The European Agency for the Evaluation of Medicinal Products
Directorate

London, 28 February 2000
Doc. Ref: EMEA/D/6135/00

Public consultation on new EMEA transparency initiatives

Significant progress has been made over the past years towards improving the transparency in the work of the EMEA and its scientific opinions. That this has been achieved in partnership with the EU institutions, national authorities and interested parties is a mark of success. The current practice of the EMEA is set out in the document Points to consider for an EMEA communication policy (EMEA/MB/011/98 - Rev.2) available on the EMEA web site, dated 3 December 1998.

As part of our ongoing efforts, the Management Board considered a new proposal from EFPIA at its meeting of 22 February 2000 on the publication of a summary of opinion – whether positive or negative – on the day of adoption by the scientific committees.

All interested parties in both the human and veterinary medicines sectors are now being consulted on the proposal to publish summaries of opinions and to seek your views on the development of a more coherent post-marketing communications strategy.

A. Publication of summaries of opinions

Views are invited on the following points:

- It is the intention of the EMEA to publish a *Summary of opinion* for all opinions on the granting of a marketing authorisation adopted by both the CPMP and CVMP.
- This policy is expected to take effect from the April 2000 meetings of the CPMP and CVMP.
- Summaries, for both positive and negative opinions, will be based on the attached templates; templates I and II for medicines for human use, and templates III and IV for veterinary medicines. Summaries will be published on the EMEA web site. Copies of these templates are attached.

Full information relating to the evaluation of the medicinal product and other product information, including the summary of product characteristics, will continue to be published on the day of authorisation in the European public assessment report (EPAR).

B. Post-marketing communications

Post-marketing communication has significant public health implications for patients, users of medicines and health professionals. Views are invited as to the points to be taken into consideration by the EMEA in the development of a post-marketing communications strategy.

Comments on any of the above points are invited by 1 April 2000 and should be sent to:

By mail to:

Directorate
EMEA
7 Westferry Circus
Canary Wharf
London
UK – E14 4HB

By fax to:

00.44.20.7418 8409

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Switchboard (44-20-7) 418 8400 Fax (44-20-7) 418 8409
E-mail: mail@emea.eudra.org http://www.eudra.org/emea.html

Annex I - Draft Template to be used in case of a positive or negative CPMP opinion in the initial review phase, i.e. = day 210

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS SUMMARY OF OPINION*
for <name of the product>

International Non-proprietary Name (INN): <name of the active substance>

On *<date of the adoption of the opinion>* the Committee for Proprietary Medicinal Products (CPMP) adopted a *<positive/negative>* opinion** *<to/not to>* recommend the granting of a Marketing Authorisation for the medicinal product *<name of the product>* intended for *<treatment of /prophylaxis against/diagnosis of>* *<disease>*. The Applicant for this medicinal product is<name of the company>.

The active substance of *<name of the product>* is a *<therapeutic class –cfr. ATC system and brief description of mode of action>*.

(For a positive opinion)

- The benefits with *<name of product>* relate to its *<brief statement on the character of the main clinical benefits>* and its most significant side effects relate to *<brief statement on the character of the main safety concerns>*.

The approved indication is for *<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>>*. 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 European Union official 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 efficacy and safety data submitted, considers that there is an unfavourable benefit to risk balance for *<name of the product>* and therefore can not recommend the granting of the Marketing Authorisation.

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* Summaries of Opinions 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.

Annex II - Template to be used in case of a revised CPMP opinion following an appeal or further to a request from the European Commission in the framework of the Standing Committee procedure

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COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS SUMMARY OF OPINION*
for <name of the product>

International Non-proprietary Name (INN): <name of the active substance>

On *<date of the adoption of the opinion>* the Committee for Proprietary Medicinal Products (CPMP), having considered new information, adopted a *<positive/negative>* opinion *<to/not to>* recommend the granting of a Marketing Authorisation for the medicinal product *<name of the product>* intended for *<treatment of /prophylaxis against/diagnosis of> <disease>*. *This was f*ollowing *<brief statement on the background with dates>*. The Applicant for this medicinal product is<name of the company>.

The active substance of *<name of the product>* is a *<therapeutic class –cfr. ATC system and brief description of mode of action>*.

(For a positive opinion)

- The benefits with *<name of product>* relate to its *<brief statement on the character of the main clinical benefits>* and its most significant side effects relate to *<brief statement on the character of the main safety concerns>*.

The approved indication is for *<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>>*. 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 European Union official 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 efficacy and safety data submitted, considers that there is an unfavourable benefit to risk balance for *<name of the product>* and therefore can not recommend the granting of the Marketing Authorisation.

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** 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.

Annex III - Draft Template to be used in case of a positive or negative CVMP opinion in the initial review phase, i.e. = day 210

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS SUMMARY OF OPINION*
for <name of the product>

International Non-proprietary Name (INN): <name of the active substance>

On *<date of the adoption of the opinion>* the Committee for Veterinary Medicinal Products (CVMP) adopted a *<positive/negative>* opinion** *<to/not to>* recommend the granting of a Marketing Authorisation for the veterinary medicinal product *<name of the product>* intended for *<treatment of /prophylaxis against/diagnosis of>* *<disease>* in *<species>*. The Applicant for this veterinary medicinal product is *<name of the company>*.

The active substance of *<name of the product>* is a *<therapeutic class –cfr. ATC Vet system and brief description of mode of action> and is included in Annex <no.> of Council Regulation (EEC) 2377/90 (this is deleted for immunologicals).*

(For a positive opinion)

- The benefits of *<name of product>* relate to its *<brief statement on the character of the main clinical benefits>* in *<species>* and its most significant side effects relate to *<brief statement on the character of the main safety concerns>*.

The approved indication is for *<the indication as worded in the CVMP approved SPC>* in *<species as stated on 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 European Union official languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, efficacy and safety 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 CVMP, on the basis of quality, efficacy and safety 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.

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* Summaries of Opinions 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 CVMP 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.

Annex IV - Template to be used in case of a revised CVMP opinion following an appeal or further to a request from the European Commission in the framework of the Standing Committee procedure

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COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS SUMMARY OF OPINION*
for <name of the product>

International Non-proprietary Name (INN): <name of the active substance>

On <*date of the adoption of the opinion*> the Committee for Veterinary Medicinal Products (CVMP), having considered new information, adopted a <*positive/negative*> opinion <*to/not to*> recommend the granting of a Marketing Authorisation for the veterinary medicinal product <*name of the product*> intended for <*treatment of /prophylaxis against/diagnosis of*> <*disease*> in <*species*>. *This was f*ollowing <*brief statement on the background with dates*>. The Applicant for this veterinary medicinal product is<name of the company>.

The active substance of <*name of the product*> is a <*therapeutic class –cfr. ATC Vet system and brief description of mode of action*> *and is included in Annex <no.> of Council Regulation (EEC) 2377/90 (this is deleted for immunologicals).*

(For a positive opinion)

- The benefits of <*name of product*> relate to its <*brief statement on the character of the main clinical benefits*> in <*species*>and its most significant side effects relate to <*brief statement on the character of the main safety concerns*>.

The approved indication is for <*the indication as worded in the CVMP approved SPC*> in <*species as stated in 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 European Union official languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, efficacy and safety 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 CVMP, on the basis of quality, efficacy and safety 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.

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* Summaries of Opinions are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption 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