



International Society  
of Pharmacovigilance

*Committed to safer use of medicines worldwide*

## **Guideline for ISO P National and Regional Chapters**

**April 2022**

### **Background**

As described in Article 2 of ISO P's statutes, ISO P aims to foster science, learning and research in pharmacovigilance in all countries. These objectives are met by providing:

- opportunities for networking in a friendly environment
- collegial and convivial support among fellow pharmacovigilance professionals
- an open and impartial forum for sharing experience, knowledge and solutions
- a platform for discussion and generation of new research and ideas
- meetings, education and affordable training.

Within our international professional society, ISO P Chapters are locally-established groups of ISO P members who actively address the needs arising from pharmacovigilance activities in their respective country (e.g. Italy) or region (e.g. Africa). They implement their own national or regional programmes as well as agreed global and regional strategies consistent with ISO P objectives for global pharmacovigilance.

Before official recognition as an ISO P chapter, pharmacovigilance professionals (both ISO P members and non-members) may be part of a group exploring the priorities for safe use of medicines in their territories. By examining the features of an approvable chapter described below, a plan for creating an ISO P chapter may be produced, noting that all chapter members must first become ISO P members. The ISO P Chapters Coordinator (CC) may advise on suitability of options under discussion.

## **1. Aims of ISoP Chapters**

ISoP Chapters act to develop pharmacovigilance in their territory of influence and help those in need of assistance.

- 1.1. Chapters enable ISoP members to be involved in the development of pharmacovigilance in their country or region.
- 1.2. Through their activities and feedback, ISoP Chapters may also be instrumental in shaping ISoP's strategy and policies, working together on regional priorities, as well as promoting and supporting international initiatives.
- 1.3. Chapters provide a mechanism for national and regional pharmacovigilance issues to be recognized globally.
- 1.4. Members of ISoP chapters are encouraged to collaborate with other ISoP chapters with the overall aim of enhancing patient safety worldwide.
- 1.5. Chapter activities should strengthen ISoP as a whole by being consistent with the stated global aims of ISoP in the By-laws.

## **2. Process for Establishing an ISoP Chapter**

- 2.1 As the first step, an understanding is reached between the ISoP EC and an individual or group of ISoP members who wish to work towards forming a chapter of ISoP in their country or region.
- 2.2 In order for the ISoP EC to approve a national or regional chapter, the new chapter leaders should prepare a proposal which includes the following points:
  - 2.2.1 The proposed Chapter should demonstrate its determination, diligence and competence to represent ISoP and the discipline of pharmacovigilance in its own country/region.
  - 2.2.2 The motivation behind the new chapter construction should be outlined, including how it will serve ISoP members in this country/region.
  - 2.2.3 At least 10 ISoP members are needed to form a chapter.
  - 2.2.4 There may only be one ISoP Chapter within a defined territory, for example, one country. If a Chapter is to represent more than one country, or wishes to represent a region within a country, the proposal should state the reasons for this. These may refer to the numbers of ISoP members available to start a chapter, local or regional interests, or geographical constraints.
  - 2.2.5 Chapters should have a self-supporting status while still allowing them to operate in conformity with the By-laws and principles of ISoP. Chapters will be guided by the ethical principles of ISoP, including the ISoP Code of Conduct, although details of how such principles are locally implemented may vary across the world. (*See Annex 1*)

