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Procedures for marketing authorisation

CHAPTER 6

DECISION MAKING PROCEDURE FOR THE ADOPTION OF COMMISSION DECISIONS

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This Chapter 6 "Decision making procedure" will be included in The Rules governing Medicinal Products in the European Community
The Notice to Applicants - Volume 2A - Medicinal products for human use - Procedures for marketing authorisation

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CHAPTER 6 - Decision Making Procedure for the Adoption of Commission Decisions

1. LEGAL BASIS AND SCOPE

The legal basis for Commission and Council decisions is to be found in the EC Treaty (Articles 202, 211 and 249). Community decisions in the pharmaceutical sector arise in the following instances:

- Community marketing authorisation granted in accordance with Regulation (EC) No 726/2004 and related procedures;
- Community referral procedures (arbitration);
- Designation of a medicinal product as an orphan.

Decisions adopted by Community institutions shall be binding in their entirety on their addressees which, in the pharmaceutical sector, may be Member States or pharmaceutical firms.

2. DECISION-MAKING PROCEDURE

The procedure for the adoption of Commission decisions related to Community marketing authorisations and referral procedures is laid down in the following legal texts:

- Community marketing authorisations:
    - Article 10 of Regulation (EC) No 726/2004[1];
    - Article 6 of Commission Regulation (EC) No 2141/96[2];
    - Articles 4 to 9 of Commission Regulation (EC) No 1085/2003[3].
- Community referral procedures (arbitration): Article 34 of Directive 2001/83/EC[4].
- Designation of a medicinal product as an orphan: Article 5 of Regulation (EC) No 141/2000[5].

2.1 Preparation of a draft decision

Within 15 calendar days of receipt of an opinion of the EMEA which is complete and compliant with the requirements of Regulation (EC) No 726/2004, the Commission prepares a draft decision taking the opinion and any relevant provisions of Community

[1] OJ L 136, 30.4.2004, p. 1.
[2] OJ L 286, 8.11.1996, p. 6.
[3] OJ L 159, 27.6.2003, p. 24.
[4] OJ L 311, 28.11.2001, p. 67. Directive last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).
[5] OJ L 18, 22.1.2000, p. 1.

law into account. Where the draft decision is not in accordance with the opinion of the EMEA, the Commission shall annex a detailed explanation of the reasons for the differences.

– **Internal consultation**

All decisions of the Commission must reflect the position of the entire Commission as a collegiate body. Therefore the other services of the Commission are consulted on the draft decision before it is sent for external consultation within the Standing Committee or, where the Standing Committee is not called on to intervene, before it is adopted.

– **Annexes to the draft decision**

Annexes in the case of decisions related to Community marketing authorisations:

Annex I: Summary of the product characteristics

Annex II:

A: Manufacturer of the biological active substance and manufacturing authorisation holders responsible for batch release
B: Conditions of the marketing authorisation
- Conditions or restrictions regarding supply and use imposed on the marketing authorisation holder
- Conditions or restrictions with regard to the safe and effective use of the medicinal product

C: Specific obligations to be fulfilled by the marketing authorisation holder

Annex III:

A: Labelling
B: Package leaflet

Annexes in the case of decisions in Community referral procedures:

Annex I: List of the names, pharmaceutical forms, strengths of the medicinal product, route of administration, applicant/marketing authorisation holders in the Member States

Annex II : Scientific conclusions

Annex III : Summary of product characteristics and, as appropriate, labelling and package leaflet [6]

Annex IV: Conditions of the marketing authorisation

These will become the annexes of the final Commission decision once it is adopted.

[6] See Chapter 1 section 4 referrals according to Article 31(2) of Directive 2001/83/EC

2.2. Standing Committee phase

In the area of medicinal products for human use, the Commission is assisted by the Standing Committee on Medicinal Products for Human Use (the "Standing Committee").

The Standing Committee is chaired by the Commission representative, who does not vote. Member States representatives' votes are weighted as described in Article 205(2) of the EC Treaty (decision by a qualified majority of 232 out of 321 votes).

The opinion of the Standing Committee relating to Commission decisions concerning Community marketing authorisations and referral procedures is adopted in accordance with the management procedure of Articles 4 and 7 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[7]. The period laid down in Article 4(3) of 1999/468/EC is set at one month. (See Articles 87(3) of Regulation (EC) No 726/2004 and 121(3) of Directive 2001/83/EC).

