The European Agency for the Evaluation of Medicinal Products
*Evaluation of medicines for human use*

London, 8 June 2001
CPMP/1635/01

# EMEA PUBLICATION POLICY OF CPMP SUMMARIES OF OPINION

## 1. Introduction

In February 2000, following the outcome of the public consultation on the EMEA transparency initiatives with Interested Parties and the EMEA's Management Board's decision, Summaries of Opinion were published after the adoption of the Opinion by the CPMP, once the 15 day period for notification of appeal had elapsed and the Opinion had therefore become final. It was also agreed that applicants should not communicate before "day 15". This initiative started in June last year and its implementation was monitored in collaboration with EFPIA.

Thereafter following the Transparency Workshop of November 2000, the EMEA Management Board, at its February 2001 meeting, gave a mandate to the Executive Director to implement the recommendations made by the Workshop with effect from 1 April 2001. These recommendations include the publication on the day of adoption of CPMP opinions for initial applications.

In April 2001, the EMEA published for the first time Summaries of Opinion at "day 0" corresponding to the date of adoption of the CPMP opinion (see EMEA Website). Such Summaries of Opinion will continue to be published following the conclusion of each plenary CPMP meeting. The procedure for the publication of Summaries of Opinion is outlined below.

## 2. Procedure

The process **only applies to CPMP Opinions on initial applications for Marketing Authorisation.** The EMEA will publish Summaries of Opinion after adoption of the CPMP Opinion, at "day 0", which corresponds to the day of the adoption of the CPMP Opinion. Such information will be mentioned in the CPMP Press Release published together with these Summaries of Opinion. **Both positive and negative CPMP opinions will be published**[1]. After the adoption of the CPMP opinion following an appeal procedure or further to a request from the European Commission in the framework of the Standing Committee procedure, the same procedure publication applies (see Templates I and II describing the content of such Summaries of Opinion).

| Steps | Task description |
|---|---|
| **Step 1** | ▪ The week prior to the CPMP week (at the latest the Monday of the CPMP week) the applicant will receive a copy of the draft Summary of Opinion (e-mail or fax) from the EMEA Product Team Leader **for comments** (24 hours). |
| **Step 2** | ▪ Following the adoption of the CPMP Opinion[2], the Summary of Opinion is sent (e-mail or fax) to the applicant during the last day of the CPMP plenary meeting **for information** prior to its publication on the EMEA Website and at the latest the Friday of the CPMP week. |
| **Step 3** | ▪ Once the Commission Decision is issued, the Summary of Opinion will be deleted from the EMEA Website and replaced by the EPAR. |

## 3. References

▪ Twenty-ninth meeting of the Management Board Press Release (EMEA/MB/011/01).

▪ Outcome of public consultation on new EMEA Transparency initiatives (EMEA/D/16906/00).

[1] This does not apply to any withdrawn applications prior to adoption of CPMP opinion.
[2] Applicants may appeal any CPMP opinion, provided they notify the EMEA in writing of their intention to appeal within 15 days of receipt of the opinion adopted by CPMP.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 20
E-mail: mail@emea.eudra.org http://www.emea.eu.int/

**TEMPLATE I**

London, <date>
CPMP/<no.>/01

**COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS SUMMARY OF OPINION[*] for <NAME OF THE PRODUCT>**

International Nonproprietary Name (INN): ***<name of the active substance>***

On *<date of the adoption of the opinion (last day of the CPMP meeting)>* the Committee for Proprietary Medicinal Products (CPMP) adopted a *<positive/negative>* opinion,[**] recommending *<not>* to grant a marketing authorisation for the medicinal product *<name of the product, strengths, pharmaceutical form>* intended for *<treatment of /prophylaxis against/diagnosis of> <disease>*. *<Name of product was designated as an orphan medicinal product on <date>>*. The applicant for this medicinal product is *<name of the company>*.

