

The future of EFSPI

Bernhard Huitfeldt, David Morgan, Paul Koopman

Table of contents

1. History and background
2. EFSPI is a federation of national associations
3. Strategic issues
4. Proposals for the future of EFSPI
 - 4.1 Working procedures within EFSPI
 - 4.2 Administrative support
 - 4.3 Budget
 - 4.4 Internal communication/information
 - 4.5 External communication/information
 - 4.6 Expansion of EFSPI Membership
5. Changes to the EFSPI constitution
6. Points for decision
7. Appendices
 - (i) Operational Guideline for EFSPI Council
 - (ii) Job description for EFSPI Council representatives
 - (iii) External relations
 - (iv) Proposed new Constitution

1. History and background

The federation started its activities during 1990 and the first official Council meeting took place at Duphar's office in Weesp, the Netherlands in November 1990. It was constituted at a subsequent meeting in Paris, June 1991 and thereafter officially launched at the joint ISCB/SCT meeting in Brussels July 1991. The founding members were six (France, Germany, Italy, Sweden, Switzerland, UK). Denmark joined the federation in 1992 and in 1993 Belgium, and the Netherlands became members. Finally, in 1998 Spain was adopted as a full member after having had observer status for a period of five years.

The EFSPI constitution underwent a minor revision in April 1995. According to the current constitution the aims of the EFSPI federation are:

- *to exchange information on and harmonize attitudes to the practice of statistics in the European pharmaceutical industry and within the member groups,*
- *to promote professional standards of statistics and the standing of the statistical profession in matters pertinent to the European pharmaceutical industry and*

- to offer a collective expert input on statistical matters to national and international authorities and organizations.

The federation has essentially operated in the same way since its beginning. The main activities have been concentrated to the two council meetings every year. In addition, special working parties have been assigned particular tasks such as reviewing regulatory guidelines, setting up criteria for a “qualified and experienced statistician”, and looking after non-clinical and veterinary statistics. Under the auspices of EFSPI, workshops and meetings have also been organized on pertinent issues for the federation. The awareness of EFSPI has gradually increased with regulatory agencies, trade organizations in the field, and other statistical associations.

2. EFSPI is a federation of national associations

The federation is given its mandate by the national member associations. In order to assess how this mandate has been discharged a questionnaire was sent out to all member associations in the beginning of 1998. The conclusions from this questionnaire, to which all associations responded, are summarized below:

- EFSPI is recognized in the constitution (directly or indirectly) of the member association in most of the countries, formally though only in three countries.
- Usually there is a formal procedure for electing EFSPI council members. Most often this procedure involves only the council of the member association and not the membership as a whole.
- The feedback from EFSPI council members to the member associations varies from virtually no feedback at all to a combination of forwarding minutes from EFSPI council meetings and written/oral reports to member association council or at membership meetings. In most cases the EFSPI council member is also a member of the council of the member association.
- The majority of responses indicate that the current level and relevance of EFSPI activities is appropriate. However four countries find EFSPI too passive. Suggested areas for increased activity include leverage towards regulatory agencies, global focus (USA, Japan), exchange of information between member associations and frequency of council meetings, information from EFSPI to member associations and vice versa, promotion of professional standards.
- Ideas on how EFSPI could serve the member associations better include stronger co-operation with ISCB, promotion of biostatistics with regulatory agencies, exchange of ideas on statistical methods with other associations and universities, strengthen the synergy impact of EFSPI, expand EFSPI to involve all EU countries, stimulate links to veterinary and non-clinical statistics, and a fundamental review of EFSPI operations starting with a SWOT analysis.

3. Strategic issues

Based on the aim of the federation, the response to the questionnaire and the SWOT-analysis performed by the council the following strategic issues have been identified:

1. The linkage to the member associations must be stronger and more structured.
2. The working procedures within EFSPI need to be more efficient - operational guidelines for the Council operation and a job description for the Council members are needed.
3. Administrative and financial support for the management of the federation is essential for an efficient management.
4. The internal communication between Council members and between national representatives within a country needs to be improved.
5. The communication between the representatives of the Council and their national associations needs to be more effective.
6. The communication from EFSPI to the members of the national associations should be improved by setting up an EFSPI homepage.
7. Efficient connections to other organizations in the field should be established.
8. Expansion of the membership to other European countries should be considered.

Based on these strategic issues and the discussion at the Council meeting in Prague (April 1999) the following suggestions are provided for discussion and decision at the Council meeting in Brussels (November 1999).

