COMMISSION OF THE EUROPEAN COMMUNITIES

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COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS

Draft Rules of Procedure

I

Explanatory memorandum

By Council Directive 75/319/EEC of 20 May 1975 a Committee on Proprietary Medicinal Products was set up with the main task to discuss concrete cases regarding authorization of proprietary medicinal products.

In the Directive it is stated that the Committee shall draw up its own Rules of Procedure. The Council adopted at the same time as the Directive a declaration according to which "the Commission shall submit to the Council the draft Rules of Procedure. Subject to the observation it may formulate, the Council takes notice of the draft, the adoption of which is agreed to by the Comission and the Member States" (doc. 643/75 (RP/CRS 16) of 30 July 1975).

The attached draft Rules of Procedure have been agreed to by the representatives of the Member States in the Committee.

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Draft Rules of Procedure of the Committee for Proprietary Medicinal Products

THE COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS,

Having regard to Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products(1), and in particular Article 8 (3) thereof,

HAS DRAWN UP ITS RULES OF PROCEDURE AS FOLLOWS :

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1 OJ N° L 147, 9.6.75, p.

Article 1

1. The Committee shall consist of one representative for each Member State and one representative of the Commission. One alternate shall be appointed for each of the representatives.

2. The Committee members and the alternates shall be appointed by the Member States for three years provided they continue to be national officials responsible for examining applications for authorization to market proprietary medicinal products. Their appointments shall be renewable.

3. An alternate shall sit as such on the Committee only if the full member is absent or is unable to discharge his duties.

4. Each representative may be accompanied at Committee meetings by not more than three experts.

5. Even after their duties have ceased, members, alternates and experts shall be required not to disclose information of the kind covered by the obligation of professional secrecy.

Article 2

The Committee shall elect its Chairman from among its members by absolute majority and secret ballot. If, after two ballots, no candidate has obtained an absolute majority of the votes, the member who obtains the relative majority at the third ballot shall be elected. In the event of a tie the oldest candidate shall be declared elected.

Article 3

The term of office of the Chairman shall be three years. He shall be eligible for re-election once only.

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Article 4

On taking up his duties, the Chairman shall cease to be a representative and shall be replaced in that capacity.

Article 5

Two Deputy Chairmen shall be appointed to replace the Chairman when he is absent or unable to discharge his duties. One shall be elected by the Committee and the other appointed by the Commission.

The provisions of Articles 2 and 3 of these Rules of Procedure shall apply to the election and the term of office of the elected Deputy Chairman.

Article 6

The Committee shall be convened by its Chairman, either on his own initiative or at the request of a member.

Article 7

The Chairman shall draw up the agenda, which shall distinguish between :

(a) objections to applications for marketing authorizations submitted to the Committee for an opinion under Article 11 (1) of Directive 75/319/EEC;

(b) refusals, suspensions or revocations of marketing authorizations submitted to the Committee for an opinion under Article 12 (2) of Directive 75/319/EEC;

(c) fresh examinations of previous opinions under Article 13 of Directive 75/319/EEC;

(d) specific cases submitted under Article 14 of Directive 75/319/EEC.

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Article 8

Requests to convene the Committee which are made by a member shall be drawn up in accordance with the classification in the foregoing Article and reasoned so that they may constitute the working paper of the Committee.

Article 9

1. Pursuant to Article 9 (1) of Directive 75/319/EEC, the Member State concerned shall forward to the Committee a dossier containing :

   (a) a copy of the request for forwarding to the competent authorities of the Member States specified;

   (b) a copy of the marketing authorization;

   (c) the particulars and documents specified in the second paragraph of Article 4 of Directive 65/65/EEC.

   There shall be forwarded as many dossiers as there are Member States specified, plus one for the secretariat of the Committee.

2. Pursuant to Article 9 (2) of Directive 75/319/EEC, the Committee shall forthwith forward this dossier to the competent authorities of the Member States specified.

3. The Committee shall forward to the members of the Committee the documents referred to in paragraph 1(a) and (b).

Article 10

1. The particulars and documents referred to in points (1) to (7) and (9) to (11) of the second paragraph of Article 4 of Directive 65/65/EEC shall be provided in the official language or one of the official languages of each of the Member States specified. The particulars and documents referred to in point (8) of the second paragraph of Article 4 of the said Directive may be provides in a language acceptable to the Member State specified.

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2. The particulars and documents specified in the second paragraph of Article 4 of Directive 65/65/EEC and intended to be preserved by the secretariat of the Committee shall be provided in a language acceptable to the Committee.

