



**ISoP General Assembly
28th October 2015
Clarion Congress Hotel Prague (Czech Republic)
Room Zenit, 12.45-15.15 h**

Minutes

Present: Society President H Le Louët, Executive Committee (EC) members (with apologies from Yola Moride, Kenneth Hartigan-Go, Ian Wong), and about 140 members of the Society and delegates ISoP 2015.

Agenda

- I. Welcome and approval of the agenda and minutes from the Tianjin General Assembly 2014
- II. Reports from the Officers
 - a. the President (Hervé Le Louët)
 - b. the Secretary General (Ulrich Hagemann)
 - c. the Treasurer (Brian Edwards)
 - d. the ETP group chairperson (Andrew Bate)
- III. Chapters & SIG updates
- IV. ISoP's new organization (statutes, board elections)
- V. 16th ISoP Annual meeting
- VI. Any other business

I. Welcome and approval of the agenda and minutes from the Tianjin General Assembly 2014

President H Le Louët opened the General Assembly (GA) by welcoming members and requesting approval of the agenda, as well as approval of the Tianjin GA minutes.

- a. The agenda for the 2015 GA was accepted by the General Assembly.
- b. The minutes of the Tianjin GA 2014 posted on the ISoP website last December were now accepted by majority with the following note (post meeting note):

There were no elections for the Executive Committee (EC) this year. Because roles and responsibilities of the Executive Committee (EC) may change and because of the need to maintain continuity of the EC to deliver change to the Society, the current ISoP EC has decided to postpone this year's EC elections for a new EC for up to a year (the next EC elections should be held after the reform).

II. Reports from the Officers

- a. From the President (Hervé Le Louët)

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

- There was a successful 14th Annual Meeting of ISoP in Tianjin (China) in October 2014 and 15th Annual Meeting in Prague (Czech Republic).



- A training course in conjunction with WHO/UMC was held in January 2015 in Mysore (India).
- A three-days training course was held in São Paulo in March 2015.
- More courses and requests for courses came in making necessary a capacity building at ISoP side.
- Overall the Society has stable finances.
- A new design website has been created with improved features and user friendliness. It provides a 'Training section', a 'Members section' (password protected), and an online membership payment tool;
- There is a continued networking with other scientific societies and institutions (UMC, CIOMS, EACPT; ENCePP Advisory Group at EMA).

b. From the Secretary General (Ulrich Hagemann):

The membership fees had been changed and simplified two years ago. There are two categories of fees: 215 € (normal) and 95€ (students, emerging countries residents, retired) per year. Both fees include online access to the *Drug Safety* journal.

Liaison and co-operation with the editor of *Drug Safety* has been increased. The EC thanked Nitin Joshi (Adis/Springer) for his effective support.

Two ISoP Star newsletters (No. 29 and 30) have been produced and sent to members.

c. From the Treasurer (Brian Edwards)

The Treasurer presented an overview of the current Society's finances prepared by the accountants in Geneva. He described a stable financial situation for this year, but he pointed out that the performance of members to renew their membership and to pay the fees in time was partly unsatisfactory.

The 2014 Annual Meeting in Tianjin was a success, the same is for the Mysore training course in January with surplus of 5,124 EUR (including UMC grant). The São Paulo training was also a success with a 21,161 EUR surplus.

This year, the new categories of membership fees did not cause any losses in the Society's overall income. Therefore membership fees as of January 2016 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.

He presented the 2016 budget and asked if there were any questions from the GA.

There were no questions and the ISoP membership fees for 2016, the accounts and the budget 2016 were adopted by the GA.

d. From the ETP group chairperson (Andrew Bate)

A Bate summarized the training activities since the last GA. Successful courses have been held in Mysore (India), São Paulo (Brazil) and here in Prague. For the next year training courses have been scheduled in Manila (Philippines; 25th -30th April 2016), Berlin (Germany; joint symposium with ENTIS; 2nd and 3rd June 2016), joint ISoP-UMC



course in South America; place and date tbc), and prior to the next ISoP Annual Meeting in Agra (India; 7th October 2016).

He then focused on the WHO/ISoP Pharmacovigilance curriculum published in 2014 (freely available on the Springer website), and in general on a couple of new developments and techniques to share, access and use information nowadays. The ETP group and colleagues from the UMC, Lareb, WHO centre Ghana set up a pilot to make available electronically presentations/slides from PV experts using the PV curriculum hierarchy as a tree structure. This would mean that links to teaching material are shared in a cloud. The pilot tool was developed, and a small number of PV experts were requested to test the tool and upload links (presentations were received from the WHO centre Accra, the UMC, EC members, Lareb. Technically the tool worked well; there is a need of some refinement and developing accompanying measures (caveat text, quality check, actuality, suitability etc.).

A Bate demonstrated that with this tool it will be possible to monitor the system, to spot gaps and limitations with the curriculum and adapting it as needed. It will be a great tool for an adaptive learning curriculum, and one can see how the curriculum is used how this changes over time, and how the curriculum itself develops in near-real time. The tool was developed to allow a dynamic crowd sourcing approach to PV curriculum development and follow up. He will look to publish the Proof of Concept pilot in *Drug Safety* journal.

