



# The ISoP Star

No 31. December 2015

## From Prague to Agra via Manila and Berlin

### Prague conference report and AGM

The 15<sup>th</sup> ISoP Annual Meeting, hosted by the Charles University in Prague and the Czech Pharmaceutical Society took place in Prague, Czech Republic from 27<sup>th</sup> to 30<sup>th</sup> October 2015.

The Scientific Committee (SC) chaired by Gunilla Sjölin-Forsberg (CIOMS) and the Local Organizing Committee (LOC) with Jiří Vlček had developed a stimulating programme. The scientific committee addressed the following main topics: Risk management, Herbal safety, PRAC session, Big data, Patient perspective of drug safety, Medication errors, Role of communication in patient safety (Beje Wiholm Lecture) and Women's health.

The conference started on Tuesday 27<sup>th</sup> Oct with three well attended training courses in parallel on 'Risk management and risk minimization', 'Methodologies in pharmacovigilance' and 'Pharmacovigilance in Middle East and North Africa region'. The courses aimed on informing and discussing in an interactive manner current problems and practice.

Around 400 pharmacovigilantes and international experts from 60 countries attended the meeting, including keynote speakers such as Alex John London from USA (*Beyond protection: the integrity of science as a fundamental ethical concern*) or Nick Sevdalis from UK (*Patient safety today –from identifying problems to implementing solutions*).

On the first day, a meeting of the chapter's coordinators and chapter members were held at the margins of the conference day; such meetings will be held regularly at future Annual Meetings.



Interactive training course in Prague with J Petracek



H Le Louet, ISoP President



G Sjölin-Forsberg, Chair SC



J Vlček, Chair LOC

**Season's Greetings to ISoP members!**

Most of the ISoP 2015 presentations and the winning posters are on the website of the Society under the Member Section (access to members only).

President Hervé Le Louet announced at the General Assembly of ISoP members (AGM) the launch of the new ISoP chapter of Middle East with Mayada Alkhakany and Thammer M. AlShammary as coordinators, and encouraged members to join the Special Interest Group on 'Risk Minimisation Methods in Asia' leading by Jean Christophe Delumeau and the new SIG on Ethics (see section SIGs).

**Non-members who registered at the ISoP 2015 Prague Annual Meeting and paid full registration fees, will become ISoP members from 1<sup>st</sup> January to 31<sup>st</sup> December 2016. A very warm welcome to these 167 newcomers!**

## Change of statutes

The current members received a letter dated from 5<sup>th</sup> October 2015 with the task force proposal\* informing the members about some changes in the statutes.

These recommendations of the task force strategic review were examined and discussed with the membership for their opinion during the ISoP 2015 General Assembly in Prague on the 29<sup>th</sup> October with the objectives as follow:

1. To mandate the President to consult and establish the new governance within one year
2. The General Assembly to further review and ratify the operating details in 12-months
3. To establish an Executive Board of the President, Secretary, Treasurer and one representative of the Secretariat as soon as practicable
4. To establish a board of directors to include representation from the chapters including other stakeholders as soon as practicable and by vote
5. To explore raising funds through crowd sourcing

6. To explore funding based on profit of arising from chapters activities
7. To increase the support for the secretariat [by one full time equivalent]

The GA in Prague voted by majority in favour of all these items.

However as the GA was not attended by at least half plus one of the voting members (Statutes Art 10.1;15.2/quorum), no immediate decision to change the statutes could be held at this General Assembly. Another extra General Assembly will be convened in Spring 2016 (venue details, date will be sent in due course). This assembly would then be valid whatever the number of members present with the new Executive Committee elections to be arranged in June 2016.

*\*The task force proposal with the change of statutes is available at <http://isoponline.org/about-isop/general-assembly-reports/> (General Assembly reports web page).*

## Prague Poster Prizes

239 abstracts were accepted as posters (179) or oral presentations (60), and as always, an ISoP Poster Prize was given to the three best posters. The winners are:

\* First prize:

P 034 - *vigiRank Improves Real-World Signal Detection Performance: Prospective Results from International Pharmacovigilance*  
(*O. Caster, L. Sandberg, K. Juhlin, S. Watson, G.N. Norén*)

\* Second prize:

P 112 - *Role of Serotonin 5-HT<sub>2C</sub> and Histamine H<sub>1</sub> Receptors in Antipsychotic-induced Diabetes a PharmacoEpidemiological-PharmacoDynamic study in VigiBase*  
(*F. Montastruc, A. Palmaro, H. Bagheri, L. Schmitt, J.L. Montastruc, M. Lapeyre-Mestre*)

\* Third prize:

P 062 - *Seasonal and Geographic Variation In Adverse Event Reporting*  
(*M. Hauben, E. Hung, O. Marrero*)

This year, the first prize winner receives two Adis

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print books plus a one-year online-only subscription to an Adis journal of choice. The second prize receives three Adis print books and the third prize - two Adis print book - with compliments of Adis/Springer.