4. Proposals for the future direction of EFSPI

4.1 Working procedures within EFSPI

In order to maximise effectiveness and clarify expectations, it is proposed that Operational Guidelines are adopted for Council operation (see Appendix 1) and that a 'Job Description' for Council members and other specified functions is adopted (see Appendix 2). These documents are proposed to be added as attachments to the EFSPI Constitution.

4.2 Administrative support

Rationale

Administrative support in the form of a "Administrative office" is suggested with the following tasks:

Tasks

1. Assistance to officers, communication to council members but not to individual members in the national organisations;
2. Follow-up on progress of action list by Council Members;
3. Maintenance of the Web homepage;

4. Organise and distribute regulatory guidelines for comments;
5. Production and maintenance of Public Relations material;
6. Maintain financial records and operate bank account;
7. Arrange the administrative archive.

Procedure

The need for administrative support is estimated to be on average one day per week. It should be realised that this may vary over the months and thus an arrangement should be based on a floating account principle. It would be advantageous to invite the Administrative office person to the Council meetings to enable involvement of this person in EFSPI activities and to take minutes, but it is realised that this may not be feasible under current budget restrictions.

An evaluation by the EFSPI Council of the model of administrative support and also the time needed by the administration to perform the tasks should take place 1-2 years after instalment of the Administrative office.

Various options on where to locate the Administrative office were investigated and reported to the Council separate from this document. After the Council took a decision at the November 1999 meeting, formal legal affairs and contractual discussions were initiated to enable the launch of the Administrative office function in the first months of year 2000.

4.3 Budget

It is suggested that all financial matters should be based on a yearly budget including costs for:

1. Administrative office including Web site and e-mail accounts.
2. Providing publicity information to individual member associations.
3. Ensuring that the President (or other representatives of Council) could represent EFSPI without relying on company support for all purposes.

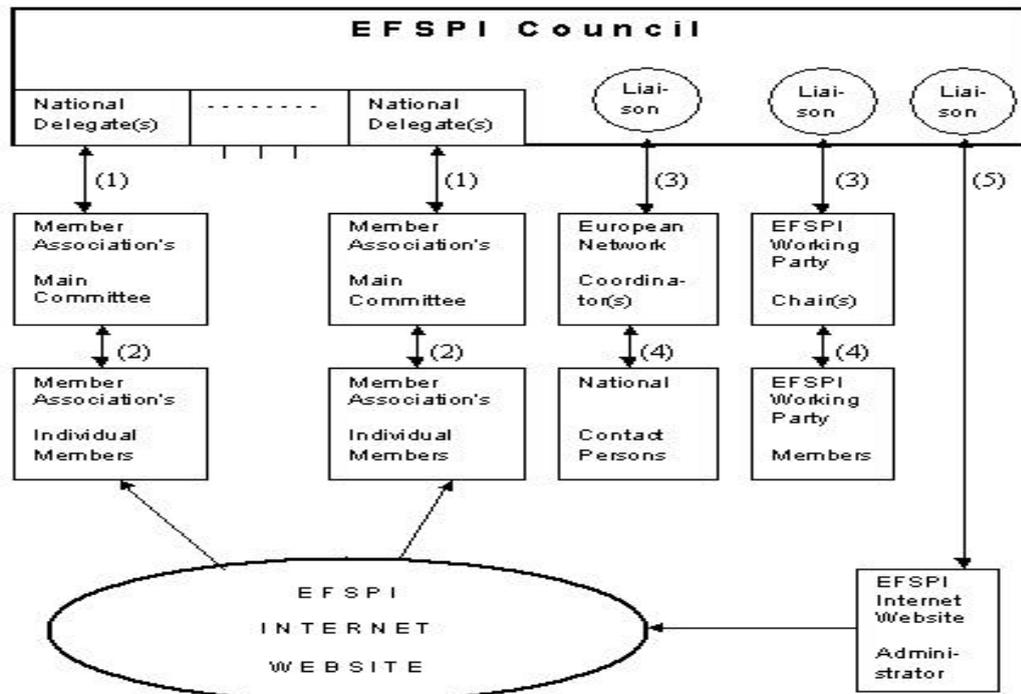
The yearly budget should be agreed upon by the Council in advance of the indicated year.

Each Member Association would be expected to pay an appropriate proportion of the yearly agreed EFSPI budget. A policy on this is at the discretion of the Council. For year 2000 it is expected that earlier commitments can be prolonged.

4.4 Internal communication/information

Internal communication refers to the exchange of information on and harmonisation of attitudes to the practice within the professional community of Statisticians in the European Pharmaceutical Industry. This is one of the constitutional objectives of the EFSPI.

