

## FIP Rules of Procedure

# BU-E1: PROCEDURE FOR PROPOSING, ADOPTING OR REVISING/UPDATING FIP STATEMENTS

### A - PROCESS TO PROPOSE NEW FIP STATEMENTS

#### Step A1: Initiating the Process

Proposals for new FIP statements may be made by:

- FIP Member Organisations
- The Bureau
- The Board of Pharmaceutical Practice and Sections
- The Board of Pharmaceutical Sciences
- The FIP Education (FIPeD)
- The FIP Executive Committee

Proposals must be submitted to the CEO in writing. In each case, a draft text should be submitted, accompanied by a memorandum setting the context and giving reasons why it is considered that the FIP should issue a statement on the topic suggested. Also the relation to existing FIP Statements should be explained.

#### Step A2: Drafting of a FIP Reference Paper

The CEO will put the proposal on the agenda of the FIP Executive Committee and Bureau Meetings.

The FIP Bureau will decide if the proposal for a Statement to be made should be taken forward. If so, the Bureau will appoint a Working Group on a Reference Paper on.... (*the subject of the FIP Statement* (WGRP). This is to be done for each Statement approved to be taken forward.

However, in some cases a reference paper may not be necessary, for example:

- a. When we already have sufficient background information on the topic (e.g. in the form of a report or research paper).
- b. When there is an urgent need to have a statement on a time sensitive topic.

This will be decided by the FIP Bureau on a case by case situation.

The CEO will send the draft text, and details of any amendments to the convenor of the (WGRP).



Based on the information and guidelines of the Bureau, the WGRP will draft a Reference Paper on the requested subject.

The WGRP will communicate by e-mail and telephone conferences, and if necessary, at a face-to-face meeting. The FIP Executive Committee and the WGRP may call upon the service of experts to assist in the development of the draft texts. The WGRP will put the texts of the draft Reference Paper in the format normally adopted by the FIP for such documents.

An assessment form, detailing the impact of the proposed policy on the existing FIP statements should be provided together with the draft Reference Paper. In cases where the draft Reference Paper calls for replacement or a partial revision of one or more existing FIP statements, it should provide a clear rationale, and in the case of revisions - a brief summary of the proposed changes.

The convener of the WGRP will send the proposed texts for the draft Reference Paper and the assessment form to the CEO who will place them on the agenda for the next meeting of the FIP ExCo and the Bureau. The Bureau may accept, amend or reject a proposed text. A draft text accepted by the Bureau in its original or amended form will then proceed along the path of Step A3: The consultation process.

If the Bureau rejects a proposed Draft Reference Paper, it will decide the best way to make progress and will appropriately inform the Convener of the WGRP and the structure or structures from which the proposal submitted by the CEO to the WGRP emanated.

### **Step A3: The consultation process**

The consultation process is designed to ensure that all interested parties and particularly Member Organisations have maximum opportunity for input to the draft Reference Paper, and to provide guidance as to what the key elements in a FIP Statement should be. Two questions will be leading this consultation process:

1. What elements are missing in the Reference Paper and should be added?
2. What are the key issues from this Reference Paper that should be incorporated or highlighted in the FIP Statement?

The CEO will send the draft Reference Paper accepted by the Bureau to all Council Members with voting rights, being all Member Organisations, the Bureau and the BPP Section Presidents, as well as the representative of the Academic Institutional Membership for comments. A minimum of six weeks will be allowed for the receipt of comments by the CEO. The CEO will send the comments from



the Council Members and the answers to question 1. to the WGRP. The WGRP will then incorporate the relevant comments in the Reference Paper and send the final Reference Paper to the CEO.

This final version will be adopted by the FIP Bureau and presented at the next FIP Council meeting for information only.

The FIP Bureau will appoint a Policy Committee on the specific topic of the Reference Paper, who will draft the FIP Statement and propose revisions to the existing FIP policy as directed by the approved assessment form as described in step A4.

#### **Step A4: Drafting of a new FIP Statement**

The CEO will send the final Reference Paper, if applicable, and the approved assessment form, together with the comments of the Council Members and answers to Question 2 of the Consultation process and any other relevant information to the Chair of the Policy Committee (PC). The PC will draft an FIP Statement based on the Reference Paper or other background information, comments from the Council Members, and further guidance of the CEO.

The PC will communicate by e-mail and telephone conferences, and if necessary at a face-to-face meeting.