*1<sup>st</sup> Poster winner O Caster with M Tuccori, Chair Poster Prize committee*

## **ISoP course in Manila**

ISoP is organizing its mid-year training course in Makati/Manila, Philippines from 25<sup>th</sup> to 27<sup>th</sup> April 2016.



This three day-course is conducted to leverage the Pharmacovigilance expertise of ISoP and designed for interdisciplinary groups to learn and work together in contributing to patient safety when medicines are used.

This course will take place at the AIM Conference Center (Makati city) and is aimed to engage all interested pharmacovigilance professionals in a regulatory, industry, hospital, university or community setting. The programme will cover topics such as:

- Introduction to Management and Management in everyday practice (Re Chapters of the PV curriculum are chapters 11, 12, and 13)
- The epidemiology of PV, Risk assessment and 'Benefit-to-harm assessment' (Relevant chapters of the PV curriculum are: Chapters 7, 8, and 15)
- Clinical Science of PV (Re Chapters of the PV curriculum are chapters 2, and 3)
- Laboratory science of PV (Re Chapter of the PV curriculum is chapter 4)
- Education and training of PV and ICT aspects of PV (Re Chapter of the PV curriculum is chapter 12)
- Risk management (Re Chapter of the PV curriculum is chapter 11)

Register now!

More details about programme and registrations are available from the ISoP Administration office ([administration@isoponline.org](mailto:administration@isoponline.org)), or visit <http://www.isoponline.org/index.php?page=training>.

## **ISoP UMC Training**

**ISoP and UMC jointly go to Latin America!**

ISoP and the Uppsala Monitoring Centre (UMC) continue their collaboration in the field of teaching pharmacovigilance. After ISoP and UMC had started two years ago to hold joint training courses in Asia, both partners currently put in writing a basic arrangement and a strategic framework for organizing joint training courses in Latin America and the Caribbean. The new Memorandum of Understanding (MoU) aims to offer a set of training courses or symposia over the next years (starting from September 2016) and to

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build capacity in pharmacovigilance in countries of this continent. The training courses and symposia will be based on the WHO-ISoP Pharmacovigilance curriculum published in 2014. ISoP and UMC intend to provide intense and interactive courses to achieve a high effectiveness for the participants.

Visit regularly our websites for more information (available soon).

## ENTIS – ISoP Training



The International Society of Pharmacovigilance (ISoP) in co-operation with the European Network of Teratology Information Services (ENTIS) will hold a joint training course on 2nd to 3rd June 2016 in Berlin, Germany “Risk assessment of drugs used during pregnancy and lactation” (Berlin Brandenburg Academy of Science (BB-A)).

This training course will address the specific areas of drug use during pregnancy or breastfeeding and pharmacovigilance. Experts working on these fields either in hospitals or community settings, drug agencies, pharmaceutical companies or in academia are the target audiences. Items in the programme will address basic and specific aspects of teratology, some epidemiologic tools to monitor drug use during pregnancy or breastfeeding, and communication about risks in this specific setting.

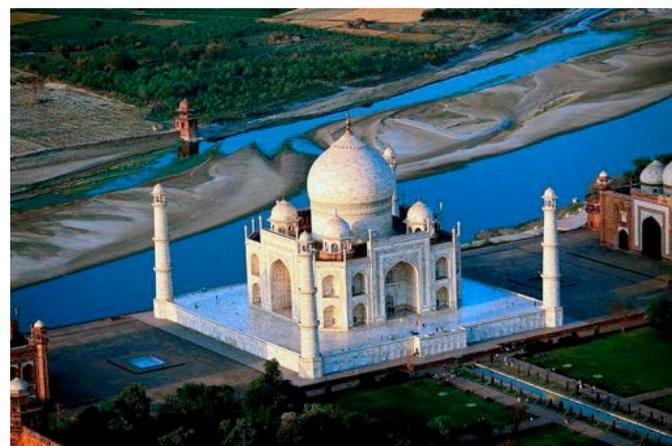
More information about programme and registration on [www.isoonline.org](http://www.isoonline.org) (under Training)

## ISoP Joint sessions

ISoP is very interested in co-organizing joint symposia with other scientific societies aimed at improving the culture of Pharmacovigilance all over the world. Scientific societies interested in such co-operations can contact the ISoP Secretariat: [administration@isoonline.org](mailto:administration@isoonline.org)

## ISoP 2016 Agra

16<sup>th</sup> - 19<sup>th</sup> October 2016



The 16<sup>th</sup> ISoP Annual Meeting is hosted by the Society of Pharmacovigilance India (SOPI) and the chairman of the Local Organizing Committee is Prof KC Singhal and Dr Kenneth Hartigan-Go (Philippines FDA) is chairing the Scientific Committee.

