjoy a varied program with main topics as described below.

Plenary Lecture: Health Care Improvement Through Clinical Research

ICPM 2012 will provide a plenary lecture presenting renowned figures of the Pharmaceutical Medicine world. Pending final date arrangements, Dr José Gomes do Amaral, Brazil, President-Elect of the World Medical Association, has kindly accepted to deliver a Keynote lecture on "Health Care Improvement Through Clinical Research".

Bild: Fotolia

Drug Advertising – Ethics and Compliance

With this roundtable, chaired by Dr Roberto Ruiz, Glaxo SmithKline, Spain, ICPM 2012 intends to open a debate on the impact and evolution of drug advertising, its ethics and compliance issues within the pharmaceutical industry. The following issues will be discussed:

- Regional regulations on drug promotion – what do they have in common? What are their differences? And what is their impact on local codes for global corporations?
- Burning issues: Is the pharmaceutical environment becoming more ethical? What is the role of the authorities and the self-regulated approach? What are their advantages and disadvantages? And what is the public perception?

Dr Rudolf van Olden
IFAPP President, The Netherlands

Dr Arturo Lopez-Gil
President AMIFE, Spain

- Sharing best practices: What is the role of the companies' Medical Departments and its stakeholders? What are the most efficient structures and roles for ensuring compliance?
- Devising the way forward: Common future goals.

Pharmacovigilance Legislation in the European Union

The new pharmacovigilance legislation in the European Union published in 2010 is moving forward and its implementation will be mandatory starting in July 2012. This roundtable, chaired by Dr Neus Gascón, Esteve S.A., Spain, will bring together experts from different disciplines to provide an overview and share opinions on the impact of the implementation of these new measures.

The new EU pharmacoviglance legislation and the status of its implementation into national rules and regulations will be reviewed. Representatives of the European Medicines Agency (EMA) and of different national competent authorities will share their experience from a regulatory perspective. To complete the picture, a representative of a globally operating pharmaceutical corporation will analyze the impact of the implementation on different areas of the company.

Current Patent Issues – Developments and Conflicts, Implications and Solutions

Linked with patent issues, there are several topics of growing interest for pharmaceutical companies. Such topics – touched upon in this roundtable, chaired by Dr Belén Sopesén, Noscira, Spain – are as follows:

- Supplementary Certificates of Protection (SPCs): recent developments.
- Patent reform's first experience: "first-to-file", post-grant opposition procedure.
- Relevance of branding in view of blockbuster patent expiry
- Enforcement of industrial property in China

Presenters from a variety of different disciplines – legal experts, patent officials, regulators and pharmaceutical industry experts – will share their views and perspectives on these topics.

Patient Associations

This roundtable, chaired by Dr Anna Jurczynska, Quantum Experimental, Spain, will bring on a discussion on how pharmaceutical companies and the pharmaceutical industry in general should best approach patient organizations in order to enhance collaboration in the field of clinical research.

- Research in rare diseases: The point of view of investigators and patients' associations
- Network of European Patients' Associations
- Approach to clinical research from Patients' Associations in the US and in Asia
- EMA focus on drug research and the role of patients' associations.

Pharmaceutical Medicine's Role Within the Companies' Medical Departments

This roundtable of experts, chaired by Dr Carlos Corral, Merck Sharp & Dohme, Spain, will clearly delineate the new roles and functions and the super specialization roles of the Medical Affairs and Medical Department with regards to the role of Pharmaceutical Medicine.

On the Edge of Therapeutic Innovations: New Ways of Developing Medicines and the Regulators' View

A focused look at the role of therapeutic innovation, therapy individualization and experimental medicine as viewed from the pharmaceutical industry, the evaluator and the regulator.

Chaired by Dr José Antonio Sacristán, Lilly S.A., Spain.

The Impact of the Economic Crisis and the Changing Economy on Conceptions and Opportunities for Market Access

Chaired by Dr Carme Piñol, Bayer HealthCare, Spain.

Clinical Research Associates' (CRAs) Workshop

As is the tradition in the biannual ICPM, AMIFE will organize a practice-oriented hands-on workshop aimed at CRAs and others involved in clinical research and clinical operations, which will be chaired by Anna Serret, Merck Sharp & Dohme,

IFAPP and AMIFE kindly invite any and all interested persons and parties worldwide to attend ICPM 2012, a two-and-a–half-day journey through topics that have an undoubted impact in our professional activity, are of notorious relevance in today's environment and are core to our association's goal to make key contributions towards procuring better medicines to patients.

If you wish to be alerted about these IFAPP information services immediately upon availability, just click here and subscribe at www.ifapp.org/subscribe. For details see "e-Mail Alert" on page 4 of this IFAPP WORLD issue.

In subsequent bulletins IFAPP will provide updates of the ICPM 2012 program and details of each roundtable and the panel of experts and speakers.

Please join us at this important event for Pharmaceutical Medicine and mark this date in your calendar already now. Looking forward to seeing you in Barcelona!

Dr Rudolf van Olden
IFAPP President, The Netherlands

Dr Arturo Lopez-Gil
President AMIFE, Spain

Dr Jose Maria Taboada
Vicepresident, AMIFE,Spain

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