

International Society of Pharmacovigilance

By laws

These by laws are set in accordance to article 17 of ISoP Statutes, as approved on: 17/10/05

They describe the operating procedures for the Society.

They are divided into two parts:

- by laws related to individual articles of the statutes
- general by laws pertaining to the general function of the Society, to the yearly meetings etc, or concerning matters not covered in the Statutes

By laws related to specific Statutes, as indicated by statute paragraph number

Article 1.5 – Address:

“The administrative address of the Society shall be decided by its Executive Committee”

- i) All members are informed as necessary of any change in the administrative address of ISoP.

Article 1.6 - Language “The working language of the Society shall be English. Other languages may be used as described in the by laws”

- i) The use of other languages is possible in local ISoP-sponsored activities, in agreement with the organisers, as long as English support is provided.
- ii) English support can take the form of, e.g., bilingual presentations in meetings (Text in local language, slides in English, or the opposite), or the provision of an English summary of abstract on posters.

Article 2.2 - ISoP meetings: “Promoting a regular exchange of information bearing on Pharmacovigilance by means of meetings, symposia, workshops, and bulletins, and specifically organizing **ISoP** congresses, including an Annual Meeting”.

Annual Meeting

- i) The Executive Committee in its meeting votes by secret ballot the location and dates of annual meetings, after consideration of bids from putative organizers, two years before the putative meetings.

- ii) The organizer of the Annual Meeting must provide adequate time and place for the General Assembly, and announce the date for a meeting of the Executive Committee at least 3 months in advance.
- iii) Two temporary committees are established for the organisation of the Annual Meeting, at the invitation of the Executive Committee: a Local Organising Committee and a Scientific Committee.
- iv) The Local Organising Committee is responsible for vetting and choosing, booking and thereafter liaising with the venue for scientific sessions and where necessary the hotel/residential facilities, keeping accounts and generally managing the finances of the meeting including speaker travel expenses, setting registration fees and handling all registrations, organising adjuvant social activities, ensuring the smooth running of the event itself. The organising committee invites the speakers and chairpersons designated by the scientific committee.
- v) The Local Organising Committee will designate one of its members as liaison with the Executive Committee.
- vi) The Scientific Committee is responsible for the structure of the scientific programme and running order, choosing speakers and chairpersons (but not queries relating to accommodation and travel), handling abstracts for invited papers, oral presentations and poster presentations.
- vii) The Scientific Committee will comprise a minimum of 5 members, including at least one member of the Society's Executive Committee. The chairman of the scientific meeting is a member of the ISoP Executive Committee. The co-chairman represents the local organising committee. Membership in the scientific committee may be proposed by the local organizers, but final acceptance rests in the Executive Committee, who sends the formal invitations to participate in the scientific committee.
- viii) A contract is signed between ISoP and the organizer of the ISoP Annual Meeting which provides for:
 - a) financial agreement:
 - Start-up money, provided by ISoP to the organizer. The Executive Committee decides the amount of this start-up money. The start-up money is to be reimbursed in full to ISoP before the meeting accounts are closed.
 - In the event of a negative result, waiver of this reimbursement can be decided by the Executive Committee, after inspection of the meeting accounts by ISoP's treasurer, assisted as needed.
 - In the event of a positive result after deduction of expenses, start-up money and pre-agreed fees for included membership as relevant, the gains are divided between ISoP and the organizer, according to a preset proportion, which will generally be 50 / 50 (ISoP/local organiser).