Back-to-back training courses will be held on 16<sup>th</sup> October.

The organisers look forward to welcome you to the ISoP 2016 Annual Meeting!

## Call for abstracts

**Opening date for registration and submission of oral and poster abstracts is 1<sup>st</sup> February 2016.** When submitting an abstract, presenters must register to attend the meeting and before an abstract (oral or poster) can be accepted by the Scientific Committee. Abstracts must be submitted in ENGLISH.

More information on ISoP 2016 will be available soon on the conference website or from the secretariat: [isop2016@gmail.com](mailto:isop2016@gmail.com)  
Website: [www.isop2016agra.org](http://www.isop2016agra.org)

## ISoP 2017 Liverpool

Liverpool, city of North West England, will host the 2017 Annual Meeting. More details will be available in due course.

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## Call for Annual Meetings bids

If you would like your country to host the 2018 Annual Meeting, please do contact the Administration Office and ask for guidelines for your bid.

## PV Curriculum databank

A year after the WHO-ISoP pharmacovigilance curriculum was published [Springer online](#), ISoP is now undertaking an innovative and, we hope, inspired step to enrich the concept and structure of the pharmacovigilance curriculum with teaching material. In recent years speakers at ISoP Annual Meetings and training courses in different parts of the world – ISoP members or not – gave talks on many and various topics in pharmacovigilance, and since the pharmacovigilance curriculum has been published speakers at ISoP meetings have been encouraged to align their talk with the curriculum structure. In fact there is now a variety of material for teaching addressing many specific items of pharmacovigilance.

ISoP is currently developing a sort of ‘cloud of pharmacovigilance material’, i.e. a web-based archive of presentations, texts and publications, that can be used by everyone who is confronted with the task to teach or give a talk on pharmacovigilance whatever the setting is: an isolated talk or a study course programme. ISoP will offer via its website access to such pharmacovigilance related documents which are ordered by the curriculum structure and for which the authors gave permission for publication. The curriculum structure therefore providing a tool for users to find material of most relevance for their presentation. Also, a search tool will be available to find documents which fit to the area of interest. For this pilot project ISoP takes no responsibility for the accuracy of the links, and no judgement on the content of the educational material. Further choice of linkage is not endorsed by ISoP but entirely a judgement of the uploading individual. Available soon.

## Special Interest Groups - SIGs

A SIG is a group of ISoP members (min. 5) and non-ISoP members acting as volunteers and working on a specific and relevant topic within the scope and aims of the Society.

Three SIGs, i.e. ‘Women’s Medicines’, ‘Risk Communication (ISoP CommSIG)’ and ‘Risk minimization methods for Asian countries’ have been established and already approved by the Executive Committee.

The EC will continue to be very supportive with the creation of SIGs. If members want to create resp. establish a SIG, please contact the ISoP administrative secretariat.

## ISoP CommSIG

The ISoP CommSIG, the special interest group on medicinal product risk communication, has had a productive first year. The founding members’ paper, outlining why and how the CommSIG came into being and summarising its mandate and planned activities, was published in *Drug Safety* (Drug Saf. 2015; 38: 621-627) and has already served to make us known to experts outside ISoP. Moreover the CommSIG sponsored the ‘Beje Wiholm lecture’ at ISoP conference in 2015 in Prague, a 90-minutes session with presentations by Peter Mol and Viola Macolić Šarinić on latest initiatives regarding communication in Europe and brief lectures from two invited experts, namely DK Theo Raynor, pharmacy practice researcher from the University of Leeds, UK and Hansjörg Neth,

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communication psychologist from the University of Konstanz, Germany. This was followed by an interactive debate with the audience, which could have well continued, as there was so much interest. At the margins of the conference, the CommSIG also held its 2<sup>nd</sup> annual meeting of the CommSIG members and welcomed new members. It now counts 21 members from different continents, representing stakeholders from industry, academia, healthcare as well as regulatory and other public bodies. For 2016, the CommSIG has set itself ambitious goals for progress: the publication of the considerations from the 2015 conference and the preparation of a session as well as a training course at the 2016 conference. The CommSIG also plans to collaborate with the ISoP SIG on women's medicines and the ISoP Israel chapter. Keep an eye on the CommSIG's webpage...!

*From Priya Bahri, ISoP CommSIG coordinator.*

## Risk Minimisation for Asian Countries SIG

The SIG on Risk Minimisation for Asian Countries is moving ahead designing novel methods suitable for a large array of health care systems. Those methods will be customisable in order to make them applicable in a risk proportionate manner. The Post-Approval Vigilance Program (PAVP) concept, under preparation, is aimed to be applicable in any country including those having implemented a pharmacovigilance system only recently. It is also aimed to address the needs of countries facing a strong reluctance of health care professionals to report suspected adverse drug reactions. Other concepts will be worked out in subsequent steps. Our goal is to start communicating on those methods from May 2016 and to provide a consolidated picture at the 16th Annual ISoP Meeting in Agra.