The Rules of Procedure of the Committee can be consulted in [insert link once RoP adopted and published]

In the cases where the consultation of the Standing Committee is not necessary, the decision is adopted by the Commission within 15 calendar days of receipt of the opinion of the EMEA.

– **Procedures which require the consultation of the Standing Committee:**

(a) Decisions related to Community marketing authorisations, in the following cases:

- new application (Article 10 of Regulation (EC) No 726/2004);
- application for an extension (Article 2 and Annex II to Commission Regulation (EC) No 1085/2003);
- conditional marketing authorisation (Article 14(7) of Regulation (EC) No 726/2004 and Commission Regulation (EC) No …/2005);
- annual reassessment of a marketing authorisation granted under exceptional circumstances (Article 14(8) of Regulation (EC) No 726/2004);
- renewal of the marketing authorisation (Article 14 of Regulation (EC) No 726/2004);
- suspension and revocation (Article 10 of Regulation (EC) No 726/2004);
- provisional measures (Article 20 of Regulation (EC) No 726/2004).

(b) Decisions adopted in Community referral procedures

[7] OJ L 184, 17.7.1999, p.23.

- where Member States fail to reach an agreement in the framework of a mutual recognition or decentralised procedure (Article 29 of Directive 2001/83/EC);

- where divergent decisions have been taken by Member States (Article 30 of Directive 2001/83/EC);

- in cases of Community interest (Article 31 of Directive 2001/83/EC);

- where mutual recognition of variations has not been accepted (Article 35 of Directive 2001/83/EC);

- where a Member State considers that the variation of a marketing authorization or its suspension or withdrawal is necessary for the protection of public health (Article 36 of Directive 2001/83/EC);

- where a medicinal product is to be authorised in accordance with Regulation (EC) No 726/2004 and the scientific opinion by the EMEA contains conditions or restrictions with regard to the safe and effective use of the product (Article 127a of Directive 2001/83/EC).

(c) Decisions concerning designation of a medicinal product as an orphan where the draft Commission decision is <u>not</u> in accordance with the opinion of the Committee on Orphan Medicinal Products.

– **Procedures which do <u>not</u> require the consultation of the Standing Committee:**

(a) Decisions related to Community marketing authorisations, in the following cases:

- transfer of the marketing authorisation (Article 6 of Commission Regulation (EC) No 2141/96);

- withdrawal at the marketing authorisation holder's request;

- type II variations (Article 6 of Commission Regulation (EC) No 1085/2003);

- type I variations (Article 4, notification type IA, and Article 5, notification type IB, of Commission Regulation (EC) No 1085/2003. The Commission does not adopt decisions for any opinion on a type I variation adopted after 1 October 2003. These variations are included in the first six-monthly update of the marketing authorisation in accordance with Article 4(5) and Article 5(7) of the said Regulation for type IA and type IB notifications, respectively, or at the occasion of the next change to the Commission Decision (type II variation, transfer, renewal, annual reassessment, extension …), whichever is the earlier.

- variations for human influenza vaccines (Articles 7 and 8 of Commission Regulation (EC) No 1085/2003);

- variations reflecting urgent safety restrictions (Article 9 of Commission Regulation (EC) No 1085/2003);

(b) Decisions concerning designation of a medicinal product as an orphan where the draft Commission decision is in accordance with the opinion of the Committee on Orphan Medicinal Products.

– **Standing Committee – Written procedure**

The opinion of the Standing Committee will normally be given by written procedure.

The draft decision is forwarded by the Commission to the competent national authorities designated by each Member State (in their own language) by electronic telecommunication or in written form.

Member States shall have 22 calendar days to forward their written observations on the draft decision to the Commission. However, if a decision has to be taken urgently, a shorter time-limit may be set by the Commission according to the degree of urgency involved. This time-limit shall not, otherwise than in exceptional circumstances, be shorter than 5 calendar days.

Within this time-limit, Member States must inform the Commission whether they approve the draft, reject it, or abstain. Any Member State failing to respond within the time-limit to express its opposition or intention to abstain from voting is deemed to have approved the draft.

