The European Agency for the Evaluation of Medicinal Products
Directorate

London, 13 August 2003
Doc. Ref: EMEA/D/21621/03/Consultation

Public consultation on EMEA transparency initiatives

The EMEA has introduced a number of initiatives since 1995 to improve the openness and transparency of its activities. In each case these initiatives were the subject of public consultation before their introduction.

This latest consultation exercise is being held at the same time as the European Union institutions are looking at proposals to revise EU pharmaceutical legislation. These legislative proposals include a number of important changes to the sort of information that the EMEA will be required to make public, but will depend on the final outcome of the legislative process. The progress of these discussions can be followed on the web site of the European Commission Pharmaceuticals Unit at *http://pharmacos.eudra.org/F2/review/index.htm*

The attached document sets out eleven initiatives, which are divided into two groups. The first group looks to build on existing EMEA communication tools and the second group consists of new initiatives that are independent of the transparency aspects of the European Commission legislative proposals.

Views are invited on the proposals. It is intended to present the outcome of the consultation exercise to the Management Board at its meeting of 2 October 2003. Comments should be received by Monday 15 September 2003 to ensure that they are taken into account in the paper that will be presented to the Management Board.

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Part I – Initiatives relating to existing communication tools

1. EMEA web site

The EMEA web site (*http://www.emea.eu.int*) is currently being revised in order to further improve its user-friendliness, e.g. by creating a specific "safety information update" folder in order to allow quick and easy access to safety information, by making available a specific folder on orphan drugs. The presentation, user-interface and search tool will be improved.

2. European public assessment reports (EPARs)

In case of divergent opinions (both for pre- and post-authorisation activities) more details will be provided in EPARs by including the minority view of members of the Committee for Proprietary Medicinal Products (CPMP) and Committee for Veterinary Medicinal Products (CVMP) members, although the names of these members will not be disclosed.

Information as to whether good clinical practice and good laboratory practice inspections have been performed will also be added.

3. Information on Community referral procedures

The availability of information in relation to Community referral procedures will be improved after discussion with the scientific committees. These improvements include:

- More consistency as to the amount of available information irrespective of the legal basis of the referral procedure
- Release of more details at the start of the procedure (e.g. in relation to the scope of the referral procedure)
- Release of background information on the CPMP/CVMP opinion, scientific conclusions, summary of conditions (e.g. post-authorisation studies) and amended product information (if relevant), at the moment of the Commission decision

4. Product information for centrally authorised medicinal products

It is proposed that a cross reference to the availability of the EPAR on the EMEA web site will be included in both the summary of product characteristics (SPC) and package leaflet for centrally authorised products.

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5. Press releases and meeting reports

- Information on opinions on applications for new indications has been included in CPMP press releases since the third quarter of 2002. This will be extended to include information on other major post-authorisation activities and will be linked to the publication of summaries of opinions for such post-authorisation activities (see initiative number 8 below).
- The layout of CPMP technical meeting reports will be revised to make these reports more readable. In addition, the outcome of MRFG meetings will no longer be attached to the CPMP technical meeting reports, but be made available at the Heads of Agencies website (*http://heads.medagencies.org*). A more visible link between the EMEA and the heads of agencies web sites will be created.
- The press releases from the Management Board, Committee for Veterinary Medicinal Products and Committee for Orphan Medicinal Products will also be reviewed.

6. CPMP guidance documents

The layout of CPMP guidance documents will be changed, for example to include an executive summary that provides high-level information on any changes that have been introduced as a result of the revision of such guidance documents.

In addition, the current consultation process should be made more transparent by disclosing the list of consulted parties and by publishing a summary of the comments made during the consultation process.

This will be done within the context of a revision of the current procedure for developing guidance documents.

7. Interaction with EMEA stakeholders in relation to medicines for human use

- Interaction between the EMEA and stakeholders should in general be more proactive and more targeted information should be provided. Initiatives that could be undertaken range from informing interested parties in a proactive way about the availability on the EMEA web site of new information in relation to topics for which they had expressed an interest, to the development of an EMEA strategy on interaction with patients.
- Interaction with the press could be further strengthened by the organisation of press info days. Access by pharmaceutical analysts to such briefing events will need to be determined. In addition, the possibility of holding embargoed pre-briefing meetings with the press will be explored.

Part II – New initiatives

8. Publication of CPMP summaries of opinions for post-authorisation applications

Summaries of opinions for initial marketing authorisations were introduced as a result of a public consultation exercise in 2000. It is proposed to extend this policy to include publication of summaries of opinions for post-authorisation applications, where they have an important impact on the use of the medicinal product.

This will include line extensions (new strengths, new pharmaceutical forms) and variations affecting the following sections of the product information: therapeutic indications, posology and method of administration, contra-indications, special warnings and special conditions for use. Other sections may be considered on a case-by-case basis, e.g. pregnancy.

9. Publication of 'question and answer' documents

In major public health situations leading to the publication of an EMEA press release or public statement (whether or not related to an authorised product), it is proposed to publish simple 'question and answer' documents. The documents will be drafted in easily understandable terms for the target audience (health care professionals, patients, general public, media).

10. Publication of safety bulletins for medicines for human use

The EMEA is exploring the possibility of publishing regular safety information under the format of a bulletin. Issues to be considered include the content, how often the bulletin will be published, as well as how it will be made available. Additional items that could be included in the bulletin could include profiles of new centrally authorised products, information on risk management programmes, stimulation of reporting of adverse drug reactions, etc.

11. Inspection-related activities

Consideration will be given to making the work of regulatory meetings such as the ad hoc meetings of good clinical practice and good manufacturing practice inspection services more transparent. This could include publication of suitably adapted work plans, meeting summaries and information on procedural documents developed. Question and answer documents will be prepared as necessary to assist industry and regulators in understanding new legislative or operational initiatives such as the implications of mutual recognition agreements and the clinical trials directive.