



Guideline for ISoP National and Regional Chapters

October 2017

What is an ISoP Chapter?

ISoP Chapters are, locally-established organisations that actively address the needs arising from the whole range of pharmacovigilance activities in their respective countries (e.g. Italy) or regions (e.g. Africa). They implement their own national or regional programmes as well as agreed global and regional strategies consistent with ISoP objectives for global pharmacovigilance. Chapters enable ISoP members to lead and be personally involved in the future development of pharmacovigilance in their country or region. Through its activities and feedback, ISoP Chapters are also instrumental in shaping ISoP's strategy and policies, and can work together on regional priorities as well as promote and support national initiatives. Chapters provide a mechanism for such national and regional issues to be recognized globally. Members of established chapters are encouraged to collaborate in the recruitment of members to keep new chapters viable.

As Chapters are ambassadors for ISoP, by contributing to the achievement of ISoP's goals and aims, they should keep ISoP informed of the local needs towards achieving that aim. As described in Article 2 of ISoP's statutes, ISoP 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.

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. This includes identifying potentially suitable

sites and willing and competent organisers for an Annual Meeting and encouraging submission of a proposal two years in advance of proposed date.

On a case by case basis, a chapter may voluntarily seek the option of becoming a legally independent entity within their own national legislative framework (such as a charity) and, if so, then discussions with and approval of the Executive Committee will be required (see below).

Rationale for chapters

ISoP should aim to contribute to the development of national or regional chapters. The strategy should take into account the needs, opportunities and benefits that may be involved in particular areas while also developing the aims of the wider Society. This would refer to better knowledge and understanding of the safe and effective pre- and post-marketing use of medicines (including all types of product used to pharmacologically alter or manipulate human pathophysiology such as herbals, natural medicines, OTC products, drug-devices. In many countries these are not defined and so a Chapter is free to define what is in scope). In some cases, in discussion with the ISoP executive Committee, it may be appropriate for ISoP itself to develop specific programmes of support e.g. supporting conferences and workshops at a local level to stimulate or further develop national chapters. Before official recognition as an ISoP chapter, PV professionals may be part of a group that can explore the priorities for safe use of medicines in their territories. By examining the features of an approvable chapter described below, a plan for creating a chapter can be produced. The ISoP chapter coordinator would be delighted to advise on suitability of options under discussion.

Oversight by ISoP Executive Committee (EC)

A member of the Advisory Board (Chapters Coordinator –CC), appointed by the EC, will be responsible and have a co-ordinating and supporting function for the network of chapters to ensure they stay in line with ISoP's global vision and aims while remaining organisationally self-supporting at the national or regional level. Neither the CC nor the ISoP Board are directly responsible for chapters' internal and organizational matters.

A system of Chapter review by the ISoP CC on behalf of the Board and executive committee helps ensure that the quality and integrity of Chapters is acceptably high around the world. Such review procedures by means of the CC have been developed to empower locally meaningful activity while retaining an overall commitment to the joint achievement of ISoP's common mission. The objective is to assure and achieve strong, effective and accountable Chapters. The ISoP Board and Executive Committee will assist in any reasonable way in the functions of the Chapters such as, on request, by providing teaching materials or speakers. Where weaknesses are identified, at any time, they should be addressed jointly and constructively, with a primary view to strengthening the position of the National or Regional Chapter and thus of the Society as a whole.

Expectations of chapters

Within their own countries or region, Chapters are standalone organisations working with ISoP members acting as volunteers. They should develop their own written procedures (which may vary according to national legislation) and shall agree (by e-mail) in writing to abide with ISoP bylaws and the constitution. These written procedures will be available on request.

Through the CC and Board, ISoP retains the responsibility of checking that all Chapters abide by acceptable standards of conduct as defined in the bylaws. According to an agreed process, ISoP reserves the right to withdraw recognition of Chapters and permission for the Chapter to use the ISoP name according to an agreed internal process within ISoP. The reasons chosen by the ISoP board will be made public.

ISoP Chapters act to develop pharmacovigilance in their territory of influence and help those in need of assistance. Their activities should strengthen ISoP as a whole by being consistent with the stated global aims of ISoP.

Chapters can organize themselves in any way that they see fit and can meet at a periodicity of their own choosing. National or regional chapters shall inform the ISoP Secretariat on any scheduled events such as meetings, symposia, conferences etc.

What is required for the ISoP EC to approve a chapter?

In order for the ISoP EC to approve a national or regional chapter, the following points need to be addressed in a submission to the ISoP EC either by affirming commitment or demonstrating evidence as follows:

1. The proposed Chapter must be able demonstrate its determination, diligence and competence to represent ISoP and the discipline of pharmacovigilance in its own country and act as a member of ISoP.
2. Normally at least 10 ISoP members are needed to form a chapter. Alternatively, a lower number might be acceptable if a demonstrably significant amount of PV activity was being initiated by the chapter or an alliance was planned with large national PV association.
3. There can only be one ISoP Chapter within a defined territory. Typically this will represent one country. If a Chapter is to represent more than one country, or wishes to represent a region within a country, it must 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.
4. Chapters have a self-supporting status while still allowing them to operate in conformity with the fundamental principles of ISoP. Chapters agree to be guided in their work by internationally acceptable ethical principles of ISoP although details of how such principles are locally implemented vary across the

world. The specific legal nature of the status, 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 desirable and required legally, e.g. to declare and manage funding by any organizations or companies involved in meetings, courses and travel or other activities. If there is doubt about interpretation of ethical principles, this should be discussed with the ISoP CC at the earliest opportunity.

