

## **EFSPI strategy – background document for Council meeting: 26 September 2001**

**[Updated after that meeting]**

### **1. Achievements** (related to objectives of EFSPI)

To promote professional standards of statistics and the standing of the statistical profession in matters pertinent to the European pharmaceutical industry

- EFSPI Working Party published report and paper on the qualifications and experience needed to be a professional statistician in the pharmaceutical industry
  - Published in Drug Information Journal, vol 33 (2), 1999
  - Presented at conferences of International Statistical Institute (Helsinki, 1999), Royal Statistical Society (Reading, 2000), PSI (Southampton, 1999), FMS (Umea, Sweden, 1999), Italian Statistical Society (Bressanone, Italy, 2000)
- EFSPI set up clinical statistics meetings with DIA in London (1993), Edinburgh (1994), Nice (1997) and Brussels (1999)
- EFSPI set up non-clinical statistics meetings with DIA in Bruges (1996), Nice (1998), Montreux (2000)
- EFSPI organised invited sessions at the International Statistical Institute conference in Florence (1993) and Helsinki (1999)

To offer a collective expert input on statistical matters to national and international authorities and organisations

- Joint EFSPI/EFPIA working party provided European input on consultation draft of ICH E9 (1997)
- EFSPI co-ordinated input from national member groups to provide single European pharmaceutical statistics view on ICH and CPMP consultation documents
- EFSPI was asked specifically for input by CPMP on Points to Consider document on Meta Analysis and One Single Study
- EFSPI published a critical review of ICH E10 in Drug Information Journal, vol 35 (4), 2001

To exchange information on and harmonise attitudes to the practice of statistics in the European Pharmaceutical Industry and within member groups

- EFSPI web-site contains links to all member groups web-sites
- There is a free exchange of information between Federation member groups in the areas of meetings, courses, conferences, working parties, expert teams and ad hoc groups
- Activities organised by member groups are open to individual members of any Federation member group
- EFSPI exchanges information with corresponding US and Japanese groups

- Informal networks established to facilitate communication between statisticians working in the non-clinical and veterinary areas

## **2. Revised SWOT analysis (updated from Rome Council meeting 1998)**

### **Strengths:**

- A federation representing 11 member groups and about 2 000 statisticians engaged in pharmaceutical industry activities implying a potential great impact
- A platform from which in particular smaller countries can exert influence on local authorities and clinical investigators
- The council constitutes a strong network of professionals with broad geographical coverage, which could be used for different purposes, such as setting up working parties, arranging meetings, identifying individuals with special competence, fostering cross-border activities etc.
- EFSPi does exist and has gradually increased its recognition among authorities and other professional associations.
  - recognition by EMEA in requesting input to CPMP consultative documents
  - recognition by ISI and IFAPP in requesting input to conferences
- Some structure in place
  - Regulatory Affairs Committee
  - Web-site liaison Officer
- Executive Office established
- Web-site under construction
- Processes in place for rapid response to consultative documents

### **Weaknesses:**

- Activities largely concentrated to the biannual meetings and to ad hoc temporary working parties.
- Council members and national associations are not always doing the basic activities of EFSPi (see Job Description).
- EFSPi is largely dependent on voluntary contributions from council members and the support from their employers
- Limited financial resources are available
- EFSPi is less known within the pharmaceutical companies and its member groups
- EFSPi does not cover the whole European union and cannot speak on behalf of non-member countries

### **Opportunities:**

- A co-ordination of opinions through a federation with a strong back-up from member

associations can be much more influential than the sum of impact from individual activities of the member associations

- EFSPI could be the European official spokesman of the profession (pharmaceutical biostatistics)
  - progress is being made
- EFSPI constitutes an established channel through which regulatory agencies, trade organizations (EFPIA), professional organizations (DIA, ISCB) can reach a large community of statisticians and through which EFSPI member associations can exert influence on these organizations
- EFSPI could counter-balance the strong influence from US in regulatory issues.
- Expand links with US and Japanese industry statisticians to create a ‘global federation’.
- Use EFSPI web-site to create the best pharmaceutical statistics site, with links to all relevant regulatory documents and maximum number of publications.
- Influence the provision and content of statistical education.
- Increase buy-in by giving feedback on regulatory comments to all who have contributed.
- Successful groups share knowledge /experience to assist smaller/weaker groups and foster cross-border activities.