3. The dossier preserved by the secretariat of the Committee may be consulted by any member of the Committee or by the experts referred to in Article 1 (4) with the written authority of the member.

Article 11

1. The notice convening the meeting, the agenda and the working papers shall be forwarded by the Chairman to the members of the Committee in accordance with the procedure laid down in Article 18 (2) and (3).

2. These papers shall be drawn up in a language acceptable to the Committee.

3. These papers shall be delivered to the Permanent Representatives of the Member States and to the Commission not later than fifteen days before the date of the meeting.

4. In urgent cases, the Chairman may, at the request of a member of the Committee or on his own initiative, shorten this period of notice by up to three clear working days, stating the grounds for his decision.

Article 12

1. There shall be a quorum at meetings of the Committee if six Member States are represented.

2. The representative of a Member State may, if necessary, act as the representative of one other Member State. The Chairman of the Committee shall be informed accordingly by the Permanent Representative of the Member State who is to be so represented.

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Article 13

The Committee may set up panels of experts to study matters of common interest.

Article 14

The secretarial services for the Committee shall be provided by the Commission, assisted, if necessary, by experts.

Article 15

1. The Member States concerned shall be informed forthwith of the reasoned opinions delivered under Articles 11 and 12 of Directive 75/319/EEC in accordance with the procedure set out in the first subparagraph of Article 18 (2).

2. Minutes shall be prepared under the responsibility of the Chairman for each meeting; they shall be forwarded to the members of the Committee in accordance with the procedure set out in Article 18 (2) and (3). Any comments which the members may wish to make shall be communicated to the Chairman in writing. The Chairman shall pass them on to the Committee; if there is disagreement, the proposed amendment shall be discussed at the following meeting. If disagreement persists, this amendment shall be appended to the relevant minutes.

Article 16

The Chairman of the Committee shall act on behalf of the Committee for the purpose of making the formal record referred to in Article 10 (1) of Directive 75/319/EEC.

He shall forthwith inform the Member States concerned of such formal record in accordance with the procedure set out in the first subparagraph of Article 18 (2).

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Article 17

1. The secretariat of the Committee shall act on behalf of the Committee for the purpose of forwarding the dossier referred to in Article 9 (2) to the competent authorities of the Member States in accordance with the procedure set out in the first subparagraph of Article 18 (2) and, for the purpose of forwarding the documents referred to in Article 9 (3).

2. Any information forwarded to the Committee in accordance with Articles 11 (3), 12 (4) and 33 of Directive 75/319/EEC shall be brought to the knowledge of the members of the Committee by the secretariat in accordance with the procedure set out in the second subparagraph of Article 18 (2).

Article 18

1. Correspondence concerning the Committee shall be addressed to the secretariat of the Committee, Directorate-General for the Internal Market, for the attention of the Chairman.

2. Correspondence intended for the representatives of the Member States shall be addressed to the Permanent Representatives.

   Copies of such correspondence shall be addressed directly to the representatives of the Member States.

3. Correspondence intended for the representative of the Commission shall be addressed to the Commission, Directorate-General for the Internal Market.

Article 19

Notwithstanding Article 214 of the Treaty, the work of the Committee and of the panels of experts and all the documents submitted to them shall be treated as confidential. Nevertheless, the representatives of the Member States may, in accordance with the national laws in force, inform the person responsible for marketing a medicinal product or products of the reasoned objection of a Member State, as referred to in Article 10 (2) of Directive 75/319/EEC.

Financial Record Sheet

1. The Committee on Proprietary Medicinal Products is composed by representatives of the Member States and of the Commission.

   The Committee will meet in the following cases:

   - When it is wanted to market the product in at least five Member States other than the first Member State having authorized the product
   - When Member States have taken different decisions regarding the same product
   - When in specific cases, Member States ask for the opinion of the Committee before reaching a decision concerning a marketing authorization

2. It is not possible to predict anything exact about the frequency of the meetings of the Committee because it depends on manufacturers and Member States to what extent the Committee-procedure will be used. However, taking into account the time-limits which shall be followed by the Committee when a case is brought for it it would be reasonable to estimate the annual number of meetings to twelve. Every Member State may send a delegation with 4 Members (one administrator, one analyst, one pharmacologist and one clinician) to the meetings. They will only be paid the travel costs from the Commission.

3. Under the mentioned suppositions the costs for the Commission will be around 250.000 FB per meeting or annually 3.000.000 FB.