Member States may forward written comments during the written procedure.

a) Member States may ask in writing, duly stating the reasons, for the draft decision to be considered at a Standing Committee meeting. In this case, the Commission closes the written procedure with no result, and calls a Committee meeting as soon as possible.

b) If, in the opinion of the Commission, the written comments forwarded by a Member State raise important new scientific or technical questions not addressed in the EMEA's opinion, it suspends the written procedure, submits a request for a further opinion to the EMEA, and informs the Standing Committee.

– **Standing Committee meeting**

A meeting of the Standing Committee is convened by the Commission in the following cases:

a) arising from comments raised during the written procedure (see above);

b) in the framework of a referral procedure, in exceptional cases where the draft decision prepared by the Commission is not in accordance with the EMEA's opinion (third paragraph of Article 33 of Directive 2001/83/EC);

c) in urgent cases and where measures are to be applied immediately.

– **Adoption of the opinion of the Committee**

- Favourable opinion

If the opinion is favourable (i.e. a qualified majority of 232 out of 321 votes is in favour of the draft Commission decision), the Commission will proceed to the adoption of the decision.

- Negative opinion - submission to the Council

If the opinion is unfavourable, the Commission will equally proceed to the adoption of the decision and communicate it to the Council. The Commission may defer application of the decision for a period of one month from the date of such communication. The Council, acting by qualified majority, may take a different decision within the mentioned period.

2.3 Adoption and notification of the decision

The Commission will take a final decision within 15 calendar days after the end of the Standing Committee phase.

The decision takes effect from the date of the notification of the decision. Both the date of the decision and the date of notification are mentioned in the Official Journal. Details of decisions on Community marketing authorisation and related procedures and of decisions on Community referral procedures are published in volume C of the Official Journal at one-monthly intervals.

For decisions concerning centralised marketing authorisations, the final Commission decision with annexes in the authentic language is addressed and notified to the marketing authorisation holder. The 19 Community linguistic versions[8] of the decision are sent in electronic form.

For decisions concerning referral procedures, the final Commission decision with annexes is addressed to the Member States and notified to them via the Permanent Representatives. It is also sent in electronic form in the 19 Community linguistic versions to the companies concerned.

For decisions concerning the designation of a medicinal product as an orphan, the final Commission decision is addressed and notified to the sponsor.

For all decisions, the members of the Standing Committee, the EMEA and the EEA States Norway, Iceland and Liechtenstein also receive the final Commission decision with annexes in the 19 Community linguistic versions in electronic form.

[8] Council Regulation (EC) No 930/2004 of 1 May 2004 on temporary derogation measures relating to the drafting in Maltese of the acts of the institutions of the European Union, OJ L169, 1.5.2004.

EMEA opinion

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15 days	***Reception by the European Commission services of the appropriate documentation*** - Documentation checking - Generation of the draft Commission decision - Inter-service consultation (around 10 days)
22 days	***Written Procedure (22[9] days according to Regulation (EC) No726/2004)*** - Draft Commission decision with the annexes sent in the 19 Community linguistic versions[10] to the Member States and marketing authorisation holder
15 days	***Adoption phase*** - Receipt of the amended version of the annexes if required - Generation of the final Commission decision - Sending of the final Commission decision with annexes in the authentic language (language of the marketing authorisation holder) to the Secretariat-General - Signature of the Director General of DG Enterprise and Industry on behalf of the Commissioner: sub-delegation procedure

[9] However, if a decision has to be taken urgently, a shorter time-limit may be set by the Chairman according to the degree of urgency involved. This time-limit shall not, otherwise than in exceptional circumstances, be shorter than 5 days.

[10] Council Regulation (EC) No 930/2004 of 1 May 2004 on temporary derogation measures relating to the drafting in Maltese of the acts of the institutions of the European Union

	Notification phase - Notification of decisions concerning centralised marketing authorisation: by paper copy to the marketing authorisation holder of the final Commission decision with the annexes in the authentic language only. - Notification of decisions concerning referral procedures: the decisions with annexes are notified to the Permanent Representatives who are in charge of their transmission to the National Authorities. - Notification of decisions concerning the designation of a medicinal product as an orphan: by paper copy to the sponsor. - Sending of the final Commission decision with Annexes in the 19 Community linguistic versions to the members of the Standing Committee, the EMEA, the EEA States Norway, Iceland and Liechtenstein and the marketing authorisation holder in electronic form (Eudralink)