It is suggested that an information model is adopted for EFSPI as outlined in the diagram below.



The explanation of the symbols that are used in this diagram, is as follows :

- (1) The interaction between the Council members and the Main Committee of their National Association is discussed in the 'Job description' for EFSPI Council representatives as given in Appendix 2.
- (2) The expanding availability of e-mail makes it the communication vehicle of the future. EFSPI should stimulate its Member Associations to create e-mail directories of its membership, since as a spin-off the 'forward' option enables a direct two-step information flow opportunity amongst Member associations and from EFSPI to individual statisticians, which is particularly of interest when communicating shortcut information.
- (3) Each European Network and EFSPI Working Party has its own co-ordinator/chair. If this person is not a Council Member, one of the Council Members shall act as Liaison Officer.
- (4) Communication within Networks or Working Parties shall be co-ordinated by their respective chairs.

- (5) The EFSPI internet website administrator may be from outside the Council. One of the Council Members shall act as Liaison Officer.

The current website can be found under: <http://www.medizin.Uni-Koeln.DE/projekte/efspi/index.htm>

Maintenance and responsibility of the website shall be transferred to the Administrative office. Update of the website is aimed for on a regular basis, e.g. monthly. The target group for the website is the European community of pharmaceutical statisticians. It is not meant as a communication vehicle for internal EFSPI Council affairs.

The EFSPI Internet Website shall contain the following basic material:

1. General information about EFSPI and its officers;
2. EFSPI Constitution;
3. Executive summaries of Council meetings;
4. Status reports of Working Parties of EFSPI and its Networks;
5. Annual reports;
6. General information about the Member groups;
7. Links to member groups.

In addition, the following material could be incorporated as deemed fit in due course:

1. Agenda for meeting/conferences/courses/seminars in Europe;
2. Selected publications from Member groups;
3. Information on selected Working Parties within Member groups;
4. Information on websites that contain Regulatory Guidelines and other interesting material;
5. Information on websites of organisations to which EFSPI holds external relationships;
6. Inventory of speakers and their subjects from past and future European meetings and conferences;
7. Inventory of European organisations/individuals that offer professional training courses.
8. Hyperlinks to other relevant websites.

4.5 External communication/information

External communication refers to the promotion of the standing of the statistical profession in matters pertinent to the pharmaceutical industry and the collective input on statistical matters to authorities and organisations. This is another constitutional objective of the EFSPI.

The table of organisations towards which EFSPI and on its behalf the European Networks and EFSPI Working Parties should have external relationships is given in Appendix 3. For consistency of communications, a single permanent address of EFSPI would be favourable, i.e. to the Administrative office.

In order to raise the profile of EFSPI it is proposed that a leaflet and other Public Relations material should be produced for delivery at conferences etc. Production of this material is suggested as a task for the Administrative office.

4.6 Expansion of EFSPI membership

The following countries with its national organisations are currently members of EFSPI: Belgium, Denmark, France, Germany, Italy, Netherlands, Spain, Sweden, Switzerland, United Kingdom:

Of the member countries Switzerland is not a member of the European Union (EU).

The following countries are members of EU but have no representation in EFSPI: Austria, Finland, Greece, Ireland, Luxembourg, and Portugal. A first wave expansion of EU will include countries such as Estonia, Hungary, and Czech Republic.

The way EFSPI is constituted there must be an exclusive national organisation that becomes a member and thereby represents the country. In the mentioned countries there does not exist an obvious national organisation with the required direction with the exception for Finland, with which EFSPI has started a discussion about a possible membership. Of other European countries, Norway has also showed an interest to be a member of EFSPI, but has presently no national organisation, which could apply for membership.

The recommendation is that we do not change the membership policy, for example to allow for individuals to be members or to create a system for indirect membership via a formal liaison to a neighbouring country. However, it should be possible for a country, which have a suitable national organization, to receive an associate membership and participate in the EFSPI activities on a non-voting basis. This should be possible for initially a period of at most two years to explore if a permanent membership would be of interest.

5. Changes to the EFSPI constitution

As consequence of the proposed changes the EFSPI Constitution must be revised. The previous version of the Constitution was dated 27 April 1995. In the proposed revision we have also included a few clarifications and spelling corrections. The proposed new version of the Constitution is enclosed as Appendix 4.

The following changes are proposed (with references to paragraphs of the Constitution):

1.2: A reference to the Administrative office is made.

2.1: A reordering of the objectives is proposed to emphasise the promotion of standards etc. as the primary objective. No new wording!

3.3 and 3.4: New paragraphs to cover the proposed associate membership and the financial support issue.