## Chapters

The International Society of Pharmacovigilance is proud of the rapidly growing number of regional chapters. Currently, nine chapters are active in ISoP: Italy, Western Pacific Region, Mexico, Latin

America, Switzerland/Austria, Africa, South Eastern European, North America, Israel chapters. We welcome the new chapter from the Middle East and look forward to the creation of other chapters in Asia.

The chapters can communicate with the ISoP website ([www.isoonline.org](http://www.isoonline.org) under *Chapters*) and also directly via the LinkedIn ISoP group (follow: [www.linkedin.com](http://www.linkedin.com))

## Prof. Chalbi Belkahia 1944-2015



It is with great sadness that we have learnt of Professor Chalbi Belkahia's passing. ISoP and the World of Pharmacology have lost a dear colleague and friend.

As a strong supporter of pharmacovigilance since 1976, when he was Assistant Professor at the Regional Centre of Pharmacovigilance in Lyon, France, he went onto create the Pharmacovigilance Unit at the Medical School in Tunis in 1977 and the Tunisian National Centre of Pharmacovigilance in 1983.

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An Emeritus Professor, ex-dean of the Faculty of Medicine of Tunis, a distinguished doctor, loyal, and always proud of his students, he will be remembered for his scientific and public health contributions at national and international levels; at ISoP we will remember how much he was dedicated to pharmacovigilance and to ISoP.

Prof Chalbi Belkahia was an Executive Committee member of ISoP in 2002-2003, a keen participant in ESOP (European Society of Pharmacovigilance)/ISoP meetings and he played an important role in the founding of the Society internationally by organizing successfully the very first international ISoP annual meeting in 2001 in Tunis-Carthage, just a few weeks after 9/11.

He was Vice-President of the Society from 2003 to 2006 and became a honorary member in 2010.

He will be missed and today our thoughts and prayers are with Prof Belkahia's family and friends.

## ISoP Monograph

There is a final agreement and a contract to sign from the Springer Global Editorial Meeting that we should go ahead with the ISoP monograph, under the title, 'Pharmacovigilance: critique and ways forward' (printing early 2016).

We would like to thank the contributors for sending timely their articles and kindly ask those who have not yet sent their contribution to do so, before 31<sup>st</sup> December 2015. **Don't miss out, your thoughts count.**

The world changes continuously and Pharmacovigilance, as a new discipline also changes, perhaps even faster, striving to make its mark and its voice for better patient care heard. We continually need to review where we are and debate ideas on the future. New stakeholders come into the field not knowing the history of Pharmacovigilance. Their new perspectives must be sifted, the good incorporated and the duplications and irrelevancies managed.

ISoP must show the way, so PLEASE make this an exceptional publication, and write something NOW: your last chance.

Send your contributions or queries to ISoP (administration@isoponline.org)

## 2016 Membership renewal

Renewal forms have been sent out by electronic mail. Only members who are paid-up will have access to incentives and voting rights.

This year the membership fees have been frozen and students, retired and emerging countries will still be able to subscribe to the journal *Drug Safety* for the price of 95 EUR (online subscription).

**IMPORTANT:** If there is a mistake in our database, or you have changed your e-mail address, do let us know as soon as possible!

## Benefits for members

20% discount on Wiley-Blackwell Pharmacology and Pharmaceutical Medicine books for all ISoP members!

Fast, simple and secure ordering! You can order books online at [www.wiley.com](http://www.wiley.com) (this offer is not available through bookstores). The promotion code to allow access to the 20% discount has been sent with your renewal membership notice.

More discounts for books at

<http://www.isoponline.org/index.php?page=membership>

## Drug Safety Journal



As part of their membership, all ISoP members will receive electronic access to the journal *Drug Safety*, and therefore the printed version of the *Drug Safety* journal is not anymore available to members.

The link to the journal *Drug Safety* must be clicked from within **the ISoP Members' Area on the ISoP website** in order to obtain online access (and not from the Springer/Drug Safety website). Only members who are paid-up will have access to membership benefits.

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## www.isoonline.org

Please visit our website regularly to stay informed about ISoP and its many activities!

Please send your letters, comments, ideas and contributions for ISoP Star to:

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Internet: [www.isoonline.org](http://www.isoonline.org)

### Contact details

If you have changed your address, and most importantly your address e-mail, do let us know as soon as possible. Some members don't receive accurate information because of not providing their e-mail address. We would like to keep members informed of Society news with an easy access to the journal *Drug Safety*, and electronic mail is the way of sending certain types of information. Please e-mail your correct details to us, we will be able to update our address lists. Thank you!



**Have  
you  
moved?**

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