DECISION No 2/2002
of 20 June 2002
of the Joint Committee set up under the Agreement on mutual recognition between the European Community and Japan on establishing a subcommittee for the Sectoral Annex on good manufacturing practice (GMP) for medicinal products
(2002/619/EC)

THE JOINT COMMITTEE,

Having regard to the Agreement on mutual recognition between the European Community and Japan, and in particular Article 8(2) thereof,

Whereas paragraph 6 of the Sectoral Annex on good manufacturing practice (GMP) for medicinal products calls for the establishment of a subcommittee,

HAS DECIDED AS FOLLOWS:

1. A subcommittee of the Joint Committee, for the Sectoral Annex on good manufacturing practice (GMP) for medicinal products, is hereby established. The subcommittee shall function according to the attached rules of procedure.

2. This Decision, done in duplicate, shall be signed by the co-chairs. This Decision shall be effective from the date of the later of these signatures.

Tokyo, 6 June 2002

On behalf of Japan
Jun SHIMMI

Brussels, 20 June 2002

On behalf of the European Community
Philippe MEYER
ANNEX

RULES OF PROCEDURE

for the subcommittee under the Sectoral Annex on good manufacturing practice (GMP) for medicinal products

1. Introduction

The role of the subcommittee (‘SC’) for the Sectoral Annex on good manufacturing practices for medicinal products (‘Annex’) to the Agreement on mutual recognition (MRA) between the European Community (‘EC’) and Japan is, according to paragraph 6 of the Annex, to monitor the activities under both the preparatory and operational phases. In order to ensure the efficient operation of the SC, the description in the Annex is supplemented as follows to explain the SCs responsibilities, composition, and procedures in detail.

2. Responsibilities

The responsibilities of the Pharmaceutical SC are as follows:
(a) to report to and communicate with the Joint Committee;
(b) to coordinate joint activities;
(c) to monitor progress of the preparatory work of the Annex and the operation of the same;
(d) to facilitate regulatory collaboration and communications between the Japanese and EC competent authorities;
(e) to establish a procedure for coordinating equivalence of GMP for specific products or classes of products;
(f) to discuss and resolve where possible any major problems that occur and to present to the Joint Committee any issue which cannot be resolved;
(g) to establish and maintain a list of contact points for each Party;
and in particular with regard to the preparatory phase,
(h) to ensure that documentation and other information needed to reconfirm equivalence are communicated to the appropriate bodies;
(i) to agree detailed alert procedures;
(j) to reconfirm equivalence of GMP and their implementation;
(k) to identify products and classes of products falling under the definition of medicinal products under the scope of the Annex;
(l) to prepare, for adoption by the Joint Committee, the definition of emergency and modalities of visits to manufacturing facilities in such cases;
(m) to develop procedures to exchange documents and information;
(n) to prepare the detailed procedures for the implementation of the Annex, which are to be decided by the Joint Committee.

3. Composition of the SC

The SC will be composed as follows:
(a) each Party shall nominate a representative who shall jointly chair meetings of the SC. Participation in the SC from each Party should be balanced in terms of the size of their respective delegations;
(b) participants in the subcommittee meetings shall not include external parties such as representatives of industry, trade associations, or the press. All meeting attendees will be bound by the same confidentiality, conflict of interest and non-disclosure requirements as regulatory authority employees. The party on whose behalf a person is attending will ensure the attendee is bound by the relevant confidentiality, conflict of interest and non-disclosure requirements.

4. Procedures of meetings

(a) Unless otherwise decided, the meetings of the SC shall not be open to the public.
(b) The SC will meet at least once a year in person, or by teleconference with the agreement of both Parties. If required for the effective functioning of the Annex, and at the request of any one Party, additional meetings will be held.
(c) The SC will meet four times during the 18 month preparatory phase, unless it decides otherwise.
(d) The date and exact venue of the prospective meetings will be agreed to by the co-chairs.
(e) The draft agenda for each meeting will be prepared by the host co-chair and circulated to the participants in advance of the meeting along with the list of participants.
(f) Co-chairs are to agree the draft agenda.
(g) Each Party will endeavour to circulate the papers and reports to be tabled at each meeting at least two weeks beforehand.
(h) The host will prepare and circulate a table of agreed actions within two weeks from the end of each meeting and the draft summary record of each meeting within one month from the end of each meeting.
(i) Draft summary record and table of agreed actions should be finalised within a further four weeks and agreed to by the co-chairs.
(j) The SC will hold ad hoc meetings as requested by either party and as frequently as both Parties agree is necessary to fulfil the obligations of the Annex.
(k) The Party hosting a meeting shall arrange logistical matters. Meetings convened by teleconferencing shall be arranged by the co-chair that requested the meeting.
(l) The following shall apply with regard to the use of languages:
   — written communication between the co-chairs shall be in English,
   — the Party hosting a meeting of the SC shall provide interpretation between Japanese and English and bear the cost for this.

5. Adoption of documents

The SC shall:
(a) adopt the agenda at each meeting.
(b) review the table of agreed upon actions from the previous meeting during each meeting.
(c) adopt all documents to be submitted to the Joint Committee.
(d) adopt documents by consensus. If the Parties have different positions on a topic, a document may describe each Party's views.

6. Reporting arrangements with the Joint Committee

The SC shall:
(a) report in writing on the outcome of the preparatory phase to the Joint Committee.
(b) transmit copies of the adopted agendas and summary records of at least its formal annual meetings to the Joint Committee.

7. Communications to external parties

(a) Both Parties will agree on a common statement on the status and operation of the Annex, as appropriate, at the end of each meeting.
(b) This external communication is to be issued as soon as possible after the meeting; each Party will distribute the common statement as it determines is appropriate.