**[next step: C1]**

Fédération  
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International  
Pharmaceutical  
Federation

## **B - PROCESS TO REVISE EXISTING FIP STATEMENTS**

### **B1 - Initiating the process**

Proposals may be made by:

- FIP Member Organisations
- The Bureau
- The Board of Pharmaceutical Practice and Sections
- The Board of Pharmaceutical Sciences
- The FIP Education (FIPeD)
- The FIP Executive Committee

Proposals must be submitted to the CEO in writing, with a rationale highlighting the need for updating an existing FIP statement.



The FIP Executive Committee and Bureau will discuss this proposal and, if accepted, appoint a Policy Committee on the specific topic of the existing FIP statement.

The Policy Committee will ensure a first public consultation of the FIP Council members to identify key issues that are missing or are no longer relevant in the current FIP statement.

Further to this consultation, the PC will update the FIP Statement based on the comments from the Council Members, and further guidance from the CEO.

The PC will communicate by e-mail and telephone conferences, and if necessary, at a face-to-face meeting.

## C - DISCUSSION AND ADOPTION OF AN FIP STATEMENT

### **C1 – Consultation prior to the FIP Council meeting**

The PC will develop and send a first draft of the FIP Statement to the CEO, who will circulate this to the FIP Executive Committee and then Bureau for comments. The approved version will then be circulated to all FIP Council members for review, with the following question:

*“Are there any corrections, modifications or additions you would like to suggest? If so, please provide them with rationale.”*

Further to this consultation, the Policy Committee will revise and adjust the statement. At this stage, the Policy Committee should also draft the required revisions to any related existing FIP statements as directed in the approved assessment form. All draft documents should be submitted together to the FIP Executive Committee and Bureau for their final approval before its inclusion in the FIP Council agenda.

**Any suggested changes for revision in the statement should be sent during the consultation process before the Council meeting and only major issues should be discussed at the Council meeting to be incorporated.**

### **C2 – Discussion at the FIP Council**

#### **C2.a. First discussion at the FIP Council**

During the first sessions of the Council Meeting, the draft Statement and the Reference Paper (if applicable), together with the draft of the required revisions



to any related existing FIP statements will be presented to the meeting by the Chair of the Policy Committee.

The Chair will present the background information of the Reference Paper (if applicable) and/or Statement where applicable and a summary of the results of the consultation process. The Chair would also provide further information in cases where the proposed Statement: a.) replaces one or more existing FIP statement; b.) revises one or more existing FIP statement.

Delegates will then be invited to speak on a first come first served basis, with the intention to only identify significant changes that have consensus approval within the Council.

Any “wordsmithing” comments are deferred to a special semi-open hearing, in between the Council Meetings (whether face to face or virtual) or have to be submitted in writing for consideration by the PC between the Council meetings.

At the end of the allocated time, no decision on adoption or otherwise will be taken.

#### **C2.b. informal hearing in between the Council meetings**

The Policy Committee will conduct an informal hearing in between the two Council Meetings during the Congress to consider proposals for changes that appear to have the support of the Council, as well as suggested editing changes.

In the case that two or more Council delegates have expressed conflicting views on one or more points in the draft Statement, the Chair will invite them to join the semi-open hearing to further discuss these views. If no consensus can be achieved during the semi-open hearing, representatives of the different views will be asked to present their views at the next Council meeting.

#### **C2.c. Updated version of the FIP statements**

The amended texts for consideration at a resumed meeting of the Council will be available at the FIP Secretariat from 17.00 on the previous day to enable Council members to review the proposed changes, which will be highlighted if possible.

#### **C2.d. Final discussion at the FIP Council**

The Chair of the Policy Committee will present the amended draft Statement as well the draft of the required revisions to any related existing FIP statements. There will be only a relatively short time for discussion. In case of conflicting views (see above paragraph), the FIP President will give the floor first to the delegates with the different views, followed by the Chair to present his/her view. If necessary, the President can ask for a vote to support a specific proposal in order to settle the difference of opinion.



At the conclusion of the discussion, the FIP President, or Chair of the Council meeting in the absence of the President, will ask the question: “Is the Council ready to vote on the adoption of this Statement?” This will be a vote on whether the Council is ready to move to a vote on the draft Statement itself.