5. The Chapter must be organized to be able to fulfil the tasks consistent with intent of ISoP statutes, and members must follow the ISoP policy in regards to the declaration of Conflicts of Interest (CoI). The ISoP form needs to be completed and annexed to any submission from the proposed chapter coordinator.

6. Each Chapter designates their own coordinator to lead a chapter with proposals as to how the roles of a deputy, a treasurer (someone to manage finances) and a Secretary might be fulfilled. They will ensure the Chapter's activities, financial management (where applicable) and records are set up and maintained up to date to enable communication with the Board and EC through the CC. The term of the chapter coordinators needs to be mentioned in the records or files and are normally 3 years subject to renewal. These Chapter Officers are typically selected from within the chapter, and a record is kept of the mechanism of selection and results. Chapters' Officers or/and coordinators must be current members of ISoP and are expected to renew their membership promptly (within one month) when renewal is due. On the ISoP website only one name and point of contact shall be given for each chapter which refers to the main chapter coordinator.g

7. As the first step, an understanding is reached between the ISoP EC and a group of persons (individuals or an existing organization) that a group will work towards forming a Chapter of ISoP in its country. The chapter will receive a letter from the President of ISoP recognizing this group as the "Chapter" of ISoP. 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. Subsequently, the formation of chapter will be officially launched at the next upcoming Annual General Assembly and announced in ISoP Star and website.

What are the expectations about chapter operations?

1. The Chapter can use the name and emblem of ISoP. It takes all necessary steps to protect the name and logo of ISoP under the laws and regulations of the NC's country or territory.

2. The Chapter must be able to extend its activities such as meetings and training courses within its defined territory.

3. The Chapter adheres to and continuously acts in accordance with the active ISoP constitution and bylaws, and shares its values. Conflicts of interests of all chapter members should be kept up to date.

4. Each chapter should set up its own financial processes especially for the creation and implementation Chapter's sponsored meetings and training activities. According to a timing agreed with the ISoP CC and Board, the Chapter will share regular financial and activity reports with the Application Committee and ISoP Executive Committee at a frequency proportionate to the chapter.

At all stages the documentation submitted to the ISoP EC is first screened by the ISoP CC who will validate submissions prior to submission through to the Board, EC and President with recommendations for action for the EC.

5. A session for all the Chapters should be held regularly at the ISoP Annual Meetings. Timing should be scheduled to allow the coordinators to attend the session. Abstracts for the session should be submitted once the request for abstract submission is issued the Annual Meeting organisers. Submissions should be discussed and agreed with the ISoP CC before submission)

Regular Review by ISoP EC

To help strengthen ISoP chapters, and to assure that a chapter continues to comply with the intent and basic principles of ISoP a regular call with the ISoP CC, at a frequency agreed with the ISoP CC, and an annual written review of chapters should take place. Approximately every year after approval by ISoP EC, chapters prepare an annual report based on criteria numbered 1.to 10. above, which concludes with a statement of its own strengths and weaknesses, and the identification of areas where strengthening efforts will be directed, if any. Criteria for the evaluation of a chapter will among others be the number of its members, and their activity, especially in teaching, education, research and promotion of the safe use of medicines. The aim of such a review by the ISoP EC and Board will be primarily to advise on what improvements might be made and how the wider Society might help develop a particular Chapter. The chapters will submit their report to the Board and EC through the ISoP CC for consideration. A form with predefined criteria for use of the coordinators should be made available (online) to report to the EC.

Annex

Declaration of Interest and Declaration of Confidentiality of members of ISoP national or regional chapters

This form consists of two parts, your personal details with biography, and the Public Declaration of Interests. It applies to the Executive Committee members of the International Society of Pharmacovigilance.

Both parts of the form should be fully completed, signed, dated and return electronically to administration@isoponline.org with a short biography (No CV please-10 lines maximum).

The Declaration of Interest and the biography will be published on isoponline.

1 Personal Details (please enclose your biography)

First Name	
Surname	
Organisation	
Country	

I enclose my biography

I, [name], do hereby declare on my honour that, to the best of my knowledge, the only direct or indirect interests I have in the pharmaceutical industry are those listed below:

2 Public Declaration of Interests

If you have interests to declare, please do so under the relevant questions. If you have no interests to declare, please indicate that the appropriate field is non-applicable. Please specify the interests that you currently have or have had in the past 5 years.

Title/Function	Period of activity (within past 5 years)	Company* or organisation**	Description of the activity
1. Employment with a pharmaceutical company or an organisation			
2. Consultancy, advice or services with a pharmaceutical company or an organisation (including training)			

3. Strategic advisory role, member of professional societies, affiliation or equivalent structure			
4. Grant / research funding including sponsorships, fellowships, non-monetary support			
5. Financial interests, direct shares of a pharmaceutical company, compensation, fees, and honoraria (excluded investment trust without direct influence on shares). Exact amounts are not required.			
6. Patents			
7. Investigator (in a pharmaceutical industry instigated/sponsored clinical trial)			
8. Family member interest			
9. Any other interests or facts			

* *Pharmaceutical company (includes supply or service companies which contribute to the research, development production and maintenance of a medicinal product)*

** *An organisation includes governmental, international or non-profit organisations (outside ISoP)*

Should there be any change to the information provided above due to the fact that I acquire additional interests, I shall promptly notify ISoP and complete a new Declaration of Interests detailing the changes.

I confirm the information declared on this form is accurate to the best of my knowledge and I consent to my information being stored electronically and published on the ISoP website.

Signature:

Date: