International Federation of Associations of Pharmaceutical Physicians & Pharmaceutical Medicine

IFAPP TODAY - NUMBER 3, JUNE 2020

Dear colleagues,

Welcome to the **IFAPP TODAY number 3:** we are pleased to introduce to you two members of the Communication Working Group. Here you can find their biographies and their photos.

INTRODUCTION TO ROB VAN MAANEN & PETER STILTING

From the country where IFAPP is formally established, here two Dutch Communication Working Group members Rob van Maanen *(left*) and Peter Stilting *(right)* present themselves.

Rob van Maanen

After joining Novartis over 20 years ago, my continuous pursuit of quality, breadth and depth in Pharmaceutical Medicine soon brought me into contact with the Dutch Association of Pharmaceutical Physicians, IFAPP and the Faculty of Pharmaceutical Medicine (FPM). As a strong believer in the fundamental value of the scientific method for practising and advancing Pharmaceutical Medicine, this needs to be embodied by well-trained and informed experts and professional organisations committed to

advancing this very interesting, complex and fast changing area of medicine. Therefore, after completion of the DipPharmMed program in Brussels and the Higher Medical Training program in the UK, a logical step was to devote some of my professional time to progressing Pharmaceutical Medicine on a national level (as a member of a committee devoted to establishing a training-program in Pharmaceutical Medicine in The Netherlands) as well as globally through the IFAPP and the FPM.

Peter Stilting

With an already broad learning and working background in different cultures, a keen interest to learn and understand new things, or understand old ones even better, made me drift into the world of Pharmaceutical Medicine more than a decade ago. Medical Anthropology and Ayurvedic Medicine, among other disciplines, root my base. Although I never expected to end up in Medical Affairs, i.e. Pharmacovigilance, Training and Coaching, supporting Big Pharma with services, I have been working in the industry with great pleasure ever since I enrolled. In 2007 I got involved in a large HIV review project, soon after that I was asked to join a PV consultancy as a part-owner. It brought me a lot of new experiences in healthcare and with the implementation of new ideas in Clinical Development, Drug Safety & Pharmacovigilance in general. A short project at J & J in Neuss in 2011 set me to make way into Germany, projects following one-another until one made me reside in the Münich area for almost 6 years from where focus was turned towards the DACH (Germany, Austria and Switzerland) region as a free-lance, while enforcing connections and collaborations in, and towards, South-America and Asia. Gradually moving into more diplomatic functions, I started representing companies and products, giving trainings. Business development, Marketing and Sales of Pharmacovigilance services among them. At the ICPM 2016 in São Paulo I got involved with IFAPP and became part of its Communications Workgroup. Motivated to enforce the network tying us together with knowledge and growth. The moving of the EMA to Amsterdam was one of the reasons to help me decide to move back to The Netherlands recently, from where I now work globally as a consultant.

Membership of IFAPP represents an interesting and wider perspective of developments in specialisms than could be obtained at a purely national level. A valuable opportunity for continuous learning from, and in, an increasing network of like-minded and dedicated experts. It is highly recommended for anyone who wants to be challenged beyond a working day at the local office.

REPORT OF WEBINAR MSL – AMMIS

As part of its annual activities, the French Association des Métiers Médicaux des Industries de Santé (AMMIS - French Association of Medical Professions in the Health Industries) organized on May 14, 2020 a webinar about the topic **“Medical Science Liaison (MSL): evolution and expectations of the profession”.**

With the moderation of Dr Epaïnète Gawa, member of the board of directors of AMMIS, Dr Chahrazed Dib-Smahi and Dr Ludovic Jube, working respectively at Sanofi laboratory and at the recruitment firm Altigapharma, were the two speakers of the webinar.

Dr Chahrazed Dib-Smahi, MSL and FBM (Field Based Medical) effectiveness lead, shared her professional experience, the missions of MSL, and the French national recommendations on the profession.

Dr Ludovic Jube, consultant, provided information on the recruitment of MSL, the requests from pharmaceutical industries, the profile sought, the salary and the benefits of being an MSL.

