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C O N T E N T

Modification of the Declaration of Helsinki – Accomplished with IFAPP and SBMF Support

Article 12 of the Declaration of Helsinki as amended most recently in October 2013:

"Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional."

The full text is available online at:
www.wma.net/en/30publications/10policies/b3/

This modification has been accomplished by the World Medical Association (WMA) with the support from IFAPP and the Brazilian Society of Pharmaceutical Medicine (Sociedade Brasileira de Medicina Farmacêutica – SBMF).

Dear Colleagues, dear Presidents of National Member Associations (NMAs) and Delegates

After entering into office as IFAPP President during the successful International Conference on Pharmaceutical Medicine (ICPM 2014) in March in Berlin, Germany, I like to share with you my plans and some news related to Pharmaceutical Medicine.

Most of you have already heard about our ICPM, where we all gather to discuss and learn matters related to our daily activities. In this IFAPP WORLD issue you find a testimony from our colleague from Spain, Anna Jurczynska, who has organized ICPM 2012 in Barcelona, Spain. She reflects on how ICPM 2012 has impacted the Spanish Association of Pharmaceutical Medicine (Asociación de Medicina de la Industria Farmaceutica Española – AMIFE) (page 3).

In fact there are National Member Associations that are highly committed to IFAPP and strive to promote its educational activities jointly organized with PharmaTrain. A particular one is the Society for Applied Pharmacological Sciences (Società di Scienze Farmacologiche Applicate – SSFA) from Italy. Thanks to the efforts of Domenico Criscuolo, SSFA has been recognized by the Italian Regulatory Agency (AIFA) to provide them an educational program in Drug Development Sciences through PharmaTrain programs. A report of this initiative is presented on page 2.

Another topic, that shows the importance and impact of our IFAPP activities for the drug development science, is the Declaration of Helsinki from the World Medical Association (WMA). The declaration has recently been amended and modified to explicitly emphasize that clinical research "must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications" (note the text left side). This modification has been accomplished with the support from IFAPP and the Brazilian Society of Pharmaceutical Medicine (Sociedade Brasileira de Medicina Farmacêutica – SBMF).

Still talking about IFAPP and the National Member Associations (NMAs) – you will soon be contacted to collaborate and answer a short survey – the IFAPP Needs Assessment Survey – about the needs of your NMA and about education in Pharmaceutical Medicine.

Last but not least I like to invite all of you to contribute to IFAPP WORLD by sending us articles from your NMAs. These articles will be published in IFAPP WORLD and reaching out for more than 5500 PM professionals all over the world.

Looking forward to collaborating with all of you.

With kind regards
Gustavo Kesselring
IFAPP President, Brazil

The International Perspective: ITALY

SSFA Meets the Italian Drug Agency

SSFA Provides the Italian Drug Agency an Educational Program in Drug Development Sciences through PharmaTrain

On March 7, 2014, a delegation of the Society for Applied Pharmacological Sciences (Società di Scienze Farmacologiche Applicate – SSFA), represented by Gianni De Crescenzo (SSFA President), Luigi Godi (SSFA Secretariat), Francesco De Tomasi (Master Catholic University Rome) and Luciano M. Fuccella (Master University Milan Bicocca), met in Rome the General Director of the Italian Drug Agency (Agenzia Italiana del Farmaco – AIFA), Luca Pani, accompanied by two AIFA Officers, Donatella Gramaglia and Michele Marangi.

Three topics were on the agenda:

1. Luca Pani talk at the XIII SSFA National Congress, i.e. "The opinion of AIFA", framed in the context of the Session "The Pharmaceutical Industry in Italy"
2. Ethics Committees status after reorganization, as stated by the Ministerial Decree
3. PharmaTrain proposal to create a training course in Italy for clinical researchers (Continuing Professional Development – CPD)

With regard to the first point on the agenda, Luca Pani confirmed his participation in the SSFA Congress, and – together with Donatella Gramaglia and Michele Marangi – will soon send a synopsis of his speech and the slides.

On the second item, Donatella Gramaglia pointed out that, despite the deadline for the reorganization of the Ethics Committees (ECs) has already expired a few months ago, some regions (Marche, Calabria, Molise and the Autonomous Province of Bolzano) have not yet taken a final position. At the moment, however, there is a significant decrease in the number of ECs (currently 83) which implies the adoption of standard procedures and a better compliance with timelines.

Regarding the third point, the most important one, objectives and activities of the PharmaTrain Project were presented to AIFA and a partnership with AIFA was proposed in adherence with the European Harmonization and Validation Training Program of the staff involved in clinical research and drugs development.