Any comments from members will be welcomed.

III. Chapters & SIG updates

Officers and EC members informed members and attendees of the GA:

- National chapter:
A new chapter has been established and was welcomed by the audience: Welcome to the Middle East chapter!
- Special Interest Groups (SIG):
 - The SIG on communication (CommSIG) developed a workplan, recruited members and contributed to the programme of the 2015 ISoP Annual Meeting (Beje Wiholm Lecture). CommSIG published in June 2015 its main goals, issues and structure in *Drug Safety* (DOI 10.1007/s40264-015-0301-0).
 - The Women's Medicine Group will restart its work after a period of low activity because of organizational reasons.
 - The new SIG 'Risk minimisation methods for Asian countries' was officially launched and will continue its work in the region.
 - The President welcomed a new SIG on 'Ethics'.

IV. ISoP's new organization (statutes, board elections)

Subsequent the discussion at the GA 2014 in Tianjin (China) about the future of ISoP, a 'task force' under the lead of Prof. Ralph Edwards, former ISoP President, analysed shortcomings in the performance and visibility of the Society, identified areas in which the Society should invest thoughts on new concepts which may need changes in the statutes and bylaws.



Note: The current membership received a letter dated from 5 October 2015 with the task force proposal and informing the members about some changes in the statutes.

Ralph Edwards presented the results of the ‘task force’s’ analysis and proposals for changes. They focus on:

1. *Finances:* An approach to increase the current and future finances was considered necessary to enable the Society to kick off a sustainable development. Elements could be a ‘crowd sourcing’, recruiting a professional fund raiser, differential membership fees, seeking membership of new stakeholders, a better management structure to retain existing members, etc.
ISoP should seek founding from all legitimate sources, including industry sponsoring.
2. *Future development of ISoP:* Apart from the a.m. financial aspects, incl. donations, and a communication strategy related to this, the ‘task force’ deemed necessary: a re-thinking of ISoP activities to make the Society worth to join; a code of conduct and transparent conflict-of-interest management plan; an increased administrative effort in contacting new stakeholders. The task force suggests that the future direction of ISoP should be endorsed by all members at a GA and communicated ‘more widely’.
Part of the plan should be that a list is developed of new challenges for the overall activities of ISoP (Annex 2) and reviewed every other year by all members.
3. *Constitutional and management changes:* The ‘task force’ proposed a smaller Executive Committee (EC) suitable for a complex, agile decision making. Its functions should be divided into more acute executive tasks/decisions and broader considerations about the direction of ISoP, strategy, the content of scientific meetings, education public communication, etc. A new Executive Committee should be the President, the Secretary General, the Treasurer with the Secretariat.

A Board of Directors should be established (suggested composition: elected national chapter co-ordinators, stakeholder representatives from each of patients, academics, regulators, pharmaceutical industry, health insurance industry, health care professionals, plus one other with interest in safe & effective use of medicines). The mode of selection and election of members of the Board of Directors needs further discussion. The Board of Directors will propose and elect the President who then selects the Officers in the Executive Committee. These constitutional and management changes will need changes in the ISoP statutes and by-laws.

In the future, there is a need for at least one more person at the ISoP Secretariat in London.

In the subsequent lively discussion about the analysis of the ‘task force’ in regards to the current state of the Society (new activities, communication strategy etc) and the challenges



in pharmacovigilance ahead of the Society were widely endorsed and supplemented by further suggestions.

However, there was some confusion amongst the audience on which topics decisions should be made by the ISO P members attending the GA and which procedure would be most appropriate.

As requested by President H Le Louët, the GA was then shortly interrupted and a small group of volunteers put together the following items resulting from the 'task force's' report and discussions for GA endorsement:

Proposal for ISO P GA 2015 with 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 chapters plus stakeholders as soon as practicable and by vote
5. To explore raising funds through crowd sourcing
6. To explore funding based on profit of chapters
7. To increase the secretariat [by one full time equivalent]

The GA 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 (Art 15/quorum), no immediate decision to change the statutes could be held at the GA in Prague.

V. 16th ISO P Annual meeting

Prof. Singhal and Dr Sandeep Agarwal from the Society of Pharmacovigilance of India (SOPI) presented their bid to host the 16th ISO P Annual Meeting in Agra (India). The date of the meeting will be the 7th to 10th October 2016. The presentation was welcomed and a close co-operation between ISO P and the local organizers was agreed upon to take the next urgent steps.

VI. Any other business

President Le Louët thanked the ISO P 2015 organizers for their work in making this Annual Meeting a great success: Prof. Jiří Vlček, Dr. Gunilla Sjölin-Forsberg, the Scientific Committee and the Local Organizing Committee with its team.

The meeting closed at 15.15h.

Signature:

Date:

Prof. Hervé Le Louët, President

Dr. Ulrich Hagemann, Secretary-General



INTERNATIONAL SOCIETY OF PHARMACOVIGILANCE

Annex 1

Task force proposal