

# TERMS OF REFERENCE

## SCIENTIFIC BOARD OF THE INTERNATIONAL SOCIETY OF PHARMACOVIGILANCE (ISoP)



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## **1. INTRODUCTION TO THE SCIENTIFIC BOARD**

- 1.1. The Scientific Board of ISoP (SB) serves the International Society of Pharmacovigilance (ISoP) as per the ISoP bylaws and these Terms of Reference.
- 1.2. The SB includes Core SB Members and Corresponding SB Members, both selected among Subject Matter Experts (SMEs) with internationally recognised expertise in knowledge relevant for pharmacovigilance.
- 1.3. SB members shall be members of ISoP and comply with ISoP's bylaws, including the ISoP Code of Conduct and other relevant annexes.
- 1.4. The mission of the SB is to support ISoP's scientific, educational, and professional enhancement activities and to offer expert advice on pharmacovigilance-relevant matters globally.
- 1.5. The secretariat of the SB uses the resources of the secretariat of ISoP but upon needs, may receive support from IPV staff operating on behalf of and under the supervision of ISoP.

## **2. RESPONSIBILITIES AND REMIT OF THE SCIENTIFIC BOARD**

The SB will convene and discuss matters brought to its agenda by a) any of its members, b) or by ISoP's Executive Committee (EC) or Advisory Board (AB), c) or received from the task forces involved in the GPPC or from IPV.

*Examples include:*

- 2.1. Provides scientific and academic authority to ISoP, supporting any ISoP project by offering input, revision, opinion, recommendations, publications, and networking,
- 2.2. Provide expert consultation services on matters related to the scientific mission of pharmacovigilance.
- 2.3. Assists the relevant ISoP Scientific Committees, in the organisation of conferences and training materials for ISoP events,
- 2.4. Advises how ISoP can capitalise on its expertise and experience in innovation, and how ISoP contribution to innovation can best be promoted to stakeholders,
- 2.5. Advises on approaches for capturing, measuring, and communicating the impact derived from innovation activities supported by ISoP, both in the short term and long term, including the criteria for success,
- 2.6. Provides SMEs for the collection and interpretation of PV-relevant regulatory intelligence information,
- 2.7. Discuss new approaches to delivering innovation within ISoP,
- 2.8. Answers in a timely manner any scientific or strategic orientation questions received from the ISoP EC or AB,
- 2.9. Advises on any specific matter should be communicated to the EC of ISoP. The EC will make decisions about the implementation of SB advice. In the event of a disagreement

between the SB and the EC, the issue should be brought to the AB for a joint discussion involving the EC, AB, and the SB.

- 2.10. If judged appropriate and useful to serve a public health interest, the SB may forward to the EC their opinion on the benefits or risks of classes of medicinal products or specific medicines. Subsequently, the EC will decide if, where and how this opinion will be published, with potential conflicts of interests of individual SB members clearly disclosed.
- 2.11. The SB shall not publicly release opinion or advice relating to individual regulatory authorities or governmental institutions. Alternatively, it may advise such institutions confidentially whenever judged appropriate and useful to serve public health interest.
- 2.12. The SB may recommend expert commentaries, opinion pieces or ISoP position statements on international pharmacovigilance matters are submitted to peer reviewed journals.

#### *Roles and responsibilities relative to the GPPC*

- 2.13. The SB serves as Advisory and Steering Committee of ISoP's *Global Pharmacovigilance Professional Certification* programme (GPPC) developed and delivered by the Institute of Pharmacovigilance (IPV), exerting oversight on this programme.
- 2.14. To supervise at an operational level the GPPC-related activities conducted by IPV, the SB shall appoint a *GPPC Supervision Task Force* (GPPC-STF) composed of a minimum of three ISoP members selected among the SB, Special Interest Groups (SiGs) and Chapters. The SB will designate the Chairperson of the GPPC-STF.
- 2.15. On behalf of the SB, the GPPC-STF is responsible for supervising GPPC-related activities conducted by IPV not limited to the endorsement of the batches MCQs. The GPPC-STF is expected to collaborate with the GPPC Project Manager appointed by IPV to set-up and coordinate the *GPPC Examination Boards* supporting GPPC-related activities at the regional or country level. The GPPC-STF will be expected to keep the SB inform of the progress of the GPPC programme and escalate any concern.
- 2.16. The SB recommends qualified SMEs to review and ensure the quality of the Multiple-Choice Questions (MCQs) to be used in the GPPC. Those SMEs constitute the MCQ Review Task Force (MCQ-RTF) appointed by IPV. The appointment of MCQ-RTF members shall be approved by the GPPC-STF. SMEs joining the MCQ-RTF shall not be part of the GPPC-STF. The same applied to any person involved in GPPC operations on the IPV side.
- 2.17. Before release, any communication intended to the ISoP organisation issued by IPV should be endorsed by the GPPC-STF appointed by the ISoP-SB. Stationeries used for communications are described in Annex-1 of the MoU between ISoP and IPV.
- 2.18. Interactions between the ISoP-SB, the GPPC-STF, the MCQ-RTF and IPV are described in the Memorandum of Understanding (MoU) established between those ISoP and IPV.