- 2.3 There are two ways to set-up a new chapter:
- 2.3.1 The *first* option is a simplified procedure, as an informal regional subgroup of ISoP without its own bank account. Members communicate by email and online events are usually organised using the ISoP Zoom platforms.
- 2.3.2 A *second* option applies for those chapters that wish to have their own bank account and independent financial management: the new chapter may be created as a separate entity according to specific laws in a particular country. However, all ISoP memberships should be paid centrally via the ISoP Secretariat, with the financial management only applying for the organization of meetings or training, always in coordination with the ISoP EC.
- If chapter leaders seek to have this option, the main reasons for having independent financial processes (for example, for creating and implementing sponsored regional meetings and training activities) should be specified in the proposal letter.
- 2.4 The specific legal nature of the chapter, such as a charity status, may vary from country to country. It may not be necessary to have any specific legal status, but such a legal status may be required locally, e.g. to declare and manage funding by any organizations or companies involved in meetings, courses and travel or other activities. If there is any doubt, this should be discussed with the ISoP CC before submission of the chapter proposal.
- 2.5 The ISoP EC will discuss any new chapter proposals at their monthly EC meeting. Proposals should be submitted to the ISoP Secretary at least 7 working days before the EC meeting.
- 2.6 If approval is granted by the EC, the chapter leaders will receive a letter from the ISoP President recognizing this group as an ISoP Chapter. At this stage, the national contact may use the ISoP name or logo but may not (unless specifically authorised to do so by the EC) speak on behalf of ISoP.
- 2.7 Subsequently, the formation of the new chapter will be approved by the ISoP AB and officially launched at the next mid-year or annual ISoP General Assembly.
- 2.8 New ISoP chapters will also be announced in the ISoP Star and on the ISoP website as well as via relevant social media channels.

### **3. Organisational Structure of ISoP Chapters**

- 3.1 Chapters may informally decide who will lead the chapter without the need for elections of an Executive Committee, if agreement can be reached by emailing all chapter members. The ISoP CC should be informed of the chapter Head/Lead by email.
- 3.2 Alternatively, larger chapters may elect an Executive Committee to lead the chapter. The following roles are recommended: a president/coordinator, a vice-president, a secretary, and a treasurer (if applicable, see 3.2 above).
- 3.3 Those standing for selection or election as chapter leaders/EC officers must

be current members of ISoP and are expected to renew their membership promptly (within one month) when renewal is due.

- 3.4 Elections should be held online after the official launching of the Chapter, in conjunction with the ISoP CC and the ISoP Secretariat. A record should be kept of the mechanism of election and the results.
- 3.5 The term of the Chapter Leader/Executive Committee officers is normally 3 years, subject to renewal.
- 3.6 The Chapter EC will ensure the Chapter's activities, financial management (where applicable) and records are set up and maintained to enable communication with the ISoP CC.
- 3.7 All ISoP memberships within each chapter are centralized with ISoP administration. Individual chapters do not process annual ISoP membership applications fees.
- 3.8 The contact details (email addresses) of Chapter Leaders or Executive Committee members shall be given for each chapter on the ISoP website.

#### **4. Operational Organisation of ISoP Chapters**

- 4.1. New ISoP members will be referred to the appropriate chapter by the ISoP Secretary, based on their application. Upon request, members located in a different region may be part of a specific chapter. ISoP members may also be a part of more than one chapter.
- 4.2. Chapters are responsible for updating their participant list in liaison with ISoP Administration. The chapter Leader/Secretary is responsible for keeping all chapter members informed about chapter activities and events.
- 4.3. Within their own countries or region, ISoP chapters are standalone organisations working with ISoP members acting as volunteers. If Chapters wish to develop their own bylaws, they should be consistent with ISoP bylaws. These written procedures will be available on request.
- 4.4. Chapters may organize themselves in any way they see fit and can meet at a periodicity of their own choosing. National or regional chapters shall inform the ISoP Secretariat about any scheduled events such as meetings, symposia, conferences etc.
- 4.5. Each ISoP Chapter may use the name and emblem of ISoP. It should take all necessary steps to protect the name and logo of ISoP under the laws and regulations of the NC's country or territory. The Chapter may consider the creation of a specific Chapter logo, but it must be limited to the use of an unaltered version of the ISoP logo with the Chapter name underneath. Here some examples:

	<p>The map of the country or region under scope placed behind the globe keeping the corpus of the ISoP logo unaltered.</p>
	<p>Adding a country or region-specific shape on the side of the unaltered ISoP logo.</p>