**Threats:**

- A continuation of the present (modest) level of ambition for EFSPI may imply the take over by other actors (including some of our member associations)
- A failure to have appropriate communication with and back-up from our member associations may reduce our legitimacy to act on their behalf
- The inclusion of new members to cover all EU countries may require changes to organization, information, working procedures etc
- Perception among member groups that EFSPI exists only to exist, not to do things.

**3. Current regular services / committees**

<b>Committee /service</b>	<b>Responsible</b>	<b>Comment</b>
Regulatory affairs	Schmidt, DK; Jorgensen, DK; Aubin, FR  Rapporteurs for EFSPI Driessen (NL) / Martinez (ES) / Danielson (BE) / Astrom (SW) / Ebbutt (UK)	Respond to regulatory documents, chiefly ICH and CPMP. Proposal pending to develop process / structure.

	/ Huitfeldt (SW) / Schmidt (DK) / Koopman (NL)	
List of meetings and courses	Lemarie, FR	
Web-site	Aubin, FR	
ENSIGNS - non-clinical network	Jorgensen, DK - plus network of 9 national co-ordinators	Contribute to DIA non-clinical statistics meetings
Veterinary network	Smith, UK	Minimal activity
Meetings - ESAC/DIA - ISI - IFAPP	Ad hoc Huitfeldt, SW Morgan, UK TBD, UK	Contribute to DIA clinical statistics meetings.
Fund-raising WP	Huitfeldt, SW	
Strategy WP	Morgan, UK	
Public Relations materials	Koopman, NL	

#### 4. Benchmarking

One comparable organisation is IFAPP, the International Federation of Associations of Pharmaceutical Physicians. Appendix 1 gives some historical information. Further information is available from their website [www.ifapp.org](http://www.ifapp.org). The main activities of IFAPP are:

- international scientific meetings approx. every two years
- books of conference proceedings
- joint meetings with EMEA [which EFSPi have been invited to contribute to]
- Executive Committee holds monthly teleconferences
  - plus 2-3 face to face meetings per year
- Quarterly newsletter as special section in International Journal of Pharmaceutical Medicine.
- Press releases
- Web site, including electronic discussion board
- Annual budget of US\$20,000

What can EFSPI learn from the IFAPP experience?

## Appendix 1:



# International Federation of Associations of Pharmaceutical Physicians

————— *founded 1975* —————

## The History of IFAPP

*By Richard K Rondel, FRCP. FFPM (United Kingdom)*

The foundations of IFAPP were laid in 1970 by three British pharmaceutical physicians – Bill Burland, Jan Jouhar and Richard Rondel, who conceived the idea of holding an international meeting of medical advisers (as pharmaceutical physicians were then known), that would bring together physicians and scientists from the pharmaceutical industry with those working in research institutes and academic medicine. Their objective was to internationalise the advancement of knowledge of therapeutic agents and their actions, and also to foster the relationship between industry and academia.

They formed an organising committee, drafted a program, contacted speakers, found a conference venue and, importantly for the discipline, were able to secure the Patronage of His Royal Highness, Prince Philip, the Duke of Edinburgh. The resulting “International Meeting of Medical Advisers in the Pharmaceutical Industry” (IMAPPI) was held in London in April 1972 and attracted 500 delegates, drawn from virtually every country in the world. The success of this meeting led to a decision that it should be repeated, and that this should be linked to the formation of some form of International Association to which the Associations of Medical Advisers around the world could affiliate themselves. A steering committee was formed immediately, consisting of

- 1) a Working Party representing all existing Associations and
- 2) a body of correspondents representing those countries without such an Association.

First, it was agreed that an International Federation of Associations of Medical Advisers to the Pharmaceutical Industry (IFAMAPI) should be formed. An outline constitution was drafted and circulated to the 12 countries (Argentina, Belgium, Brazil, France, Germany, Holland, India, Italy, Japan, South Africa, Sweden and

the United Kingdom) that had Associations of Medical Advisers at that time. The Working Party had its first meeting in April 1973.