### **3. COMPOSITION OF THE SCIENTIFIC BOARD**

- 3.1. The SB is intended to include  $10 \pm 3$  (i.e., 7 to 13) Core Members. In addition, to cover specific topics of interest in Pharmacovigilance up to 8 Corresponding Members may be nominated.

- 3.2. SB members should be selected primarily on their academic and professional record in pharmacovigilance and in a way that, as a committee, they will provide experience from the continents where ISoP has members. Ideally, SB members should complement each other's knowledge and understanding of different therapeutic cultures and regional differences.
- 3.3. Candidates may be recommended by Advisory Board members or may be chosen from spontaneous applications in response to calls for nominations. Initial applications will be reviewed by the ISoP Scoping Group chairs, then presented to the ISoP EC and AB for consideration.
- 3.4. Members of the SB shall be approved by the AB from the following three groups of candidates (some candidates will belong to all 3 groups):
  - 3.4.1. Highly recognized academics with scientific educational experience predominantly related to pharmacovigilance,
  - 3.4.2. Respected members of the pharmacovigilance community, with high levels of scientific, operational, clinical and/or regulatory competency in pharmacovigilance e.g., i) Public Health professionals, ii) Clinical pharmacologists, iii) Senior regulators, and iv) Senior pharmacovigilance professionals with industry background,
  - 3.4.3. ISoP experts and high contributors, e.g., ISoP Fellows, current or former EC/AB members, Special Interest Group Chairpersons/Coordinators.
- 3.5. The SB shall:
  - 3.5.1. Cover the entire thematic spectrum of pharmacovigilance,
  - 3.5.2. Use a trans-disciplinary approach,
  - 3.5.3. Ensure that the clinical needs of patients worldwide are at the forefront of its discussions,
  - 3.5.4. Cover the diversity of methodological and paradigmatic approaches,
  - 3.5.5. Have experience with applied health research and research policy.
- 3.6. Obligations applying to Core Members and/or Corresponding Members.
  - 3.6.1. Valuable Experts meeting the selection criteria, but who cannot commit to attending regular meetings, or who would experience challenges contributing to verbal discussions in English, may be asked to join the SB as Corresponding Members.
  - 3.6.2. Core Members will be expected to: i) contribute to projects supported by the SB, ii) to attend all online or on-site scheduled SB meetings, iii) to contribute to verbal discussions in English, iv) to self-evaluate their contribution to SB projects and activities.
  - 3.6.3. Corresponding Members will be expected to: i) provide written input in their field of knowledge, ii) have no obligation to participate in verbal discussions either face-to-face or on web-based platform, iii) will not be required to attend ISoP SB meetings, iv) will be informed about the agenda of SB meetings.

- 3.6.4. Corresponding Members may ask to join specific SB meetings to provide input verbally. They may also be asked by the SB Chairs to become a Core Member if their specific expertise is required, or if a Core Member resigns for any reason.
- 3.7. ISoP SB members may be proposed by the AB or apply as spontaneous candidates. Applications will be screened by the EC, and then approved by the whole AB, by a majority of at least two thirds of AB members. ISoP members interested in serving as a Scientific Board member should approach a member of the AB, or email the ISoP Secretary, to put their name forward.
- 3.8. The EC may also decide to actively approach experts aiming at onboarding the necessary expertise.
- 3.9. The EC and AB must ensure candidates with the relevant competencies and experience should be considered in the appointment process. Consideration will also be given to achieving balance of the committee in terms of age, gender, ethnicity, geographic location and other personal factors which may affect the functioning of the SB in providing objective and independent scientific advice.
- 3.10. Should any member of the ISoP SB fail to meet the expectations of the SB Chair/s, then the AB may dismiss that member and appoint another member in their place.

