REPORT FROM 15TH ISoP ANNUAL MEETING IN PRAGUE, THE CEZCH REPUBLIC

Pharmacovigilance is a part of applied science concerned with the medicines and pharmacotherapy.
Historically, pharmacovigilance evaluated drug safety from the prospective of ADR occurring after the drug launch. The main function of pharmacovigilance, which began with the WHO spontaneous reporting system in the 1960s, to monitor the new ADRs and factors which influence ADRs occurrence. Pharmacovigilance was enhanced by the development of pharmacoepidemiology – a new discipline originated during the 1960s and concerned with the therapeutic value of drugs, using electronic databases of collecting lifetime drug exposure history to perform cohort and case-control studies.
Pharmacovigilance is an important field for the public, regulators, pharma industry and according to our recent research the discipline is not widely incorporated into medical sciences curricula of universities across Europe. However, the course of pharmacovigilance is integrated into curricula of Charles University in Prague. During the recent year we have tried to change the content of pharmacovigilance topics.
Pharmacovigilance addresses the complex view on patient safety including medication errors. It was a great opportunity to support the development of pharmacovigilance by Charles University (CU), as the Department of social & clinical pharmacy (DSCP) addresses and manages research in a science which applies to real life. The staff of DSCP expanded pharmacoepidemiology research, including analyses of patient behaviour (medication adherence) and the attitudes of health care professionals (medication errors) in Czech conditions. CU proposed to host the International society of pharmacovigilance symposium in Prague. The invitation was accepted considering our experience in patient safety and the 15th ISoP symposium – Cubism in Pharmacovigilance was held in Prague from 26th to 30th October 2015. There were 384 participants from 60 countries (see Table 1). There were presented 31 lectures by industry, FDA, EMA and universities; 179 posters, 29 oral presentations. About 150 participants took part in pre-conference courses: Risk management and risk minimization, Methodologies in pharmacovigilance, Pharmacovigilance in Middle East and North Africa region. A welcome party was held in a big aula of Carolinum and chair of the local organizing committee (LOC) prof. J. Vlček, president of ISoP prof. H. Le Louët and director of the Czech regulatory drug agency PharmDr. Z. Blahuta welcomed the guests as well as vice-rector assoc. prof. J. Konvalinka during the opening ceremony of next day.

Country	**# Delegates**	**Country**	**# Delegates**	**Country**	**# Delegates**
Czech Republic	**59**	Netherlands	**11**	Slovak Republic	**7**
France	**36**	Switzerland	**11**	Canada	**6**
United Kingdom	**31**	Argentina	**9**	Ghana	**6**
USA	**25**	Portugal	**9**	India	**6**
Germany	**18**	South Korea	**8**	Turkey	**6**
Sweden	**12**	Mexico	**8**	Brazil	**5**
Italy	**11**	Belgium	**7**	Morocco	**5**

Programme establishing was challenging. The first proposal to the ISoP executive committee was done from the LOC (consisting of experts on pharmacovigilance J. Petraček, R. Běla, M.Votava, and pharmacists V. Deščíková, T. Belkina, P. Matoulková, K. Schneiderova, I. Storová, and J. Vlček). Our initial idea was to include the following topics into the ISoP symposium:

1. Patient safety;
2. Scientific methods in pharmacovigilance - PhD projects;
3. Risk management on individual and population level;
4. Individual alert making harm and how they are recognized;
5. Future in pharmacovigilance;
6. Education in pharmacovigilance;
7. Pharmaceutical care and patient safety.

After discussion with the scientific committee and in order to honor the expectations of the "Cubism in pharmacovigilance" we tried to adjust topics of the meeting and to cover the following fields:

1. Risk management in pharmacotherapy;
2. Herbal safety;
3. PRAC (Pharmacovigilance risk assessment committee) in Prague and their final role in decision on the withdrawal or strengthening warnings for medications in EU;
4. Big data associated with social media and how to use them for creation of risk signal;
5. Patient perspective of drug safety;
6. Medication errors;
7. Role of communication in patient safety;
8. Women health.

According to a speech made by president of ISoP prof. H .Le Louët, the 15th symposium historically changed the content of pharmacovigilance symposiums. The main events discussed during symposium can be summarized:

1. Patient should be included into the risk management of pharmacotherapy;
2. Social media can be used for pharmacovigilance purposes;
3. Medication adherence management is a challenge in risk management in pharmacotherapy;
4. Different tools for risk management and risk minimization of pharmacotherapy is necessary to develop;
5. Medication errors are important part of risk management;
6. Pharmacological knowledge is an important part of pharmacovigilance and we need to learn how to use it;

7. Discussion with PRAC members should be important discussion about their decision – to understand the risks and methods how to build a signal; Prague inform Czech citizens on their websites;
8. Team work in pharmacovigilance is important and ISoP seems to be a good base for it;
9. To focus on women and monitoring their condition during pregnancy, breast feeding and in postmenopausal state. Safe use of postmenopausal hormone therapy was clarified.
10. To focus on changes in pharmacokinetics, communication skills, etc.;
11. To focus on herbal safety because herbal medicine can cause harm and the methods that can be used to identify safety risks were discussed.

Conclusion

An important global symposium of pharmacovigilance was conducted under the auspices of Rector of Charles University in Prague prof. Tomáš Zima, MD and director of the Czech State Institute for Drug Control PharmDr. Zdeněk Blahuta. It was a great opportunity to share experience and knowledge with participants with different professional background – physicians, pharmacists, psychologists, statisticians, and data base managers employed in drug regulatory agencies, pharmacovigilance departments of hospitals or industries, academia and to get in contact with the leading professionals concerned with the safe use of medicines worldwide. We (as members of CU) have to educate teachers and health care professionals about the trends in pharmacovigilance and its role in patient safety, and to establish an educational programme to develop the field of pharmacovigilance. It requires also inter-professional education and co-operation of faculties and drug agencies as well as private organizations. The ISoP helped us to meet these professionals and we are ready to join to this activity.

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