



**General Assembly
13 November 2018
CICG Geneva (Switzerland)
Room 2 - 13.15-14.00**

Present: Society President Sten Olsson, and about 200 members of the Society and delegates ISoP 2018.

Chair: Society Secretary Mira Harrison-Woolrych

Agenda

1. Welcome and approval of Agenda and Minutes GA Liverpool
2. Fellowship and by-laws
3. Financial position and membership fee for 2019
4. Highlights since Liverpool (governance, partnership, meetings, chapters and SIGs)
5. Planning for the future
6. ISoP 2019 Bogota
7. Any other business

I/ Welcome

President Sten Olsson and Secretary M Harrison-Woolrych opened the General Assembly by welcoming members and requesting approval of the agenda, as well as approval of the Liverpool GA minutes which were accepted by the General Assembly (the Liverpool GA minutes have been posted on the ISoP website).

II/ Fellowship and by-laws

Vice President Ian CK Wong presented the creation of the ISoP Fellowship status as follows:

Fellows of the International Society of Pharmacovigilance are members who have demonstrated significant achievement and distinction in their field, including peer recognition in pharmacovigilance. Our Fellows have made substantial contributions to the discipline of pharmacovigilance through their work (including publications or similar outputs) and have also shown service to the Society, for example by involvement in ISoP meetings, and/or by leadership of ISoP Chapters and Special Interest Groups (SIGs).

Members wishing to apply for Fellowship must demonstrate distinction and peer recognition in the practice, research and/or education of pharmacovigilance. The normal criteria are:

1. Contribution to pharmacovigilance, demonstrated by
 - a. career record/progression and



- b. publication record in peer-reviewed scientific journals or
 - c. for those in industry, regulatory or voluntary organisations, similar outputs e.g. unpublished reports, committee papers and/or involvement in significant working parties/committees
2. Contribution to the Society, demonstrated by committee or board work, leadership of ISO P chapters or SIGs; or contribution to Society meetings (e.g. teaching, lecturing, chairing sessions)
 3. At least five years as a Full Member of the Society
 4. Applications must be supported by two ISO P Fellows, or one member of the Fellows Nominations Sub- Committee (FNCS) and another member of ISO P.

Member K Ilic (USA) asked about Fellowship nominations and criteria.

I CK Wong confirmed that applicants will be asked to complete an application form and a statement outlining how they meet the above criteria for Fellowship.

Member U Hagemann (Germany) wondered if the General Assembly should vote on this new Fellowship membership status.

Adoption of the by-laws

The Secretary explained that the ISO P Advisory Board members have been reviewing the ISO P by-laws (Articles 4-5 & 9) and the revised by-laws had to be endorsed by the General Assembly (no need to vote). The revised by-laws had been circulated by e-mail to all members. After the President had invited for questions, the new by-laws was adopted by the General Assembly.

III/ Financial report

Treasurer Jean-Christophe Delumeau presented an overview of the current Society's finances prepared by the accountants in Geneva with the balance on 30th September 2018 which stood with a benefit of 36'000 EUR.

The treasurer Jean-Christophe Delumeau described the general financial situation which showed incomes from successful training courses and an increase in membership. The total income increased by 44'000 EUR.

He also reported back that the Executive Committee was exploring ways of facilitating payment for some countries in which there have been financial difficulties, for example, in Argentina with the collapse of Argentina's Pesos and also other Low/Medium Income countries.

In view of the considerable increase in membership, and to reduce the administrative costs, a new, more automated system for membership renewal will begin in the New Year,

and from then each annual membership will run from the date of joining/renewal (by-laws Art 4.)

The Treasurer presented the 2019 budget and asked if there were any questions from the General Assembly.

The accounts were accepted by the General Assembly.

The Executive Committee suggests Society's membership fees to be kept unchanged for 2019. Consequently, membership fees as of January 2019 will continue to be 215 EUR (with *Drug Safety* online) and 95 EUR (with *Drug Safety* online) for members from emerging countries/ Low/Medium Income countries, students and retired individuals. The proposal was approved by the General Assembly.