- b) The use of the ISoP data files (members and contacts) for the promotion of the meeting.
- c) The use of the ISoP logo.
- d) Registration fees for the Executive Committee members are waived.
- ix) The Executive Committee provides the organiser of the Annual Meeting with all necessary assistance for the scientific aspects, and especially in the provision of the Scientific Committee, to ensure a scientific quality consistent with the use of ISoP material.
- x) The Scientific Committee sets up rules for abstract selection, reviews the abstract, decides upon the scientific programme of the meeting, in coordination with the meeting organizer. (see document on Standard Operation Procedure: Scientific Committee)
- xi) The abstracts may be published in a scientific journal after acceptance of the presentation by the Scientific Committee
- xii) Presentations may be published on the Society's official web site.
- xiii) Speakers and presenters in the Annual Meeting may be invited to submit their papers for publication in the Society's Official Journal. These submissions will be submitted to the usual peer-review process. Presentation at the meeting will be mentioned on any eventual publication.
- xiv) Meeting logo: the Annual Meeting may develop a specific logo for the conference. However, ISoP's logo must also be included on all communication materials related to the Society's annual meeting.
- xv) Sponsorships and support by non-commercial organisations (cities, regions, ministries, agencies, universities or other institutions or non-profit organisations), whether financial or non-financial are acceptable. They will be acknowledged in the programme and the organisation's logo may be displayed, under ISoP's.
- xvi) Paid sponsorships by commercial societies for the Annual Meetings are acceptable, provided they are unconditional. They will be acknowledged at the end of the meeting programme. No logos may be included. Sponsored symposia related to the sponsor's commercial or other interests are not acceptable.
- xvii) Annual Meeting symposia may be co-sponsored by other scientific societies with similar objectives as ISoP. Such societies will then publicize the ISoP meeting to their members.

Meetings outside the Annual meeting:

Training Courses and other meetings may be organised by ISoP

ISoP Sponsorship:

Any scientific meeting or course may request ISOP sponsorship or co-sponsorship. Requests for sponsorship must be submitted in writing to the

Secretary General, with a description of the aims and objectives of the meeting.
Decision to accept or reject sponsorship will be made by the Officers.
ISoP will advertise such co-sponsored meetings to its members.
Name and logo of ISoP can then be used on communication material upon request of the organiser.

Article 3 - Membership

- i) Active members are those who are up to date in the payment of their fees. They can vote, be elected to the Executive Committee, and receive discounts and other benefits.
- ii) Honorary members have the right to vote, and receive benefits, but may not be elected to the Executive Committee. Membership fees are waived.
- iii) Benefactor members have no voting rights and cannot be elected to the Executive Committee. They can be represented at assemblies by one specified person of their choice. Benefactors shall not be liable for the payment of the membership fee.
- iv) Affiliate members have no voting rights. Membership fees are waived for affiliate members. International organisations which have similar interests to the Society and wish to collaborate with the Society may become Affiliate Members. An application should be made in writing to the President and be approved by a full meeting of the Executive Committee before being recognised by the General Assembly. Each Affiliate Member of the Society has the right to be represented by a single delegate on the Assembly of the Society.
- v) The society can be affiliated to scientific organisations that share similar aims. The membership is approved by the Executive Committee and announced at the annual general assembly.
- vi) Past presidents are *ex officio* members of the Executive Committee, and are not eligible for election to the executive committee during their term(s) as past president. Past presidents lose that status upon the election of a new president and past president. Past presidents have voting right. They are liable to payment of membership fees.
- vii) ISoP members in one country or geographical region may form a chapter to facilitate the organisation of meetings, training courses, or other activities related to the missions of ISoP. At least ten members are needed to constitute a national chapter. The organisation of a chapter is approved by the Executive Committee and announced at the annual general assembly. The Executive Committee will assist in any reasonable way the function of such chapters by providing, for instance, speakers or teaching materials. Such chapters cannot talk in the name of ISoP, nor represent ISoP without prior authorisation of the Executive Committee. Contact persons should be members of the Executive Committee. ISoP logo maybe provided upon request.
- viii) Retired people may have on request a reduced membership fee

Article 4 - Membership fee

The membership year runs from the beginning of January to the end of the following December.

Article 5 - Admission to membership

- 5.1 New memberships will be audited by a subcommittee for suitability before final approval of the application by the officers. The subcommittee is nominated by the Executive Committee and lasts three years, renewable once consecutively.
- 5.2 (i) Members have the right to review the information on file concerning them, upon written request to the Secretary General. They have the right to request amendment or deletion of all or part of the information concerning them. They may also request that the information concerning them not be made available to other parties.
- (ii) The list of members and relevant information may be made available to outside organisations, upon written request to the Secretary General. Any such request can only be approved with the explicit proviso that this list will not be made available to further parties, and will be destroyed after the use for which approval was granted. A charge may be made for this.

Article 6.3 - Exclusion for non-payment of fees

- i) All ISO P members must be current in their fees to participate in ISO P activities and receive membership benefits. All members receive three notices and fees statements before they are dropped from the Society membership roster [within 3 months after the expiration date]. The last notice will provide for a single ten-day period for response, after which membership privileges will be revoked. Individuals must then apply for new membership. Individuals may apply for reinstatement in ISO P by full payment of fees within a calendar year.

Article 7 - Structure

- 7.1 Members of the Executive Committee must be members in good standing of the Society. If a member of the Executive Committee resigns from the committee, is excluded, expelled or leaves for any other reason, this position will be filled until the next election by the candidate who obtained most votes after the successful candidates during the election at which they became members of the Executive Committee. The person thus elected will serve until the normal time of renewal of the person that was replaced, so that the normal replacement schedule is maintained. This “partial tenure” will not be counted in the re-election limits.
- 7.2 The Executive Committee will be renewed every three years, to ensure coordination with the terms for officers of the society.

- 7.3 Executive Committee members may be elected for a maximum of two consecutive terms. They may be further re-elected after at least one term has elapsed since their last tenure.

The Executive Committee members start and end their tenure during the Annual Meeting of the Society. For administrative purposes, and to ensure a smooth transition between Executive Committees, they may be invited to participate in Executive Committee meetings during the 3 months following the end of their tenure.

Any documents pertaining to the Society Executive Committee members received during their tenure remain the property of the Society. Current and former Executive Committee members have an obligation of discretion and reserve concerning the information they may have received as committee members, and concerning Executive Committee meetings. Any request for such information must be directed to the President of the Society.

- 7.4 Election process: the Executive Committee is elected by mail ballot. In the case the mail ballot does not produce the appropriate number of committee members to fill the available positions, a second ballot will be taken during the General Assembly at the yearly meeting.

- 7.9 During the years of its appointment the Nominating Committee organises the election of the new members of the Executive Committee. The past president of the Executive Committee (not elected member) becomes *ex officio* the president of the Nominating Committee for the following elections.

Article 8 - Elections of Officers

- 8.1 Officers must be duly elected members of the Executive Committee.. Loss of membership from the Executive Committee results in automatic forfeiture from office.
- 8.2 The forfeit Officer will be replaced until the time of normal renewal.

At least one term of office must elapse before a member of the Executive Committee can be candidate for the same office, if the above limit for consecutive tenures has been reached.

Candidates for office are declared during an Executive Committee meeting. Any member may be candidate for several of the positions but may only be elected to one office.

Officers are elected by the Executive Committee during the Annual Meeting before the General Assembly if all executive members have been elected at that time, or after the Assembly if some vacant positions need to be filled at that time. The names of the new Officers are made public before the end of the Annual Meeting.

Temporary measure (2004)

Elections to the committee will continue as previously in 2004.

In 2006 the Executive Committee as a whole will resign, and a new election of the whole EC will take place.

For EC members elected in 2004, the term from 2004 to 2006 will be considered as a full term for renewal limits in 2006

For EC members who should have been renewed in 2005, their term of office will be prolonged for a year, and considered as a simple term for renewal limitations.

EC members will be re-eligible -- in 2006 if they have not already served for 2 consecutive terms, as defined above.

Thereafter the elections will take place every three years (2006, 2009, 2012,...)

Article 9 - Executive Committee

9.1 Agendas, minutes of meetings, proposals and other papers associated with meetings will be prepared and circulated to all Executive Board members not less than two weeks before the meeting, or four weeks after meetings in the case of minutes, under the direction of the Secretary General. Summary of Minutes of the EC meeting will be made available on the society's website in the section reserved for members.

9.3 Role and function of the officers.

The President:

- i) The President represents the Society in all its dealings, and is ultimately responsible for the Society. The president can delegate representation to another officer or Executive Committee member, who will the report to the president as to this representation.
- ii) The President signs all documents pertaining to the life of the Society. The president can delegate signatures to the secretary for administrative purposes, to the Treasurer for financial purposes.
- iii) Documents that engage the life of the Society, such as (but not limited to) associations with other societies, sponsoring of events, or financial contracts in excess of 2000 Euro must bear a double signature, that of the President and that of another officer (relevant to the matter at hand).
- iv) The President reports to the Executive Committee on all such commitments.
- v) The President prepares a yearly annual report, which is presented to the general assembly for approval.
- vi) The President chairs the Executive Committee and the General Assembly of the Society
- vii) The President may optionally request a meeting of the Officers prior to an Executive Meeting to handle regular administrative items and prepare proposals for resolution at the Executive Meeting.

