General Assembly
18 October 2016
ITC Mughal Hotel, Agra (India)
Hall A - 13.30-14.45

Present: Society President H Le Louet, and about 80 members of the Society and delegates ISoP 2016.

Agenda

- Approval of the Agenda & GA minutes (Prague 2015)
- Tribute to Prof R Royer
- ISoP new organisation (Statutes, By-laws)
- Financial position and membership situation
- Membership fees 2017
- Training programme
- Elections 2016
- Planning for the future
- AOB

In his last GA as President, Prof Hervé Le Louet opened the General Assembly by welcoming members and requesting approval of the agenda, as well as approval of the Prague GA minutes which were accepted by the General Assembly (the Prague GA minutes had been posted on the ISoP website for several months prior to the GA).

I) President's Report

President Prof Hervé Le Louet outlined some of the activities that had occurred during the year:

- 16th Annual Meeting of ISoP Agra
- Successful training course in Manila, Philippines
- 3rd ISoP UMC training course in Lima, Peru
- Stable finances
- > 455 members
- New chapter: Welcome to the ISoP China Chapter!
- Globalisation and a continued networking with other scientific societies and institutions (UMC, CIOMS, EACPT, ENCePP).
- Adoption of new statutes at an Extraordinary General Assembly on July 8, 2016 in London followed by a new organisation,
- Board and President elections.
II/ Tribute to Professor René-Jean Royer (1931-2016)

The President Prof Hervé Le Louet paid tribute to Professor René-Jean Royer who passed away in July. He was Professor of Clinical Pharmacology in Nancy (France). Prof Royer was fundamental to Pharmacovigilance and to our Society, having founded the European Society of Pharmacovigilance (ESOP) in 1992, chaired it as president, which led in 2000 the change to ISoP, the International Society of Pharmacovigilance, of which he was the first (founding) president. He presided over the French national Pharmacovigilance Commission and the Pharmacovigilance Working party of CHMP, the predecessor to PRAC.

The President, EC members and the Assembly observed silence to honour and remember Prof Royer.

IV/ New organisation

The President Prof Hervé Le Louet confirmed the organisational changes through the new Statutes approved at the Extraordinary General Assembly in London (8 July 2016) - A smaller and more compact Executive Committee (four members) within an Advisory Board structure (10 members) will have new tasks and responsibilities.

The new by-laws are to be finalized by the newly elected Board.

V/ Financial report

For his last year as treasurer, Brian Edwards presented an overview of the current Society’s finances prepared by the accountants in Geneva with the balance on 30th September 2016 and which stood at a deficit of EUR 19,000.

Treasurer Brian Edwards described the general financial situation for this year, which showed incomes from successful training courses and the Prague Annual Meeting but the main expenditure are for the new website and the loss in currency exchange (EUR/Pound).

In 2016, there was an important variation in EUR/GBP exchange rate. This has generated an unrealized (i.e. potential reversible) loss on exchange (mostly on the GBP bank balance) of EUR 12,920.

In 2015, ISoP has invested in a new website for EUR 24,000. This amount was initially capitalized (booked into assets in the balance sheet) and is depreciated (i.e. put into expenses) over a period of 3 years.

Brian Edwards presented the 2017 budget and asked if there were any questions from the General Assembly. There were 2 questions from members about the Lima training financial result and Sophie Spence’s salary currency. The accounts were accepted by the General Assembly.

The Society’s membership fees are frozen for 2017. Therefore membership fees as of January 2017 will continue to be 215 EUR (with Drug Safety online) and 95 EUR (with Drug Safety online) for members from emerging countries, students and retired individuals.
Then Brian Edwards presented briefly some marketing and fundraising recommendations for the new EC and Board:

- The vision of ISoP needs to be explained and communicated to the membership and beyond. A marketing and branding strategy must accompany any fundraising effort,
- ISoP must develop measures of success to show we fulfil our vision.
- ISoP needs professional help - a marketing manager with targets and incentives.

IV/ Membership services

President Prof Hervé Le Louet thanked Sophie Spence for her work regarding the membership administration with ISoP now having more than 455 members from 60 countries for the year 2016. He thanked her for the excellent support she gives to the ISoP EC and the entire membership of ISoP.

He also thanked Nitin Joshi, editor of ISoP’s official journal *Drug Safety*, for his collaboration. He also expressed gratitude to the publishers of *Drug Safety* (Springer) for their long-term support for ISoP.

ISoP website survey

Vice-President Yola Moride presented the outcomes of the survey and explained that in April 2016 members were asked to rate the new ISoP website, as it is important for the Society to understand what has been their experience in order to plan further improvements and make sure that website meets the members’ needs and interests.

The new Board will decide how best to move forward with the website.

