

THE EUROPEAN FEDERATION OF STATISTICIANS IN THE PHARMACEUTICAL INDUSTRY (EFSPI)

CONSTITUTION

Revision: August 2018
Ratified : September 2018

1. ABOUT EFSPI

1.1 The name of the Federation is "The European Federation of Statisticians in the Pharmaceutical Industry". The abbreviation EFSPI may sometimes be used.

1.2 The contact address of the EFSPI is the address of the Executive office.

1.3 English is the official language of EFSPI.

1.4 EFSPI is a not-for-profit organisation. The funds provided will be used to serve the objectives and the full member groups.

2. OBJECTIVES

- To promote professional standards of statistics and the standing of the statistical profession in matters pertinent to the European pharmaceutical industry.
- To offer a collective expert input on statistical matters to national and international authorities and organisations.
- To exchange information on and harmonise attitudes to the practice of statistics in the European pharmaceutical industry and within the member groups.

3. MEMBERSHIP

3.1 Membership of EFSPI is open to constituted groups of statisticians and not to individuals.

3.2 Eligible for full membership are constituted groups of statisticians located within a European country, which place a major emphasis on technical and scientific activities specifically directed at statisticians working within or for the pharmaceutical industry. The "pharmaceutical industry" is defined here to include the research, development, production and surveillance of drugs and medicinal devices.

3.3 EFSPI is open for an associate membership. This allows an organisation to be represented in the EFSPI council for initially a period of at most two years, after which the membership status should be reviewed.

3.4 Each full member group agrees to provide a financial support in order for EFSPI to be able to cover expenses for its operations. An associate member is not expected to contribute to the financial support. The financial support required will be based on a budget decided for the forthcoming calendar year. The budget and the policy for determining the contribution from each full member group are agreed by the Council by at least two thirds majority among the total number of countries represented by at least one full member group (excluding non-voting members). The budget should be agreed upon every year.

3.5 To be granted both new and continuing full membership of EFSPI a full member group must satisfy the Council (see Section 4) according to the above criteria.

3.6 If a full member group decides to terminate its full membership in EFSPI, a notice must be given to the Executive office one year in advance. The full member group is required to fulfill all its commitments during the term of notice.

4. COUNCIL

4.1 The direction and long term policy of EFSPI will be governed by the Council. The execution of its policy and operations is the responsibility of the President and Vice-President. Administration of EFSPI is done through an "Executive office". The co-operation between EFSPI and an "Executive office" should be regulated by a written contract, the financial commitments of which should be approved by the Council.

4.2 The Council consists of at least one delegate from each of the countries represented through the full member groups. As a rule representation of a country is assumed to be covered by two delegates. For the purpose of decision within the Council, each country represented by at least one full member group has one vote. In case representation of a country is covered by more than one full member group, the decision how to cast the country vote is left with the full member groups involved. A Council meeting will only be quorate if at least two-thirds of the countries are represented at the meeting, excluding countries with only associate member group(s). If needed (but see also 4.4), representation at the meeting can be secured through teleconference or similar virtual and interactive presence. Decisions will be taken on the strength of a simple majority (except for what is stated in section 3.4). The Council will seek unanimity wherever possible.

Should unanimity prove unachievable, minority views will be reported and documented in full.

4.3 The delegates representing a group may be chosen by that group in any manner whatsoever, but they must be vested with the authority to represent that group.

4.4 In order to maintain continuity on the Council, delegates should in principle be committed to serve for at least four years. If a delegate cannot attend a Council meeting, a member group is free to replace the delegate, under continuation of the authority of representation.

4.5 The officers of the Council shall be a President, a Vice-President, a Treasurer and a Director. The Vice-President is either the President-Elect or the immediate past president. Written job descriptions for the officers should be available at the Executive office.

4.6 The President-Elect shall be elected by the Council every two years or as needed. In case that there is more than one nomination, voting shall be by ballot. When the outcome is even, the president shall have the casting vote.

4.7 The President-Elect shall normally serve one year as Vice-President, followed by two years as President, followed by one year as Vice-President again.

4.8 If the office President becomes vacant, the Vice-President will become President and a new President-Elect will be appointed.

4.9 The Treasurer shall be elected by the Council every four years or as needed. In case that there is more than one nomination, voting shall be by ballot. When the outcome is even, the president shall have the casting vote.

4.10 The Director shall be nominated by the Danish member organization and elected by the Council. The position of Director is required in respect of EFSPi being an incorporated Association, registered in Denmark. The main role of the Director is to advise the President and the council and to be the legal representative of EFSPi. The Director shall be elected every four years or as needed.

4.11 The President and Vice-President can designate delegates to assist in the operational execution of key areas of activity for EFSPi and as such they can jointly act as Operational Board. These designated delegates will generally be Council Members, but this is not essential. The Operational Board is assisted by the Executive Office.

4.12 The President and Vice-President are responsible for the action planning and execution of the direction and policy as set by the Council,

for the day-to-day running of the Federation, and for the organisation of Council meetings. The President and the Vice-President shall represent the Federation in financial matters and for legal matters together with the Director.

4.13 The Council will meet as frequently as its business demands, two face to face meetings and two web-conferences per year are recommended.

5. CONSTITUTION

5.1 Changes to the constitution may be proposed by any full member group. These will be discussed by the Council and, if majority support is given, will be presented to full member groups for approval. Changes to the constitution will be made if approved by at least two-thirds of the countries.

6. MUTUAL CO-OPERATION

6.1 There will be a free exchange of information between EFSPI member groups in the areas of meetings, courses, conferences, working parties, expert teams and ad hoc groups. Council members are responsible for ensuring that this information is distributed within the Council, and arranging for the addition of a summary of major points in English if the original documentation is in another language.

6.2 Each EFSPI member group is encouraged to offer members of other member groups (some of) the rights afforded to its own members. In particular, activities organised by member groups (e.g. scientific meetings and courses, ad hoc groups, working parties, etc.) should be open to individual members of any EFSPI member group.