- viii) The President, and Treasurer may approve individual reduced fee memberships in cases of hardship. Such approvals (numbers and justifications) are declared at the next Executive Committee meeting. Free memberships can be renewed for a maximum of three consecutive years. Free memberships should be justified by a short report on activities concerning the promotion of pharmacovigilance.

The Vice-President:

- i) The Vice-President immediately replaces the President in the case of incapacitation, resignation, exclusion or expulsion, until such time as the president is capable again or next Executive Committee Meeting is held.
- ii) The Vice-President assists the President in all matters, and is the prime candidate for delegation.
- iii) The Vice-President chairs the Executive Committee in the absence of the President.

The Secretary General:

- i) The Secretary General is in charge of administrative matters. The secretary keeps a roster of ISoP members, and determines the active status of such members with the Treasurer.
- ii) The Secretary General receives all requests for information concerning members or member lists and information.
- iii) The Secretary General sends notice of meetings of the Executive Committee meetings, organizes such meetings, writes and circulates minutes.
- iv) The Secretary General sends notice of meetings of the General Assemblies, organizes such assemblies, writes and circulates minutes.
- v) The Secretary General presents a yearly status report on the membership of the Society, which is presented at the annual assembly, for approval.
- vi) In these and other matters the secretary may be assisted by an outside organisation, after approval by the EC.

The Treasurer:

- i) The Treasurer is in charge of all financial matters of the Society. The Treasurer keeps a roster of all members who have paid their dues and may therefore vote.
- ii) The Treasurer is delegated to sign without consultation for any amount up to 2000 Euro. Above that sum, the co-signature of the president is required.
- iii) The Treasurer reports regularly to the President and to the Executive Committee. The Treasurer prepares a yearly status report, which is presented to the general assembly for approval.

Vice-Secretary/Vice-Treasurer

- i) The vice-secretary/vice-treasurer assists the secretary general and the treasurer as needed in all matters. The vice-secretary/vice treasurer replaces the secretary general or the treasurer in the case of their incapacitation or if they are otherwise incapable of completing their duties.

Executive Committee members

- i) Members of the Executive Committee acknowledge that a developing and dynamic Society requires active participation and contribution. They therefore commit themselves to deliver or delegate effectively such tasks as may emerge for pursuing the development strategy (for example, writing material for the web-site, scientific publications and newsletters, or participating in educational or training events, and so on).
- ii) Members of the Executive Committee must attend at least one Executive Committee meeting per year.

9.5 and article 10 -Voting rules

- i) All votes are passed with a simple majority. Only personal votes are acceptable. Proxies are not accepted.
- ii) In case of a tie, the President casts the deciding vote, except for elections to the Executive Committee, where the candidate with the oldest membership in the society is declared elected.
- iii) There is no quorum for a vote in General Assembly, except for changes in Statutes, where at least half plus one of the voting members must be present.
- iv) The quorum for votes within the Executive Committee is half the members plus one.
- v) In the case of an email poll, decisions will not be made until at least half plus one of the EC members have responded. The absence of response to an email within a prespecified time period cannot be construed as a positive answer.

Article 10.4

- i) Statutes and bylaws are made public on the ISoP website
- ii) Minutes of the General Assembly will be prepared and made available to all ISoP members within ten weeks of the meeting.

Article 12 – Signatories and financial procedures

- i) Travel expenses to Executive Committee meetings will not usually be reimbursed to Executive Committee members, except upon special request.
- ii) Hotel and living expenses during the yearly winter EC meeting will be covered by ISoP.
- iii) If a specific travel is requested by the Executive Committee for Society matters, travel, hotel and other incidental expenses will be reimbursed by the Society upon approval of the expenses by the President and Treasurer, after submission of a claim supported by appropriate receipts. If the travel is done by the president or treasurer, the secretary general will also approve the expenses.

- iv) A record of income must be kept at the point of receipt (eg. administration company, training course administrator, Annual Meeting secretariat)
- v) Travel, accommodation and subsistence expenses for staff from an administrative company will be set out in the contract between the Society and the company
- vi) Printing and other supplies may be purchased after two quotes have been obtained, based on an agreed specification