- If the Council votes negative, indicating that it is not ready to vote on the adoption of the text, the draft Statement will automatically be referred back to the Policy Committee for further consideration.
- If, however, the Council votes affirmative then, without further debate, the President, or Chair of the Council meeting in the absence of the President, will propose to the Council that the statement before them is to be voted on for adoption. **If the vote is against adoption, there will be no further consideration of the Statement. If the vote is in favour of adoption, the Statement will become a policy document of FIP. A vote for the Statement is also in favour of the proposed revisions in the other related existing FIP statements, presented as part of the same decision process.**

## D - Publications

The FIP reference papers will be placed on the FIP website as soon as possible after their adoption.

All Statements adopted by the Council will be translated from English into the other FIP official languages: French, Spanish and German. These will be placed on the FIP website as soon as possible after their adoption and translation. The Statements will also be available in hard copy on request and will be sent by FIP to relevant media for consideration of publication.

## E – Timelines

There is a timetable, which is designed to allow as long a period as possible for consideration of draft Statements by Member Organisations and the Sections of the BPP, as well as BPS and/or FIPed. The timetable is illustrated below. It will be noted that, other than in circumstances considered by the President to be exceptional and requiring the issue of a Statement as a matter of urgency, for it to be possible for a draft Statement to be considered by the Council, it will be necessary for the written proposal to be in the hands of the CEO within a few weeks of the FIP Congress held in the previous year.



Adoption of new FIP statement	Date	Revision of existing FIP statements
<b>Reference paper development and adoption:</b>		<b>Updated statement development and adoption:</b>
The Bureau discusses/decides on a new topic for a statement and appoints a WGRP.	August Y1	The Bureau discusses/decides on updating an existing FIP statement and appoints a Policy Committee to revise this statement.
The WGRP will draft a Reference Paper and an impact assessment form ( <i>see above</i> ) on the selected topic for consultation by the Council Members.	August Y1 – February Y2	The Policy Committee will run a first public consultation of the FIP Council members to identify key issues missing or no longer relevant in the current FIP statement. Based on the result of this consultation, it will update the FIP statement.
The Bureau approves and/or amends the draft Reference Paper for distribution to the Member Organisations.	March Y2	The Bureau approves and/or amends the draft Statement for distribution to the Council members.
The draft Reference Paper is distributed to the Council Members for comments.	April Y2	The draft Statement is distributed to the Council Members for comments.
Comments to the draft Reference Paper are collected by the CEO and forwarded to the WGRP.	April-May Y2	Comments to the draft statement are collected by the CEO and forwarded to the WGRP.
Final reference paper and the assessment form submitted to the FIP Executive Committee and to the Bureau for approval.	May-June Y2	Final statement submitted to the FIP Executive Committee and to the Bureau for approval.
<b>Reference paper presented to the FIP Council.</b>	<b>August-September Y2</b>	Draft Statement discussed and adopted by the Council.
<b>New statement development and adoption:</b>		
The FIP Executive Committee appoints a Policy Committee, to produce a draft FIP Statement based on the Reference Paper and comments from the Council Members. The Policy Committee should also draft the required amendments to other, related Statements as defined in the approved assessment form.	August-September Y2	
The Bureau approves and/or amends the draft Statement and the revisions of the related statements	March Y3	



Adoption of new FIP statement	Date	Revision of existing FIP statements
for distribution to the Council members.		
The draft policy package (Statement and revisions to related existing FIP statements) is distributed to the Council Members.	April Y3	
Comments to the drafts are collected by the CEO and forwarded to PC.	April-May Y3	
Final statement and revised existing statements are produced by the Policy Committee and submitted to the FIP Executive Committee and to the Bureau for approval.	May-June Y3	
<b>Draft policy package (Statement and revisions to related existing FIP statements) discussed and adopted by the Council.</b>	<b>August-September Y3</b>	

## F – Validity of FIP statements

The validity of a statement is five (5) years from the date of its adoption by the FIP Council. At that moment in time, the Bureau must consider whether: a.) to extend the validity of the statement for another period of five (5) years; or b.) to appoint a Policy Committee on the specific topic to revise the current statement; or c.) to forward the statement for archiving.

The final scheduled FIP ExCo and Bureau meeting each year will have a standing agenda item included which requires review of the status of all FIP Statements available as “current statements” on the FIP website. At this meeting the Bureau may elect to proceed with any of the above options (a, b or c) depending of the currency of any particular statement.

Taking into account their importance and relevance for FIP, as well as the needs for update given significant changes in practice, sciences, policy and/or other factors, the Bureau will report to the next Council meeting on their activity with regards to the review of the FIP Statements.