#### **4. TERMS OF MEMBERSHIP**

- 4.1. In order to enable the development of long-term projects, the standard duration of appointment of Core Members is up to five years, possibly renewable up to five additional years, provided the justification is to complete an ongoing project.
- 4.2. On the other hand, Core Members completing their project(s) within less than five years (or deciding to discontinue it for any reason) may decide to abbreviate the term of their appointment. In such a case, they should inform the Chair/s of the SB at least six months ahead of their resignation. Any Core Member cannot serve more than 10 consecutive years.
- 4.3. At the mid-point of the 5-year term (after approximately two years of committee service), Core Members will be invited to self-evaluate their involvement in the projects under the scope of the SB. If, in discussion with the SB Chair, they conclude their availability or input is too limited, these members will be invited to contribute as Corresponding Members rather than Core Member.
- 4.4. ISoP must appoint a new Core Member well in advance, usually 6 months prior to the end of the membership being replaced.
- 4.5. While actively serving ISoP in those roles, both Core Members and Corresponding Members are eligible for free ISoP membership.

## **5. PROCEDURE FOR ELECTING THE SB CHAIR**

- 5.1. Core Members will elect a Chair from among their members for the duration of three years.
- 5.2. Prior to the first SB meeting, new Core Members will be asked to inform the ISoP Secretariat whether they would like to stand for election as SB Chair.
- 5.3. The ISoP President will chair the first meeting of the SB and will introduce candidates for the SB Chair. After the meeting, the President will facilitate an online election, but does not have voting rights. They will only intervene if there is not a unanimous decision, when they may offer the casting vote.
- 5.4. The SB Chair will ask another SB member to act as co-Chair to assist with the workload and act as Chair when the SB Chair may not be available.
- 5.5. The elected Chair and co-Chair shall be confirmed by the EC. Only the confirmed Chair or co-Chair can act as the SB Chair. The EC reserves the right not to confirm a Chair of the SB, while not disclosing the reason for such decision.
- 5.6. As a general principle, the Chair is expected to assess their own availability and capability to comply with the role, but any objections or concerns may be raised by SB members and reported to the ISoP EC.

## **6. TIME AND VENUE FOR MEETINGS**

- 6.1. The SB shall meet in an ordinary session at least three times a year. Meetings will be convened by the SB Chair and the SB Secretariat.
- 6.2. Project-specific working meetings, involving sub-groups of SB members, may occur on a more frequent basis depending on the agreed deliverables.
- 6.3. In situations when the SB Chair is not available, the SB shall be chaired by the co-Chair.
- 6.4. The SB may also meet in an extraordinary session. SB extraordinary meetings are convened at the request of the SB Chair or co-Chair.
- 6.5. Dates for the ordinary sessions should be announced at least three months in advance.
- 6.6. The SB Secretariat will normally notify each member of the SB of the upcoming meeting at least twenty days in advance of the date on which it is scheduled.

## **7. PREPARATION OF MEETINGS**

- 7.1. The SB Chair shall prepare and convene meetings. The SB Chair shall prepare meetings together with the SB Secretariat, including notifying SB members of scheduled meetings, supplying draft agendas and relevant supporting documentation.
- 7.2. As a general principle, the invitation to the meeting, the draft agenda, information on the advice to be adopted and other working documents, shall be submitted to SB members no later than twenty days before the scheduled meeting.
- 7.3. The draft agenda of the meeting is drawn up by the Chair together with SB co-Chair and the SB Secretariat.
- 7.4. At the beginning of a meeting, the SB shall agree on the agenda.
- 7.5. A request by a member of the SB for including or deleting an agenda item must be in writing, reasoned and sent to the Chair at least five working days prior to the scheduled meeting. Upon receiving such a request, the Chair shall immediately inform all members of the SB. Urgent matters may be added to the agenda by the Chair.

## **8. CONVENING AND RECORDING SB MEETINGS**

- 8.1. The SB Chair may call in-person meetings, or remote meetings using virtual safe platforms, such as Zoom, Google Meetings or MS Teams.
- 8.2. The SB meeting may be attended by any member of the ISoP EC or AB, with the right to contribute to deliberations, but without voting rights.
- 8.3. The Chair or Co-Chair of the SB will lead and conclude the discussion of each agenda item.
- 8.4. Under exceptional circumstances, the Chair of the SB may decide to convene a closed SB meeting only accessible to SB members and the ISoP President.
- 8.5. The SB Secretariat shall document the minutes of meetings, including advice recommended, votes cast and minority vote views, and distribute the minutes to all members of the SB no later than twenty working days after the meeting was held.
- 8.6. Comments and /or revisions to the minutes shall be submitted to the Chair, with a copy to each member of the SB, within ten working days after receiving the draft minutes. If no comments have been communicated to the Chair within the given time frame, the draft minutes shall be considered as approved.
- 8.7. It is the SB Chair's responsibility to report advice from SB meetings to the ISoP EC and AB. The final text of the minutes including advice given shall be distributed to all members of the AB no later than one week after approval.