Second, it was agreed that the Second International Meeting of Medical Advisers in the Pharmaceutical Industry (2<sup>nd</sup> IMMAPI) would be held in Florence in October 1975. A theme was agreed and the programme put into first draft. The composition of the Planning Committee for the Second IMMAPI was drawn from the membership of the Italian organisation, SSFA (Society for Applied Pharmacological Sciences). This arrangement became the model for subsequent meetings in the series. Inter alia, it was felt that in this way the position of the host Association would become more firmly established in its own country – an expectation which has been borne out in every subsequent Meeting.

In January 1975 a notice was sent out to all potential delegates attending the Second IMMAPI in Florence. This contained the draft constitution together with proposals for the election of an Executive Committee charged with running the affairs of the International Federation. One complete session of the Florence meeting was to be set aside for the Official Foundation of the IFAMAPI. At this Foundation Meeting, the title of the Association was changed to “International Federation of Associations of Pharmaceutical Physicians” (IFAPP) to reflect the general move away from regarding industry doctors as simply medical advisors.

The arrangements thus agreed became the bedrock for the future development of both IFAPP and of subsequent International Meetings.

Since then, the series has developed as follows (Table 1):

Table 1. IFAPP Meetings from 1978 to the present time.

<b>Meeting</b>	<b>City</b>	<b>Year</b>	<b>Host Association</b>	<b>IFAPP President</b>
3 <sup>rd</sup>	Brussels	1978	ABEMIP/BEVAFI, Belgium	Dr H Lahon
4 <sup>th</sup>	Paris	1981	AMIP, France	Dr R Rondel
5 <sup>th</sup>	Munich	1984	FÄPI, Germany	Dr K J Hahn
6 <sup>th</sup>	Brighton	1987	BrAPP, UK	Dr D Burley
7 <sup>th</sup>	Madrid	1990	AMIFE, Spain	Dr J Grimbert
8 <sup>th</sup>	Rome	1994	SSFA, Italy	Dr L M Fucella
9 <sup>th</sup>	Stockholm	1996	LL/SAPPI, Sweden	Prof A Rosen
10 <sup>th</sup>	Boston	1998	AAPP, USA	Prof P D Stonier
11 <sup>th</sup>	Berlin	2000	DGPharMed, Germany	Prof J-M Husson

Each meeting has produced an imaginative program, reflecting the evolving pattern of drug development internationally, and the increasingly important role of the pharmaceutical physician in that process.

The proceedings of most of these meetings have been published in book form, and provide a unique record of the development of Pharmaceutical Medicine. The list of publications so far is shown in Table 2.

Table 2. Publications resulting from the IFAPP Meetings

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International Aspects of Drug Evaluation and Usage	(1972)
The Rationality of Drug Development	(1975)
Pharmaceutical Medicine - The Future	(1978)
Drug Safety – Progress and Controversies	(1981)
Drugs Between Research and Regulations	(1984)
The Focus on Pharmaceutical Knowledge	(1987)
Communications in Pharmaceutical Medicine	(1990)
Drug Development in the 90's – A Global Commitment	(1994)

In addition to sponsoring these major international meetings IFAPP has provided a framework within which national Associations – particularly the smaller ones – can hold local meetings. This is an aspect which we hope will grow.

In collaboration with the EMEA IFAPP started in 1997 organising yearly EMEA-IFAPP conferences at EMEA, Westferry Circus, Canary Wharf, London:

Conference	Date	Title
1st	10 October 1997	Challenges in Clinical Development of Medicinal Products: How to Revitalise the Process
2 <sup>nd</sup>	29 January 1999	Improving Co-Operation in the Clinical Development Process
3 <sup>rd</sup>	21 March 2000	Crisis Management Concerning the Clinical Safety of a Medicinal Product
4 <sup>th</sup>	16 March 2001	Managing Quality in Clinical Research and Development

In summary, from its beginnings in April 1972, the International Federation has grown steadily in size and scope. It has amply fulfilled its original objectives and in particular has provided support and encouragement for the development and strengthening of Associations at the national level. IFAPP can justifiably be proud of its achievements so far and can look forward with confidence to its strong, prosperous and active development in the years ahead. Its three founders could not have asked for more.





## **Appendix 2:**

### **Extract from Constitution**

#### **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.

#### **Job Description for EFSPI Council representatives**

(Agreed at the Council meeting in Brussels, 4 November 1999)

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.