Terms of Reference
Scientific Board of The International Society of Pharmacovigilance (ISoP)

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TERMS OF REFERENCE

1 Introduction to the Scientific Board

1.1 The Scientific Board (SB) will be comprised of internationally recognised individuals in the field of pharmacovigilance. The SB will serve the International Society of Pharmacovigilance (ISoP) as per the ISoP bylaws and these Terms of Reference.

1.2 The SB's mission is to support ISoP's scientific and educational activities and to offer expert advice on pharmacovigilance worldwide.

1.3 The SB will provide expert consultation services in all matters related to the scientific mission of international pharmacovigilance.

1.4 The SB will collaborate with the Institute of Pharmacovigilance (IPV) in delivering the Global Pharmacovigilance Professional Certification (GPPC) for the ISoP.

1.5 The SB will have its own Secretariat, including the Executive Secretary of ISoP and support staff from the IPV.

2 Responsibilities and remit of the Scientific Board

2.1 The SB will convene and discuss matters brought to its agenda by any of its members,or by the ISoP Executive Committee (EC) or Advisory Board (AB), or by the Institute of Pharmacovigilance (IPV). Examples of tasks and activities include:

SCIENTIFIC ADVICE

2.1.1 Provision of scientific and academic authority to ISoP, supporting all ISoP projects by offering input, revision, opinion, recommendations, publications, and networking;

2.1.2 Assistance to the relevant Scientific Committees, in the organisation of conferences and training materials for ISoP events;

2.1.3 Advising how the ISoP can capitalise on its expertise and experience in innovation, and how ISoP contribution to innovation can best be promoted to stakeholders;

2.1.4 Advising on approaches to 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;

2.1.5 Discuss new approaches to delivering innovation within the ISoP;

2.1.6 Answer in a timely manner any scientific or strategic orientation questions, received from the EC, or the AB;

2.1.7 The SB will not provide any opinion on the benefits or risks of any individual medicinal product;

2.1.8 The SB will not provide any opinion or advice relating to individual regulatory authorities or public institutions;

2.1.9 The SB may recommend expert commentaries, opinion pieces or ISoP position statements on international pharmacovigilance matters are submitted to peer reviewed journals.

COLLABORATION WITH IPV

The SB shall act as an advisory body for the IPV in all matters related to the GPPC. Examples of this support may include:

2.1.10 Answer questions the IPV may put to the SB regarding the GPPC;

2.1.11 Support the IPV in collecting and interpreting PV-relevant regulatory intelligence information;

2.1.12 When requested, support the Examination Boards, in terms of procedures and methodology, as well as SB members serving as members of the Examination Boards;

2.1.13 Support the GPPC in getting recognition from different stakeholders constituting the pharmacovigilance community;

2.1.14 Review and advise on IPV documents, practices and procedures as appropriate;

2.1.15 Review and approve test questions used in the GPPC as requested by the IPV;

2.1.16 SB advice on any specific matter should be communicated to the ISoP EC. The EC will make decisions about 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.

3 Composition of the Scientific Board

3.1 The intention is to appoint 10 members with a flexibility of ± 2 (i.e., from 8 to 12 members). A member of the SB must be an ISoP member. SB members should be selected in a way that, altogether, they will provide experience from the several continents where ISoP has members, and complementing each other's knowledge and understanding of different therapeutic cultures or regional differences.

3.2 Members of the SB shall be suggested by the AB from the following three groups of candidates:

3.2.1 Highly recognized academics with scientific educational experience predominantly related to pharmacovigilance;

3.2.2 Respected members of the pharmacovigilance community, with high levels of scientific, operational, clinical 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;

3.2.3 ISoP experts and high contributors e.g., ISoP Fellows, current or former EC/AB members, Special Interest Group Chairpersons/Coordinators.

3.3 The SB shall:

3.3.1 Cover the entire thematic spectrum of pharmacovigilance;

3.3.2 Use a trans-disciplinary approach;

3.3.3 Ensure that the clinical needs of patients worldwide are at the forefront of its discussions;

3.3.4 Cover the diversity of methodological and paradigmatic approaches;

3.3.5 Have experience with applied health research and research policy.

4 Appointment of the Scientific Board members

4.1 The SB members will be proposed by the AB, 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 Scientific Board member should approach a member of the AB, or the ISoP Secretary, to put their name forward.