The PharmaTrain Program aims at establishing the title of Specialist in Medicines Development (SMD), with continuous updating entrusted to national scientific societies (i.e. SSFA, in collaboration with other learned societies like Società Italiana di Farmacologia [SIF] and/or Società Italiana di Farmacia Ospedaliera [SIFO]) together with universities, by means of a three or five year program and annual assessments.

As the arena of drug discovery and development is in a continuous evolution, and the outsourcing of preclinical and clinical research activities indicates a steady growth, it is essential to ensure not only the availability of professionals with in-depth knowledge acquired through appropriate education and continuous training (CPD), but also that clinical Investigators should be part of the CPD process.

It is clear that the achievement of this international program will also significantly increase job opportunities, as those who achieved the post-graduate title can easily find employment in all countries taking part into the program.

SSFA, the scientific association of professionals in drug research, in 2014 celebrates its first 50 years of life: during this period, SSFA representatives distinguished themselves for having successfully activated training courses on all areas related to the world of medicines (from preclinical to clinical trials, regulatory affairs, pharmacovigilance, and quality). We therefore have not only the skills needed to activate a process of periodic review, but also the know-how to manage this process, which is already implemented at several university masters where SSFA lecturers and tutors are already involved.

In this CPD implementation program, SSFA considers as crucial the cooperation with National Scientific Institutions (such as AIFA, Istituto Superiore di Sanità [ISS], Ministry of Health) and other learned societies (such as SIF, SIFO, and Società Italiana Attività Regolatorie [SIAR]). It would be appropriate to establish a CPD committee with these representatives, having the delegation of qualified experts, which would play the role of tutors for those who participate in the CPD program.

The AIFA General Director Luca Pani promised the full cooperation of AIFA in the CPD project as part of the activities of education and training of personnel involved in clinical research. Even if AIFA will not grant any special funding or any operational activity, adequate information will be given to this initiative in the AIFA portal, where an introductory note will be published (both in Italian and English), and where reference to the other institutional sites of SSFA, SIF and SIFO will be linked for the operational details.

Luigi Godi, SSFA Secretariat

Moving From Compliance to Competency: A Harmonized Core Competency Framework for the Clinical Research Professional

The authors – Stephen A. Sonstein, Jonathan Seltzer, Rebecca Li, Honorio Silva, Carolynn Thomas Jones, and Esther Daemen – state in an article of the Journal of Clinical Research Best Practices (Vol. 10, No. 6, June 2014): "As our understanding of pathophysiology and therapeutic intervention has increased, there has been a concomitant increase in the complexity of clinical trial protocol requirements and in the number and complexity of the regulations and guidelines related to the preclinical and clinical testing of new medicines and devices.

Quite curiously, though, the criteria for individuals who conduct human clinical trials are only very general, with scant detail in the regulatory authority definitions. […]" However, "The tide is beginning to turn."

This article results from a collaborative effort involving several professional organizations, including ACRES and PharmaTrain. The aligned core competencies may serve for multiple purposes (see the article) and its adaptation/adoption for local purposes would be desirable.

The article is online available at:
www.researchgate.net/directory/publications
– search for "Moving From Compliance"

Comments are very well appreciated!
Just mail to secretariat@ifapp.org

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The Flag

IFAPP World is a publication of the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP).

IFAPP, founded in 1975, is a non-profit organization with 30 national member associations representing ca. 5500 pharmaceutical medicine professionals worldwide.

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

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A Testimony from SPAIN

Hosting ICPM 2012 in Spain and How it Affected the Hosting Association

Almost two years ago, in November 2012, and for the second time – the first one was organized in 1990 in Madrid – in the history of the Spanish Association of Pharmaceutical Medicine (Asociación de Medicina de la Industria Farmaceutica Española – AMIFE), we were hosting the International Conference on Pharmaceutical Medicine (ICPM). It was a big challenge for all of us! The Scientific Committee, integrated by key officials and experts on an international level, had an important task to select the most important and hot topics of interest for professionals in the pharmaceutical industry, look for suitable speakers, or prepare round tables and workshops. Monthly meetings and teleconferences were necessary to establish the priorities, to contact the pre-selected speakers, to confirm their participation and topics to be developed. The Scientific Committee worked hard to provide the best knowledge and expertise on a number of important aspects in regulatory, investigational, organizational and other fields of interest.

On the same time, the Organizing Committee was striving through the economic crisis in Europe trying to reach the adequate number of sponsors, attendees, exhibiting companies, and other individuals. It was not at all an easy task!