IV/ Highlights since Liverpool

New ISoP Governance and organisation

The new Governance structure of ISoP includes the following Board and Executive Committee members (elected in 2016).

Executive Committee

Sten Olsson, President

Ian CK Wong, Vice President

Mira Harrison-Woolrych, Secretary General

Jean-Christophe Delumeau, Treasurer

Advisory Board

Hilda Ampadu, (not present) Brian Edwards, Deirdre McCarthy (not present), Jan Petracek, Phil Tregunno, Marco Tuccori

The new ISoP management

Organized monthly EC teleconferences and 2 Advisory Board meetings per year.

President S Olsson thanked Sophie Spence particularly for her work regarding the training courses and membership administration. He also confirmed Geoffrey Bowring 's contribution from UMC for some specific tasks.

Membership

ISoP now has over 650 members, its highest membership total ever.

Rolling 12-month membership (from 2019 each annual membership will run from the date of joining/renewal).



The President then outlined some of the activities that had occurred during the year:

- Comments on WHO Global Benchmarking Tool
- SIG guidelines
- Planning for annual meetings and training courses
- ISO P fellowship (By-laws Art.9)
- GDPR
Processing data according to the new EU General Data Protection Regulation (“GDPR”) (By-laws Art. 5)
- New membership management system
- Contracted conference organizer for annual meetings
- ENCePP collaboration

Partnerships

WHO - CIOMS

Additional partnerships WHO-Coalition of Interested Partners

CIOMS working group XI

Patient Involvement in the Development and Safe Use of Medicines

- ISO P representatives Sten Olsson & Brian Edwards
 - Geneva 19 – 20 April 2018
 - Berlin 23 -24 October 2018

Pre-ICDRA meeting / Dublin

- Moderating panel discussion on Smart Safety Surveillance

Springer Nature

Webinars offered by Editor-in-Chief Nitin Joshi (webinar videos now available on the Member Section of the ISO P website)

Uppsala Monitoring Centre (UMC)

3-year agreement with successful training collaboration in Latin America and China.

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance,

ENCePP - ISO P representative Hervé Le Louet

ENCePP steering group invited proposals for further activities to strengthen EU pharmacovigilance

- Draft memo discussed with Advisory Board
- Submitted to ENCePP followed by TC

Possibility for closer collaboration in specific areas.

Training programme

ISoP Seminar in Boston on automation in PV (December 2017)

Mid-year training course in Canberra, Australia (March 2018)

Chapters training (Middle East and Latin America)

Chapters

Members of the chapters can access chapter meetings presentations on the Member Section of the ISoP website (when available).

Special Interest Groups (SIGs)

Official launch and welcome to the new SIG:

- Safety Surveillance of Medical Devices: finding solutions and moving forward
Co-ordinator: Dr Jitendar Sharma, AMTZ Campus, Visakhapatnam, India

The Executive Committee will continue to be very supportive with the creation of SIGs. President explained that the Executive Committee tries to identify members with special interest/expertise in the specific area and invites them to contribute on ISoP's behalf, always welcoming volunteers to progress an area and, depending on the subject, it may be appropriate to involve other members of SIGs or even chapters.

Social media

Twitter: @ISoPonline and LinkedIn: (ISoP Group) and ISoP International Society of Pharmacovigilance

V/ Prospects for year ahead

Conferences and courses

- 2nd event in Boston on intelligent automation in PV (3-4 December 2018)
- Mid-year training in Nairobi (6-8 May 2019)
- ISoP-UMC training in China + possibly one in Latin America
- Possible training in Eurasian region
- CIOMS XI WG continuing
- ENCePP collaboration
- ISoP Israel Chapter Symposium (3-4 June 2019)
- ISoP 2019 Annual meeting in Bogota (6-9 November)



President S Olsson concluded his report, looking forward to seeing all members and other colleagues at the next ISoP Annual Meeting in Bogota, in November 2019.

The meeting closed at 14.00

Signature: Date:

Sten Olsson, President

Mira Harrison-Woolrych, Secretary-General