

ISoP: towards a vibrant future

“ISoP is a leading scientific and professional global organisation dedicated to leading the development and implementation of pharmacovigilance.

The intelligent and progressive practice of pharmacovigilance is for the benefit of patients everywhere.”



Decision

- ▶ The Annual General Meeting of ISoP in Tianjin, China November, 2014 called for a task force “.....to pursue the aims of the Berlin strategic meeting (ISoP Development Plan, 2012)... reflecting on the implementation and promotion of such new activities and the nomination of a new robust governance of the Society (including elections, committees, membership/chapters, secretariat etc) so that ISoP becomes a real force for the safety of patients.”

Weaknesses of PV recognised in Berlin (2012): impact on ISoP

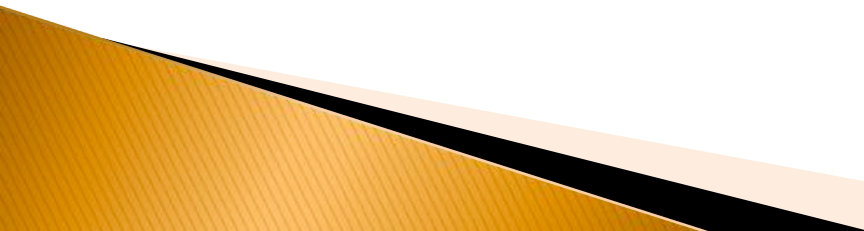
- ▶ Too few members
- ▶ *Volunteering is a scarce activity*
- ▶ *Training and education is a very low priority in many organisations*
- ▶ No contact/cooperation with patient organisations
- ▶ Limited funds
- ▶ Low visibility
- ▶ Overlap with other learned societies
- ▶ Low clout
- ▶ Shortcomings in effective management
- ▶ Limited activity
- ▶ Lack of human sciences
- ▶ Low industry following
- ▶ Equality and integration of members
- ▶ *Widespread apathy and indifference: "nothing will ever change, PV will always be a cost-burden"*

Problem summary:

- Rapid development of PV
- Fluid membership
- Governance incl. Chapters
- Limited finance for change

PROPOSALS FOR CHANGES TO ISoP:

1) FINANCES

1. Introduce crowd sourcing or some other approach to increasing the current financing to allow a kick-off for future sustainable development
 2. Consider using a professional fund raiser
 3. Introduce differential membership fees using the World Bank criteria.
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PROPOSALS FOR CHANGES TO ISoP:

1) FINANCES

1. Seek membership from new stakeholders
2. Retain existing members
3. Improve the management structure to achieve the retention of membership and to better involve the Chapters in ISoP activities
4. Introduce payments from Chapters of a proportion of their profits from their activities, paid in local currency (TBD)

PROPOSALS FOR CHANGES TO ISoP:

2) HOW WILL A FUTURE ISOP DEVELOP

- ▶ **In engaging new stakeholders there is a clear implication about the need for:**
 - Some re-thinking of the activities of ISoP to make it a Society worth their joining
 - A communication strategy
 - A financial strategy for deciding the level of donations requested and funding will be sought from all legitimate sources

PROPOSALS FOR CHANGES TO ISoP:

2) HOW WILL A FUTURE ISOP DEVELOP

- ▶ **In engaging new stakeholders there is a clear implication about the need for:**
 1. A fully described code of conduct and, transparent conflict of interest management plan
 - An increased administrative effort in contacting new stakeholders
 - Consider using a professional market researcher to investigate needs and attitudes

PROPOSALS FOR CHANGES TO ISoP:

2) HOW WILL A FUTURE ISOP DEVELOP

- ▶ The IDP proposed that a list of new challenges should be reviewed every other year by all members.
 1. We think it should also be endorsed by all member at the AGM and used to communicate the current focus of concerns, and of the work of ISoP, more widely.
- ▶ The list provides substance to the Vision of ISoP.