- 8.8. The SB Chair should present a summary of SB work to the EC and AB twice a year (at mid-year and annual full AB meetings).
- 8.9. The ISoP EC reserves the right to comment on, approve or decline advice and recommendations made by the SB.

## **9. ATTENDANCE**

- 9.1. All Core SB members shall be present at each meeting of the SB. If unable to attend, a member shall inform the Chair and Secretariat by email of their absence, preferably at least one week before the meeting and including the reason for their absence.
- 9.2. If the Chair is not able to attend a meeting of the SB, the meeting will be chaired by the co-Chair.
- 9.3. The SB Secretariat will draw up an attendance list during each meeting of the SB and record any absences.

## **10. QUORUM AND VOTING**

- 10.1. The presence of at least half of the appointed members of the SB shall constitute a quorum, unless a specific quorum for selected items is defined in the bylaws or these Terms of Reference.
- 10.2. In the absence of a valid quorum, the Chair shall deliberate as to the best course of action: for example, the Chair may close the session and convene another meeting as soon as possible, postpone agenda items until the next ordinary session or initiate a written procedure.
- 10.3. The SB shall take decisions by consensus. If consensus cannot be achieved, decisions on proposals shall be made by a simple majority vote. Should the votes be tied, the Chair shall have the casting vote.

## **11. CONFIDENTIALITY**

- 11.1. The members of the SB and/or SB Sub-groups, as well as any other participants of a meeting, must respect the confidential character of the meeting as well as of the proceedings.
- 11.2. In general, discussions within the SB and/or SB Sub-groups should not be reported to those outside the committee until proposals and advice have been recorded in the minutes and given to the ISoP EC.
- 11.3. Without prior written consent from the EC, it is prohibited to disclose any matters discussed by the SB and/or SB Sub-groups, or any materials or documents accessible to the SB.

- 11.4. Once the SB minutes have been approved by the EC, they may be published on the ISoP website, so ISoP members may be aware of advice given and decisions made.

## **12. WORKING LANGUAGE**

- 12.1. The working language of the meetings of the ISoP SB is English.
- 12.2. All minutes and articles arising from the SB will be written in English.
- 12.3. In the case of documents being translated into any language other than English, only the English language version of the document is considered as definitive and binding.

## **13. CONFLICTS OF INTEREST**

- 13.1. ISoP SB members must not participate in any decision in which a situation or circumstance of personal and/or professional nature can compromise their ability to decide in the best interests of ISoP or the IPV. For example, in a session where the SB would evaluate a deliverable intended for the GPPC project, a SB member should not participate as a voting member to the evaluation of deliverables she/he is the author of.
- 13.2. If a SB member considers themselves to be in a situation that constitutes a potential conflict of interest, they must immediately raise this issue with the Chair, who shall, in turn inform the other members of the SB. The members of the SB shall subsequently decide on whether the potentially conflicted member may participate in the meeting.
- 13.3. The input of the members of the SB, for the creation of the ISoP Certification Supervisory Board and the subsequent activities focused on the GPPC certification programme in collaboration with IPV shall be organised in such a way that any potential conflict of interest can be avoided.

## **14. URGENT MATTERS AND WRITTEN PROCEDURES**

- 14.1. In exceptional cases, the SB may take decisions by a written procedure, for example by email. A written procedure can only be initiated by the Chair when a majority of SB members agree with the written procedure.
- 14.2. A written procedure may take the form of an electronic vote, organised by the SB Secretariat. Members have three working days to approve or reject a decision. Members, who do not respond within ten working days, will be considered as being neutral.
- 14.3. The Secretariat shall immediately inform the SB members of the outcome of a written procedure.

## **15. ADOPTION, AMENDMENTS AND ENTRY INTO FORCE**

- 15.1. The SB Terms of Reference must be adopted by the ISoP AB.

- 15.2. Upon the request of one or several members, amendments may be made to the SB Terms of Reference by a simple majority of the AB.
- 15.3. The SB Terms of Reference shall be published and appended to ISoP bylaws.
- 15.4. The SB Terms of Reference enter into force once adopted by the AB. The same applies to any amendments made to these Terms of Reference.

*End of the document*