About fifty professionals from different companies with various backgrounds attended this one hour-long webinar which ended with a question and answer session that enabled participants to be advised according to their concerns about access to the profession and career development. This webinar confirmed the interest of the role of MSL in the health industries, and the fact that the profession has evolved and continues to adapt to the needs of companies. However, the evolution of the MSL towards headquarter positions remains an important concern due to the regional mobility, and the attendees expressed their interest in having experience in several therapeutic areas.
The recording of the webinar, available on the AMMIS website, is accessible to the members of the association in their private area. Membership of AMMIS gives the right to attend all annual activities that will be organized including the next webinar, scheduled for June 30, on the topic "Clinical trials in silico".

ITALY - TESTING A SINGLE NATIONAL ETHICS COMMITTEE

Clinical research in Italy has always been an area of excellence, and Italian Investigators gave a significant contribution to the scientific innovation in areas like cardiology and chemotherapy. However, in the last decades of the last century, bureaucracy created a long waiting time to the regulatory approvals of clinical trials. The situation suddenly changed in 1998 when a law of the Ministry of Health delegated to local Ethics Committees (EC) the approval of clinical trials.

Now Italy has about 100 EC: 60 are based in large University clinics or hospitals, and 40 in research hospitals. Considering that Italy has about 60 million inhabitants, this number is in line with the suggestion to have 1 EC per million inhabitants and excluding from this calculation the EC based in research hospitals. The new EU regulation for clinical trials, even if not yet implemented, is causing some concerns to several EC, as timelines are very strict: this is the reason why about 5 years ago a discussion was opened about the idea to appoint a single National EC, working full time on clinical protocols and amendments. Pharmaceutical companies were strongly against this idea, having in mind that every time activities are centralized, bureaucracy enlarges timelines to unacceptable level: and this idea arrived just in the years when clinical research in Italy was gaining momentum in Europe, moving in the last years from 17% to more than 20% of all European clinical trials. The Covid-19, with the emergency situation which has caused, suggested to test the idea of a single National EC for clinical trials related to this disease. This EC was established at the Spallanzani hospital in Rome, a hospital specialized in infectious diseases, which in the past was the referral centre for tuberculosis and more recently for HIV.

From the AIFA website we can see that this EC, in just 40 days (from March 11 to the last available input on April 24, 2020) approved 20 clinical trials against Covid-19 (remdesivir, tocilizumab, emapalumab/anakinra, sarilumab, hydroxychloroquine, colchicine, enoxiparine, baricitinib, selinexor) and 4 expanded access programs (ruxolitinib, remdesivir, canakinumab, solnatide): no information is provided about not approved protocols.

Now, the question is the following one: is this the right way to go for all clinical trials? I fear not.

The last AIFA report, released in 2019 and related to 2018, indicates that 666 new clinical trials were approved, 33 were not approved and 15 were withdrawn: no information is given about the number of relevant amendments, which indeed require a significant time of the EC. More relevant areas are oncology (260 trials), CNS (68), haematology (44), immunology (39), GI and CV (36): all other areas have 20 or less trials. These figures indicates not only the large number of studies in some areas, but also the heterogeneous scenario: therefore a single National EC will have difficulties not only to discuss all the proposed studies in a reasonable time frame (60 days) but also will lack all required competencies to make a scientifically sound analysis. The Covid-19 is still an emergency, so unusual solutions are welcome: but this test indicates that it is not possible to apply the same method to all clinical trials applications.

Domenico Criscuolo
Member of the IFAPP Communication Working Group

For more information, please visit:
www.aifa.gov.it

VIDEO ABOUT THE FUTURE VISION OF IFAPP

IFAPP invites you to watch the attached video, summarizing our recent achievements and the future vision of our Federation, as commented by our President Prof Kyoko Imamura. She talks about short and long-term goals of IFAPP, and also about changes that were implemented in our Federation, to better reflect the new environment of the drug development process.

New IFAPP ‘Company Page’ on LinkedIn - Are You Already a ‘Follower’?

Less than two months after its launch, the follower number exceeded the milestone of 200 (plus 100 since end of April). With this new communication platform IFAPP intends to ultimately reach out to more than the currently 571 pharmaceutical medicine professionals with member status in the traditional IFAPP ‘group page’ on LinkedIn. Please consider becoming a ‘follower’ of the IFAPP company page. From there you can share posts with your own comments and deliberations. You will find the new platform when you

‘Search’ on LinkedIn for ‘Companies’, and then enter ‘IFAPP’.

Our e-mail address is:
secretariat@ifapp.org

You will find our informative website at www.ifapp.org.