Europe and Spain in particular were hit by a deep financial crisis and companies were not ready to invest money in the ICPM 2012 as other priorities were under way (new drugs, promotion, sales …). And just one month ahead of the event a general strike was announced in Spain!

But in order still to spark interest for ICPM, frequent newsletters, mass mailings and other promotional activities were undertaken – but were not sufficient. Since all of us have worked for many years in pharmaceutical companies or contract research organizations (CROs), we all have our networks, and finally we had to come up with "personal and persuasive" activities: direct, personal calls to people we knew, to heads of departments, to general managers, medical directors, and any other relevant personnel.

Fortunately we could explicitly emphasize in our calls one particular aspect which made ICPM 2012 different from our biennial AMIFE congress: this time we had a large panel of exceptional speakers from all over the world, talking about their experience, about common rules and differences between countries; they focus on patients, good practices, inspections, audits, patents, and many other important topics. And people realized that there was a chance to network with individuals who normally appear in publications but are not frequently seen in Spain or other countries.

And in fact: the registration rate started to increase!

It was a fantastic experience, both from the professional as well as from the personal point of view. And our hard work and endeavor had a great reward: ICPM 2012 was a big success!

Anna Jurczynska, Secretaria de AMIFE

Training of Medicines Development and Regulation in Emerging Countries

Satellite Workshop at the 17th World Congress of Basic and Clinical Pharmacology • Cape Town, South Africa • July 13, 2014

An excellent opportunity to discuss problems concerning the postgraduate education in medicines development, regulation and clinical investigation with experts working in low- and middle-income countries was provided at the 17th World Congress of Basic and Clinical Pharmacology (WCP2014), recently held in Cape Town, South Africa. It is considered essential to teach these scientific disciplines in a harmonized approach since modern health care and research can only be successfully pursued locally, if these three mutually supportive pillars are equally developed.

To this the satellite workshop "Training of Medicines Development and Regulation in Emerging Countries" was organized by the Fundisa African Academy of Medicines Development and the Hungarian Society for Experimental and Clinical Pharmacology under the joint auspices of IFAPP and PharmaTrain.

The number of patients suffering from general ailments is rapidly increasing in low- and middle-income countries. They need more modern health care facilities, drugs, and health technologies to efficiently combat these diseases. However, new medicines have to be tested and registered under the local conditions and, if possible, manufactured locally. Unfortunately, several countries have no or only meager capacity for local production, testing and regulation of drugs and vaccines.

Neighboring Countries Network

Educational programs to address the necessary competences must be needs-oriented, practical, and should provide participants with an internationally accredited certificate or degree. E-learning programs seem suitable for the specific needs of highly autonomous, practice-oriented post-graduate students. The recently updated and harmonized European PharmaTrain medicines development program showed high level of local acceptance in South Africa, Brazil, East Asia, and Central-Eastern Europe. It would be helpful if available courses could attract more students from lesser-developed neighboring countries.

The regulation of new biological medicinal agents, advanced therapies, medical devices and technologies can only be handled efficiently by increased cooperation of various disciplines. Based on Central-Eastern-European experience the formation of university networks in neighboring countries is suggested for developing countries to provide the necessary multidisciplinary training.

An additional problem is the very rapid increase of workload of regulatory agencies, which lack adequately trained staff. A survey performed in South Africa suggests the formation of a Regulatory Science Institute to coordinate and accelerate the development of adequate competence. In addition, the implementation of mixed evaluation teams is proposed, in which academic and in-house regulatory experts cooperate.

Furthermore, regional regulatory cooperation between countries could be very helpful. Several continent-wide and regional organizations already exist, and their value in accelerating regulatory approval has been convincingly proven. Finally the formation of single national ethics committees was suggested to pool the necessary experts and shorten the time for the ethics approval of multicenter national trials.

The number of well-trained investigators has to be increased in emerging economies. In this respect the great value of the website www.GlobalHealthTrials.org, which provides a forum to address technical competence and to facilitate knowledge sharing and experience exchange for clinical investigators, has been demonstrated for supporting local clinical research. For advancing non-commercial trials, a broad multinational clinical network has been organized in Europe, which provides scientific and regulatory advice and supportive services for trials performed by the members. Similar regional organizations would be useful to support non-commercial clinical trials in developing countries.

In summary, the workshop has successfully identified the nature and volume of special needs. Several recommendations have been put forward to establish regional international co-operations for training experts in medicines development, drug regulation and clinical research.

Sandor Kerpel-Fronius (8)
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