- 4.6. The Chapter should extend its activities such as meetings and training courses within its defined territory. It is recommended that the Chapter should liaise with the ISoP CC and the appropriate AB Regional Leader, informing them about activities such as meetings and training courses within the region as a whole.
- 4.7. ISoP Chapters are encouraged to collaborate with each other, especially those in the same region, or those working on similar pharmacovigilance topics. Joint meetings/webinars/training courses are welcomed and should strengthen and promote international cooperation within ISoP.
- 4.8. Normally, chapter events (including face-to-face meetings and webinars) are offered to ISoP members only. If the Chapter wishes to organize occasional free events for non-members, this should be discussed with the ISoP EC.
- 4.9. All ISoP Chapters should adhere to and continually act in accordance with the ISoP constitution and By-Laws. If needed, Chapters may draft their own bylaws, including sponsorship rules, in accordance with ISoP standards.
- 4.10. For Chapters with independent financial management (see Section 3.2 above) records should be available for inspection by the ISoP Treasurer upon request.

## 5. Reporting of Chapter Activities

- 5.1. Each Chapter will share a regular activity report (and financial reports, if applicable) with the ISoP EC and AB, normally twice a year at the mid-year and annual ISoP meetings. A template of the activity reports is in annex 2.

- 5.2. The report should be submitted on request to the ISoP CC who will then prepare and present a summary of all chapter activities to the EC and AB.
- 5.3. A summary of ISoP chapter activity will be presented by the ISoP CC at the ISoP General Assembly each year. Due to time limitations, this will be in the form of chapter highlights, rather than a full and comprehensive report.
- 5.4. A session for chapters should be held at the ISoP annual conference. This will be chaired by the ISoP CC and timing should be scheduled to allow as many coordinators as possible to attend the session. Presentations should be discussed and agreed with the ISoP CC (before abstract submission).
- 5.5. Chapters are encouraged to propose specific events or symposia presenting their activities or other topics of interest at the annual meeting, with prior approval of the meeting's scientific committee.
- 5.6. Chapters are encouraged to identify potentially suitable sites and organisers in their region for an ISoP annual meeting. Proposals should be submitted to the ISoP EC at least two years in advance of proposed date.
- 5.7. All chapters have a space on the official ISoP website. In liaison with the ISoP Secretary, each chapter should keep updating its space on the website. This will make visible the efforts and activities offered by the Chapters; a recommended structure is described in annex 3.
- 5.8. Chapter members are encouraged to write articles/updates about chapter activities for the ISoP Newsletters, ISoP Star or ISoP Twitter feeds. These should be prepared in conjunction with the ISoP COMMS team and the ISoP Secretary.
- 5.9. Chapter articles may also be submitted to ISoP's official journal, *Drug Safety*, either for consideration of publication in the ISoP pages or as independent research articles. Articles for the ISoP pages of *Drug Safety* should be peer reviewed by the Chapters Co-ordinator and/or a member of the ISoP COMMS team before submission.

## **6. Oversight of ISoP Chapters by ISoP Advisory Board**

The ISoP EC and AB should contribute to the development of national or regional chapters, whenever possible. Our international strategy should take into account the needs, opportunities and benefits involved in particular regions, while also developing the aims of the wider society, for example, better knowledge and understanding of the safe and effective use of medicines (including all products used to pharmacologically alter or manipulate human pathophysiology such as herbals, natural medicines, OTC products, drug-devices).

- 6.1. The ISoP Chapters Coordinator (CC) is a member of the ISoP AB (appointed by the ISoP President) who is responsible for co-ordinating and supporting all ISoP chapters to ensure they operate within ISoP's global aims, while remaining organisationally self-supporting at the national or region level.
- 6.2. Other members of the ISoP AB will act as a Regional Leaders for each ISoP

region. These roles are intended to help the CC and EC follow and support activities from each chapter.