PROPOSALS FOR CHANGES TO ISoP:

2) HOW WILL A FUTURE ISOP DEVELOP

- ▶ Counterfeiting measures
- ▶ Use of richer data sources as a complement to case reports
- ▶ New analytical methods/signal detection methodology improvement
- ▶ Promoting pharmacovigilance to improve visibility and status
- ▶ Explanation/interpretation of safety issues
- ▶ Access to up-to-date information on safety/risks
- ▶ Benefit-risk decision-making methods and support
- ▶ Impact assessment & performance standards for pharmacovigilance
- ▶ Monitoring vaccines and traditional medicines
- ▶ Patient safety focus
- ▶ Risk group identification

PROPOSALS FOR CHANGES TO ISoP:

2) HOW WILL A FUTURE ISOP DEVELOP

- ▶ **Clinical trials safety**
- ▶ Harmonisation of regulation
- ▶ **Need for culture/language adaptations**
- ▶ Internet sales risks
- ▶ **GP/patient communication**
- ▶ Interface between pharmacovigilance and pharmacoepidemiology
- ▶ **Legal issues/litigation (Forensic PV)**
- ▶ Transparency (of decision and assessment)
 - Bureaucracy – hinder or help
- ▶ **How to apply pharmacoepidemiological data in clinical practice**
- ▶ Systems science including safety engineering and human factors

PROPOSALS FOR CHANGES TO ISoP:

3) CONSTITUTIONAL AND MANAGEMENT CHANGES NEEDED TO SUPPORT THE ABOVE PROPOSALS

▶ The Secretariat

- At the moment there is only one full time administrator.
- 1. **There is a need for at least a second person.**
 - Consideration should be given to using consultants in areas where the need for permanent employees is not necessary

PROPOSALS FOR CHANGES TO ISoP:

3) CONSTITUTIONAL AND MANAGEMENT CHANGES NEEDED TO SUPPORT THE ABOVE PROPOSALS

▶ Executive Committee

- The current committee is too large for the complex, agile decision making required for the future Its functions will 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.**
- 1. **The Executive Committee should be the President, Secretary and Treasurer with the Secretariat**

PROPOSALS FOR CHANGES TO ISoP:

3) CONSTITUTIONAL AND MANAGEMENT CHANGES NEEDED TO SUPPORT THE ABOVE PROPOSALS (contd)

▶ Executive Committee contd

1. In order to have a cohesive team, the President will select officers from nominations put forward by a new Board of Directors (see below)
 - *This will require a change to the Statutes*
2. The terms of office will be 3 years renewable once only
 1. This group will have the authority to meet and act on behalf of ISoP under the leadership of the President in all aspects to fulfill the work of ISoP as mandated by the new Board of Directors.

PROPOSALS FOR CHANGES TO ISoP:

3) CONSTITUTIONAL AND MANAGEMENT CHANGES NEEDED TO SUPPORT THE ABOVE PROPOSALS

▶ Board of Directors

1. **A Board of Directors be created meeting three times a year (Ideally at least once in person and then by Skype or similar).**
2. **The Board will consist of :**
 1. **Elected national Chapter Presidents**
 2. **Stakeholder domain representatives, one 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**

PROPOSALS FOR CHANGES TO ISOP:

3) CONSTITUTIONAL AND MANAGEMENT CHANGES NEEDED TO SUPPORT THE ABOVE PROPOSALS

▶ Board of Director contd

1. The Board will be convened by the past-President as an ex-officio member
2. The Executive Committee plus Secretariat will be ex-officio members with the President holding a casting vote over any decision items that do not reach consensus.
 1. Board term of office will be 3 years

PROPOSALS FOR CHANGES TO ISoP:

3) CONSTITUTIONAL AND MANAGEMENT CHANGES NEEDED TO SUPPORT THE ABOVE PROPOSALS

▶ Board of Directors (contd)

1. The procedure for election will be:

1. < five Chapter Presidents will be ex-officio members, selection of the 5 to sit on the Board will be by paid-up membership vote
2. The stakeholder representatives will be proposed by each group and the selection for the Board will be by paid-up membership vote. Proposals for vacancies may also be from the membership in the absence of proposed stakeholder candidates.

PROPOSALS FOR CHANGES TO ISO P:

3) CONSTITUTIONAL AND MANAGEMENT CHANGES NEEDED TO SUPPORT THE ABOVE PROPOSALS

▶ Board of Directors(contd)

1. The Board of Directors will propose a President from amongst its membership by secret ballot. The term of the Presidency is 3 years: non renewable

All the above in this proposal (3) will require a change to the statutes