4.1: The role of the Administrative office is given.

4.2: The “National representative” is recognised and non-voting members are not included in the basis for voting.

4.6: Clarification that the President-elect shall be elected by the Council.

4.9: States that the president and vice-president shall jointly represent the Federation in financial and legal matters.

4.11: New paragraph stating the existence of an operational guideline and a job description.

5.1 and 6.2: Small clarifications only!

6. Points for decision

In summary, the following points for decision have been raised.

- (i) Could the proposed Operational Guideline for EFSPI Council be adopted?
- (ii) Could the proposed Job description for Council members be adopted?
- (iii) Could we agree to set up an Administrative office function providing administrative support up to 20% FTE (Full Time Equivalents)?
- (iv) Could we agree that a yearly budget including both income and expenses should be set up and decided by the Council in advance of the year concerned?
- (v) Is the proposed information model appropriate?
- (vi) Is the proposed contents of the EFSPI home page acceptable?
- (vii) Is the policy for external communication acceptable and the list of organisations with which EFSPI should have a relationship adequate?
- (viii) Could we agree to allow for an associate non-voting membership of EFSPI and otherwise not change the rules for membership?
- (ix) Do the changes of the Constitution adequately reflect the proposed changes for EFSPI operations.

7. Appendices

APPENDIX 1

Operational Guideline for EFSPI Council

A preliminary date and venue for a next Council meeting will be set at least 5 months in advance.

The President will request items for the agenda of a Council meeting at least 6 weeks before the meeting. Council members should indicate specific agenda items, with estimates of time needed for report and discussion. A final agenda will be distributed at least 4 weeks before the meeting.

EFSPI Council deals with three types of business:

1. **Routine business** should be reported in writing (preferably by E-mail) 4 weeks or more before the meeting, in order to allow time to read, consider and consult. Highlights and necessary decisions should be identified. If no action is required (i.e. update purely for information) no discussion is needed. Examples would include reports of working parties or follow-up to action items.

2. **Discussion documents** should follow the same plan as 1).

3. **Incidental items** should be handled in an ad hoc fashion. Only urgent items should avoid the procedures above - urgency to be agreed by the author with the EFSPI President. If not urgent, items should be changed into a Discussion Document for the next meeting.

The President will arrange in advance for a minute-taker for the meeting. Council members are responsible for noting their own 'urgent' action points in a meeting and carrying them out. The minute-taker will distribute draft minutes to meeting attendees within 14 days of the meeting, after approval by the President. Responses to the draft should be received within 7 days, with final draft minutes issued after a further 7 days (ie within 28 days of the meeting). Formal approval of the minutes will take place at the next Council meeting.

Any Council member unable to attend a Council meeting should submit an activity report indicating progress on action items.

The Council member hosting a meeting will liaise with the President regarding arrangements for the meeting. The host should send venue, travel and hotel information to members at least 4 weeks before the meeting.

APPENDIX 2

‘Job Description’ for EFSPI Council representatives

Two people represent each association. In order to maintain continuity, delegates should in principle be willing to serve for at least four years (Constitution 4.4). Ideally these individuals will combine to bring an appreciation of the working interests of all statisticians in the pharmaceutical industry - in particular being able to represent the interests of both clinical and non-clinical statisticians.

One representative should take responsibility for ensuring good communication to and from the association’s committee.

At least one representative should attend each EFSPI Council meeting.

Each country has one vote, to be cast by the ‘national member’. The two representatives should work together to achieve consensus on how any vote should be cast.

The responsibilities of the representatives include:

- to raise agenda items on behalf of their association, with prior agreement of the association;
- to ratify EFSPI decisions on behalf of the association;
- to inform their own association of any EFSPI decisions in conflict with the aims of the national association, and vice versa;
- to facilitate interactions between members of their own association and members of other EFSPI member organisations;
- to ensure distribution of copies of Council meeting minutes (and other documents) to association committee members, in draft if necessary to ensure timely communication;
- to support this documentation by giving verbal reports on EFSPI business at association committee meetings; this will include raising for discussion and seeking committee views on any contentious issues or where the two representatives have difficulty reaching agreement;
- to seek actively to identify issues the national association may wish to raise with council;
- to distribute material from individual EFSPI member organisations to national association committee members for use with regard to their own areas of responsibility;
- to produce articles and other material based on Council meetings to ensure national association members are aware of EFSPI activities;
- on any major issue, to consider whether it is appropriate to present back to the membership at a conference or other meeting of the national association.