- 6.3. Chapters are invited to advise the EC of projects which are both in scope and of importance to patient safety in their region. The EC may suggest obtaining expert advice from the ISoP Scientific Board (SB).
- 6.4. In discussion with the ISoP CC, ISoP EC and ISoP SB, it may be appropriate for ISoP to develop specific programmes of support e.g. training, conferences and workshops at a local or regional level.
- 6.5. Neither the ISoP CC nor the ISoP EC or AB are directly responsible for Chapters' internal and organizational matters.
- 6.6. Members of the ISoP EC, AB and SB will aim to assist the functions of the Chapters, for example by providing teaching materials or speakers, if requested.
- 6.7. If problems within chapters are identified at any time, they should be addressed constructively and inclusively by Chapter Leaders. If issues cannot be resolved within a chapter, they should be reported to the ISoP CC and EC as soon as possible, with the aim of collaborative resolution.
- 6.8. Through the ISoP CC and AB, ISoP is responsible for ensuring all Chapters abide by acceptable standards of conduct as defined in the ISoP By-laws.
- 6.9. ISoP reserves the right to withdraw recognition of a chapter - for example, if the chapter does not comply with the Chapter Guidelines or ISoP bylaws - and to withdraw permission for the Chapter to use the ISoP name and/or logo.

## **Annex 1.**

### **Template of proposal letter**

*This template applies to the three options for setting up a new Chapter. However, in the second option, the proposal must have additional information according to the national regulation of each country*

- **Why Now?** *Explanation of the reason for the creation of a new ISoP chapter.*
- **Why a Regional Chapter?** *Explanation of the gaps that the Chapter's gaps expect to work within the country or region proposed.*
- **When?** *A simple timeline to set up the Chapter*
- **How?** *Explanation of the option chose to create the Chapter (first: the simplified procedure, second: a separate entity -national new entity, or third: a separate entity under another organization)*
- **Who?** *Countries (if it is applicable)*
- **Members:** *Name of the current ISoP members interesting in the creation of the Chapters*
- **Goals & Objectives**
- **Next Steps**

**Annex 2.**  
**Template of ISoP chapter's report**

*Please mark the corresponding option*

<b>Report for the Annual Meeting</b>	
<b>Report for the Mid-year meeting</b>	

**Please select your Chapter**

<b>Chapters</b>	
Africa	
China	
Egypt	
Indonesia	
Italy	
Latin America	
Middle East	
South Asia	
South Eastern Europe	
Switzerland	
North America (NASoP)	
Western Pacific region	
<i>New chapter if it is applicable</i>	

**General information about the Chapter**

Year of creation	
Number of members in the creation	
Number of current members	

**Please select the option that applies for the current establishment of your Chapter.**

Simplified procedure as an informal subgroup of ISoP	
A separate registered entity with legal national status	
<i>If the Chapter is formally registered, please explain the current status of the Chapter and submit a copy of the registration documents; if you already sent it, please omit the attachment</i>	

**Financial information**

The Chapter raises money from events or meetings	
<i>In affirmative cases, please submit a copy of the last financial report,</i>	

**Frequency of the Chapter meetings**

Type of meeting	Frequency
Executive committee or Chapters leaders	
All members	

**Description of activities**

Please describe all your activities organized during (*period of time specific for each report*).

Please use one row for each activity

<b>Name of the activity</b>	<b>Date</b>	<b>Open for non-members</b>	<b>Number of participants</b>	<b>Collaboration with other Chapter, SIG or other organization</b>
<b>1</b>				
<b>2</b>				

**Specific questions** (*every report could have specific questions, this will depend on the CC*)

**Further comments**


**List of documents attached**


**Name of Chapter Leader:**

**Date:**

### **Annex 3**

#### **Recommended structure for Chapter space on ISoP website**

- Chapter Logo and/or map of the geographical region *(if it is applicable)*
- Welcome words and history of the Chapter (date of creation, funder members, etc)
- Objectives or mission
- Country members *(if it is applicable)*/ number of members
- Chapter Activities *We recommend describing the last 3-5 years. Descending order is suggested. Other previous years can be summarized.*
- Chapter' Social Media channels