The active substance of *<name of the product>* is *<INN>*, an *<therapeutic class>* medicinal product *<(ATC Code) and brief description of mode of action>*.

***(For a positive opinion)***

The benefits with *<name of product>* are its *<brief statement on the character of the main clinical benefits in terms of the approved indication(s)>*. The most common side effects are *<brief statement on the character of the main safety concerns>*.

The approved indication is: "*<the indication as worded in the CPMP approved SPC>*". *<It is proposed that <name of the product> is prescribed by physicians experienced in the treatment of <disease>* ***the wording of this particular sentence should be in line with section 4.2 SPC****>*. Detailed conditions for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CPMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for *<name of the product>* and therefore recommends the granting of the marketing authorisation *<under exceptional circumstances>*.[***]

***(For a negative opinion)***

The grounds for the negative opinion relate to the following points*:*

*<Brief statements on the major grounds for refusal of the marketing authorisation)>*.

The CPMP, on the basis of quality, safety and efficacy data submitted, considers that there is an unfavourable benefit to risk balance for *<name of the product>* and therefore cannot recommend the granting of the marketing authorisation.

---

[*] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the Opinion.

[**] Applicants may appeal any CPMP opinion, provided they notify the EMEA in writing of their intention to appeal within 15 days of receipt of the opinion.

[***] Marketing Authorisation under exceptional circumstances refers to the fact that in exceptional circumstances an authorisation may be granted subject to certain specific obligations, to be reviewed annually.

**TEMPLATE II**

London, < date >
CPMP/<no.>/01

**COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS SUMMARY OF OPINION[*] for <NAME OF THE PRODUCT>**

***further to new information[**] or to a request from the European Commission in the framework of the Standing Committee procedure***

*International Nonproprietary Name (INN):* ***<name of the active substance>***

On *<date of the adoption of the opinion (last day of the CPMP meeting)>* the Committee for Proprietary Medicinal Products (CPMP), having considered new information, adopted a *<positive/negative>* opinion,[***] recommending *<not>* to grant a marketing authorisation for the medicinal product *<name of the product, strength(s), pharmaceutical form>* intended for *<treatment of /prophylaxis against/diagnosis of> <disease>*. *<Brief statement on the background with dates>*. *<Name of product was designated as an orphan medicinal product on <date>>*. The Applicant for this medicinal product is*<name of the company>*.

The active substance of *<name of the product>* is *<INN>*, an *<therapeutic class>* medicinal product *(ATC Code) and brief description of mode of action>*.

***(For a positive opinion)***

The benefits with *<name of product>* are its *<brief statement on the character of the main clinical benefits in terms of the recommended indication(s)>*. The most common side effects are *<brief statement on the character of the main safety concerns>*.

The approved indication is: "*<the indication as worded in the CPMP approved SPC>*". *<It is proposed that <name of the product> is prescribed by physicians experienced in the treatment of <disease>* ***the wording of this particular sentence should be in line with section 4.2 SPC*** *>*. Detailed conditions for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CPMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for *<name of the product>* and therefore recommends the granting of the marketing authorisation *<under exceptional circumstances>*.[****]

***(For a negative opinion)***

The grounds for the negative opinion relate to the following points*:*

*<Brief statements on the major grounds for refusal of the marketing authorisation: (indicate as per category in the annex of the List of Questions template)>*. The CPMP, on the basis of quality, safety and efficacy data submitted, considers that there is an unfavourable benefit to risk balance for *<name of the product>* and therefore cannot recommend the granting of the marketing authorisation.

---

[*] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the Opinion.

[**] See *Conduct of Pharmacovigilance for Centrally Authorised Products*, CPMP/183/97, page 7

[***] Applicants may appeal any CPMP opinion, provided they notify the EMEA in writing of their intention to appeal within 15 days of receipt of the opinion.

[****] Marketing authorisation under exceptional circumstances refers to the fact that in exceptional circumstances an authorisation may be granted subject to certain specific obligations, to be reviewed annually.