APPENDIX 3: External relations

Currently external relations exist with the following professional associations (in alphabetical order):

Organi- sation	Nature of contact
DIA	European Office of Drug Information Association (Basle)
	Jointly organizing annual DIA meetings on Clinical Statistics and Non-Clinical Statistics. Informal personal relationships with DIA Advisory Board on Statistical Issues
EFPIA	European Federation of Pharmaceutical Industry Associations (Brussels)
	EFPIA does not allow other formal communication channels than with the national organizations that are member of this federation. Informal cooperation with EFPIA working groups on relevant guidelines from CPMP/ICH
FEDESA	Federation Européenne de Santé Animal (Brussels)
	The ESIGVSE Network participates in FEDESA working groups to review CVMP/VICH guidelines with statistical contents
IBS	International Biometric Society (Washington) and its Regions in Europe
	Our member groups from Germany and Switzerland are sections of the respective national region of IBS.
ISCB	International Society for Clinical Biostatistics (Fredensborg, DK)
	Join forces to convince European regulatory authorities to employ more statisticians Co-operation in commenting statistical guidelines from CPMP/ICH
ISI	International Statistical Institute (The Hague)
	ISI issues a yearly global directory of statistical organizations EFSPI participates in ISI conferences by organizing sessions
JPMA Japan	Japanese Pharmaceutical Manufacturers Association
	There exists an informal network of statisticians, towards which some EFSPI Council members have individual contacts.
PharMA USA	Biostatistics Subsection of Pharmaceutical Manufacturers Association
	Regular exchange of minutes has taken place in the past. A revival of this contact is planned

APPENDIX 4: Proposed new constitution

THE EUROPEAN FEDERATION OF STATISTICIANS IN THE PHARMACEUTICAL INDUSTRY

CONSTITUTION

Revision: 4 November 1999

1. NAME AND ADDRESS

- 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 federation is the office address of the President. The federation could also be reached via the contact person of the Administrative office.

2. OBJECTIVES

- 2.1 The aims of the Federation are:
 - 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 the Federation is open to constituted groups of statisticians and not to individuals.
- 3.2 Eligible for membership is one national group per country located within Europe, 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 both drugs and medicinal devices.

- 3.3 The Federation is open for an associate membership. This allows a national organisation to be represented in the EFSPI council on a non-voting basis for initially a period of at most two years, after which the membership status should be reviewed.
- 3.4 Each Federation member group agrees to provide a financial support in order for the Federation to be able to cover expenses for its operations. The financial support required will be based on a budget decided for the coming calendar year, and a unanimously agreed policy for division of contributions from the member groups.
- 3.5 To be granted both new and continuing membership of the Federation groups must satisfy the Council (see Section 4) according to the above criteria.

4. COUNCIL

- 4.1 The affairs of the Federation will be governed by the Council and administered through an “Administrative office”. The co-operation between EFSPI and an “Administrative office” should be regulated by a written contract decided upon by the Council.
- 4.2 The Council consists of one or two delegates from each of the member groups, one of whom is named the “National representative”. For the purpose of decision within the Council, each member group has one vote. A Council meeting will only be quorate if at least two-thirds of the member groups are represented at the meeting, excluding non-voting members. Whilst decisions will be taken on the strength of a simple majority, 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 chosen to serve for at least four years.
- 4.5 The officers of the Council shall be a President and a Vice-President, who is either the President-Elect or the immediate Past-President.
- 4.6 The President-Elect shall be elected by the Council every two years or as needed.
- 4.7 The President-Elect shall normally serve one year in that position, followed by two years as President, followed by one year as Past- President.
- 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 President and Vice-President are responsible for the execution of decisions made 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 jointly represent the Federation in financial and legal matters.

4.10 The Council will meet as frequently as its business demands, with a minimum of two meetings per year.

4.11 The working procedures of the Council and for the Council representatives should be directed by the “Operational Guideline for EFSPI Council” and the “ Job description for EFSPI Council representatives”, decided by the Council (Enclosure 1 and 2)

5. CONSTITUTION

5.1 Changes to the constitution may be proposed by any member group. These will be discussed by the Council and, if majority support is given, will be presented to member groups for ratification. Changes to the constitution will be made if ratified by at least two-thirds of the member groups. The English language version of all official documents (e.g. this Constitution) is the only official version. Translations into other Federation languages will be permitted, but must be authorised by the Council on the recommendation of a Council member. In the event of any conflict between the English version of an official document and any translation thereof, the English language version will apply.

6. MUTUAL CO-OPERATION

6.1 There will be a free exchange of information between Federation 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 Federation 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 Federation member group.