4.2 The EC must ensure equality and diversity of competencies and experience 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.

4.3 Should any member of the 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.

5 Terms of membership

5.1 In order to enable the development of long-term projects, the standard duration of appointment of SB member is up to five years, possibly renewable up to five additional years, provided the justification is to complete an ongoing project.

5.2 On the other hand, SB 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 SB member cannot serve more than 10 consecutive years.

5.3 The AB must appoint a new member of the SB well in advance, usually 6 months prior to the end of the membership being replaced.

5.4 The IPV, a not-for-profit organisation devoted to elevation of pharmacovigilance profession, will reimburse members of SB for their work on GPPC project.

6 Procedure for electing the SB Chair

6.1 The SB will elect a Chair from among its members for the duration of three years. 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.

6.2 The President of ISoP must ensure the election of the SB Chair is conducted at the first meeting where a quorum is reached.

6.3 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.

6.4 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.

7 Time and venue for meetings

7.1 The SB shall meet in ordinary session at least three times a year. Meetings will be convened by the SB Chair. However, project-specific working meetings involving sub-groups of SB members, are expected to occur on a more frequent basis.

7.2 In situations when the SB Chair is not available, the SB shall be chaired by the co-Chair.

7.3 The SB may also meet in extraordinary session. The SB extraordinary meetings are convened at the request of the SB Chair or co-Chair.

7.4 As a general principle, the dates for the ordinary sessions should be announced at least three months in advance.

7.5 As a general principle, the SB Secretariat will notify each member of the SB of the upcoming meeting at least twenty days in advance of the date on which it is scheduled.

8 Preparation of meetings

8.1 The SB Chair shall prepare and convene meetings. The SB Chair shall make preparations together with the SB Secretariat, including notifying SB members of scheduled meetings, supplying draft agendas and relevant supporting documentation.

8.2 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 members of the SB no later than twenty days before the scheduled meeting.

8.3 The draft agenda of the meeting is drawn up by the Chair together with the SB Secretariat.

8.4 At the beginning of a meeting, the SB shall adopt the agenda.

8.5 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 request, the Chair shall immediately inform all members of the SB. Urgent matters may be added to the agenda by the Chair.

9 Convening and recording SB meetings

9.1 The SB Chair can call in-person meetings, or remote meetings using virtual safe platforms, such as Zoom, Google Meetings or MS Teams.

9.2 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.

9.3 The Chair or Co-Chair of the SB will lead and conclude the discussion of each agenda item.

9.4 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.

9.5 The Secretariat shall record the minutes of meetings, including advice recommended, votes cast and (minority vote) views, and distribute them to all members of the SB no later than twenty working days after the meeting was held.

9.6 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.

9.7 It is the SB Chair's responsibility to report advice from SB meetings to the ISoP EC. 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.

9.8 The ISoP EC reserves the right to comment on, approve or decline advice and recommendations made by the SB.

10 Attendance

10.1 All 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.

10.2 If the Chair is not able to attend a meeting of the SB, the meeting will be chaired by the co-Chair.

10.3 The SB Secretariat will draw up an attendance list during each meeting of the SB and record any absences.

11 Quorum and voting

11.1 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.

11.2 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.

11.3 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.

12 Confidentiality

12.1 The members of the SB, as well as any other participants of a meeting, must respect the confidential character of the meeting as well as of the proceedings.

12.2 In general, discussions within the SB 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.

12.3 Without prior written consent from the EC, it is prohibited to disclose any matters discussed by the SB, or any materials or documents accessible to the SB.

12.4 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.

13 Working language

13.1 The working language of the meetings of the SB is English.

13.2 All minutes and articles arising from the SB will be written in English.

13.3 In 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.

14 Conflicts of interest

14.1 SB member 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 the 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.

14.2 If a member of the SB 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.

14.3 The input of the members of the SB, for the creation of the ISoP Certification Supervisory Board and the subsequent implementation of the certification programme of the IPV shall be organised in such a way that any potential conflict of interest can be avoided.

15 Urgent matters and written procedures

15.1 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 majority of SB members agree with the written procedure.

15.2 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.

15.3 The Secretariat shall immediately inform the SB members of the outcome of a written procedure.

16 Adoption, amendments and entry into force

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

16.2 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.

16.3 The SB Terms of Reference shall be published and appended to ISoP bylaws.

16.4 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.