Dr. Ulrich Hagemann
ISoP 2011, Scientific Committee, Chair
November 3rd, 2011

The 11th ISoP Annual Meeting in Istanbul – new ideas, new plans and new relationships

In the last week of October 2011, the 11th Annual Meeting of the International Society of Pharmacovigilance took place in Istanbul, an ideal place to bring together pharmacovigilance experts and newcomers in this field from all continents. Here is a short summary on these inspiring days.

ISoP addressed at the first meeting day an important issue with relevance for pharmacovigilance which, however, has possibly been neglected a bit so far: it deals with ethics in clinical research and in pharmacovigilance. Joerg Hasford (Munich) gave a comprehensive overview on existing international rules and guidelines and also distilled open questions which might be of importance for researchers and patients participating in various forms of pre- or post-licensing studies. This ethics issue has a link to globalization and politicization of pharmacovigilance. Both raise new general problems, e.g. in regards to the conduct of clinical trials in emerging countries mainly because pharmaceutical companies intend to save money in the developmental phase. Proper conduct and, more importantly, the rights of patients included in studies in such countries and pressure resulting from politicization in pharmacovigilance have been lively discussed in the panel discussion after the key lecture.

As new tools and methodological challenges come up with the existence of large databases containing data of different type (claims databases, reports on adverse drug reaction etc.), parallel sessions dealt with epidemiological aspects and specific requirements and problems when running a register. Nancy Dreyer (USA) summarized the state of the art in establishing registers for various purposes. Presenters from the UK, Turkey, France and Serbia contributed results derived from their register studies.

Robin Ferner and Jeffrey Aronson (UK), both with much reputation in their scientific work on how to define and understand medication errors as well as on how to prevent adverse drug reactions gave a double-pack overview-lecture on this issue that has great relevance in daily medical practice. This issued seemed to be of great interest: a number of short communications were selected requiring an extension of the session's time frame. Medication errors are overlapping with the practice of 'off - label' prescription or use of medicinal products. In this session, I myself discussed existing, but still unsatisfactory definitions for the 'off – label' – term and proposed a very preliminary categorization of 'off – label' prescription and use.

What should regulators do when new results from large clinical trials show that patients with a chronic disease (diabetes, hyperlipidaemia) do not benefit substantially from a treatment in an approved indication or even carry an increased risk e.g. in terms of mortality? An interesting question that was lively discussed after a brilliant talk from Faramarz Ismail-Beigi (USA). He presented data from the ACCORD study in which efficacy of rosiglitazone compared to standard diabetes therapy was investigated looking on patient - relevant clinical endpoints like myocardial infarction or death.

New therapeutic options using monoclonals and new technologies in genetic research raise new questions on the benefit and safety of these drugs. Are pre-treatment investigations appropriate to identify genetic biomarkers in individual patients and thus may prevent them from major harm, and should such investigations, if available, be performed in large patient groups? Basic concepts in using monoclonals therapeutically and their inherent risks, known or still theoretical, were presented in a separate session.

50 years after the first marketing of combined hormonal oral contraceptives in European countries, it was a perfect occasion to listen to Valerie Beral in the session on 'Pharmacovigilance in women's medicines'. She gave a historical overview and focussed on our still growing knowledge on hormonal contraception, peri-menopausal hormone therapy and bisphosphonate used in women with osteoporosis. Results from recent epidemiological studies on long term effects of these treatments make clear, sometimes painfully, that one must be aware of new findings that may change our benefit – to- harm assessment substantially, even after many years of usage.

The H1N1 pandemic and the vaccination campaigns have been a major topic in the scientific and public discussions in 2010. A year later there was now a good reason to learn which experiences have been made on national or international level. How to explain the low preparedness of people to be vaccinated, what kinds of risks were identified and what was their magnitude? No doubt, communication on the severity of an H1N1 infection as well as on the possible harm when being vaccinated had a major impact on the public debate last year, and this complex matter was presented in a session on vaccine pharmacovigilance. Moreover and interestingly, an intensive monitoring programme following the first launch of a new Meningococcus vaccine in some Sub-Sahara African countries was presented by Téné Yaméogo (Burkina Faso) in this session.

To educate and train people who are working in pharmacovigilance is one of the major goals of ISoP. In a separate session, principal concepts of education and training in pharmacovigilance, taking into consideration the various roles, i.e. of regulators, industry representatives, health care professionals, or researchers, were outlined. That fitted well to presentations and discussions on the 'Human factor' in risk assessment and decision making and problems when weighing benefit and harm or chance and risk, resp.

Most of those working in pharmacovigilance have been faced with problems in risk perception and communication, especially in crises, either towards healthcare professionals or to the public. Ragnar Löfstedt (UK) gave an inspiring talk on both, risk perception and communication. The participants on this session will have understood the high importance of good risk communication especially to the benefit of patients.

The 11th ISoP Annual Meeting brought together experts and friends from all continents and more than 60 countries. There have been lively discussions in sessions and during coffee and lunch breaks. Not to forget the great scene of Istanbul and the ship cruise on the Bosporus at night, a good opportunity to socialize with colleagues and become friends across the world. I am convinced that the ISoP 2011 contributed substantially to further develop pharmacovigilance as a science and practice.