VII/ Training programme

Andrew Bate, Chair of the ETP group, summarized the training activities since the last GA. Successful courses have been held in:

*ISoP 2016 Agra (pre-conference courses), India (50 people)*
*ISoP mid-year training 2016: Manila, Philippines (65 people)*
*ISoP-UMC joint training: Lima, Peru (71 people)*
*ISoP-ENTIS joint course, Berlin, Germany (91 people)*

In addition to ISoP training courses, Andrew Bate made clear that the following collaborations were established or strengthened during his term as ETP chair:

- Strategic joint collaboration for training with UMC, who recently signed a new Memorandum of Understanding
  - First training with a focus on Asia,
  - Second training was focussed on South America.
ISoP had conducted joint training courses with ENTIS and TOPRA, and on request, when judged appropriate, contributed (as speakers) to other training courses e.g. ASOP and chapters, for example in Latin America.

He then mentioned the development of a web-based PV Curriculum tool which generated interest, and the results from a pilot are summarised in a submitted publication (currently under review at Drug Safety). It is up to new EC and Board to decide if and how to take the Curriculum pilot tool forward.

Andrew Bate concluded by inviting all ISoP members to help in teaching/organising training courses and propose ideas for topics. He thanked all ETP group members for their very successful work, President Prof Hervé Le Louet for his leadership and EC colleagues for their training contributions.

II) Advisory Board Elections 2016

President Prof Hervé Le Louet addressed the results of the elections for the Advisory Board conducted by the Nominations Committee headed by Alexander Dodoo (Chair of the Nominations Committee and Past President).

The results were announced:

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<th>Total ballots returned = 178</th>
<th>Total number of eligible voters = 456</th>
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<td>Percent of ballot return = 39.03%</td>
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**Brian Edwards** receives 87 votes, 47.54% of the total.

**Sten Olsson** receives 78 votes, 42.62% of the total.

**Marco Tuccori** receives 77 votes, 42.08% of the total.

**Phil Tregunno** receives 67 votes, 36.61% of the total.

**Ian CK Wong** receives 65 votes, 35.52% of the total.

**Jean-Christophe Delumeau** receives 64 votes, 34.97% of the total.

**Mira Harrison-Woolrych** receives 63 votes, 34.43% of the total.

**Deirdre McCarthy** receives 62 votes, 33.88% of the total.

**Hilda Ampadu** receives 60 votes, 32.79% of the total.

**Jan Petracek** receives 57 votes, 31.15% of the total.

**Retiring members:**
Luis Alesso, Andrew Bate, Ian Boyd, Ulrich Hagemann, Kenneth Hartigan-Go, Yola Moride, Gunilla Sjolin-Forsberg and Alexander Dodoo.

**Welcome to the new Board:**
Hilda Ampadu, Jean-Christophe Delumeau, Mira Harrison-Woolrych, Deirdre McCarthy, Sten Olsson, Jan Petracek, Phil Tregunno

**Re-elected to the new Board:**
Brian Edwards, Marco Tuccori, Ian CK Wong
Past President: Hervé Le Louet

President Prof Hervé Le Louet thanked all out-going members of the Executive Committee by distributing a certificate to each of them. He thanked the 2016 nominations committee and then announced the results of the President election conducted just after the Board election among the Board members and the nominations of the Executive Committee by the new President.

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<th>Total ballots returned = 10</th>
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<td>Total number of eligible voters = 10</td>
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<td>Percent of ballot return = 100%</td>
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**ISoP President**

Sten Olsson receives 6 votes

- Brian Edwards receives 1 vote
- Ian C K Wong receives 1 vote
- Marco Tuccori receives 1 vote
- Mira Harrison-Woolrych receives 1 vote

The General Assembly welcomed the new elected Board members and the Executive Committee as follows:

Sten Olsson, President,
Ian CK Wong*, Vice-President,
Jean-Christophe Delumeau, Treasurer,
Mira Harrison-Woolrych*, Secretary,
and the Board members:
Hilda Ampadu, Brian Edwards, Deirdre McCarthy, Jan Petracek*, Phil Tregunno, Marco Tuccori and Hervé Le Louet as Past President.

* Ian CK Wong, Mira Harrison-Woolrych and Jan Petracek were not present at ISoP 2016 and at the GA but sent their apologies.

President Prof Hervé Le Louet warmly congratulated the new ISoP President Mr Sten Olsson and wished a successful work to the new Executive Committee and Board. The new President Sten Olsson thanked also Prof Hervé Le Louet as outgoing President and the previous Executive Committee members to have paved the way to the ISoP future.

As a newcomer and operating with brand new statutes, the newly elected President Sten Olsson shared his vision of ISoP to the Assembly: pharmacovigilance first and foremost as a public health activity but with a robust scientific basis.

He referred to the expansion of pharmacovigilance in terms of the scope of the science, the profession and its geographical coverage. In providing relevant professional support and competence development for its members, ISoP should seek collaboration with relevant scientific organizations but also with public academic institutions that may be able
to provide expertise in the scientific fields required and preferably in the geographic regions of the specific training activity.

With the new Advisory Board, President Sten Olsson expressed strong commitment to expand the ISoP membership and to work together and leading ISoP for the next three years for the benefit of its members and towards a more prominent global position in pharmacovigilance.

We are looking forward to seeing all members and others colleagues at the next ISoP Annual Meeting in Liverpool, UK from 15 to 18 October 2017.

The meeting closed at 14.45

Signature: Hervé Le Louet, President
Date: Ulrich Hagemann, Secretary-General