



New EMEA transparency policy measures

Background

A public consultation exercise was launched on 13 August 2003 on a number of new EMEA transparency proposals. The proposals were based on the document endorsed by the Management Board at its October 2002 meeting (EMEA/MB/041/02).

The public consultation document set out eleven initiatives, divided into two groups. The first group looked to build on existing EMEA communication tools and the second group consisted of new initiatives that are independent of the transparency aspects of the European Commission legislative proposals.

Responses

There were 17 responses to the EMEA transparency consultation. Two of the responses are from the same respondent and one response is on behalf of two bodies. The type of responses varied greatly, with some short general comments, some short contributions on specific issues and some in-depth and some responses addressing transparency in its widest sense.

The respondents are also varied. There is one individual response from a respected academic in the area of health policy, from two pharmaceutical companies, two responses from media organisations in the pharmaceutical field, two regulatory affairs consultancies, one response from a healthcare professional representative group, two contributions from patient and consumer groups and six contributions from pharmaceutical industry associations. The contributors were as follows:

1. Prof. John Abrahams (Centre for Research in Health and Medicine, University of Sussex, UK)
2. Alliance ERAS Ltd
3. Association Mieux Prescrire/La revue Prescrire
4. European Association for BioIndustries (EuropaBio)¹
5. European Consumers Organisation (BEUC)
6. European Federation of Pharmaceutical Industries and Associations (EFPIA)
7. European Generic manufacturers Association (EGA)
8. European Group for Generic Veterinary Products (EGGVP)
9. European Patients Primary Immunodeficiency Collaboration (EPPIC) and Primary Immunodeficiency Association (PiA)
10. Eye-Care Industries EEIG
11. Global Regulatory Solutions Ltd
12. International Federation of Animal Health-Europe (IFAH-Europe)
13. Pharmaceutical Group of the European Union (PGEU-GPUE)
14. PharmaNor hf.
15. Reuters Health
16. Wyeth

Contributions are published on the EMEA web site where permission has been given to do so.

¹ Due to technical issues this contribution was received after the Management Board meeting. It has been included in this revised document since it largely supports comments made by other contributors.

Public

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.

All aspects of this proposal were welcomed in the contributions, which also acknowledged recent improvements to the EMEA web site.

The EMEA relies on the web site as its principal means of communicating and giving access to information on the Agency’s work. There were comments however on the lack of transparency for people without access to the Internet and also the need to improve the availability of information in all official EU languages, not just English.

Criticism was made of the search tools and the technical style in which some documents are written. EMEA was asked to make efforts to make its documentation more patient-friendly.

A number of contributors also asked for more information on the organisational structure of the Agency and contact points for specific issues. There were also calls for easier access to guidelines and in particular more visibility to guidelines and other documents under public consultation.

EMEA recommendations:

- (a) That the proposed initiative should be implemented as part of the ongoing revision of the EMEA web site.
- (b) That multi-lingual navigation of the web site should be made possible once a stable web site environment has been achieved.
- (c) That the EMEA/CPMP Working group with patients’ organisations should be asked to look at ways of making available more patient-friendly information, both through the web site and other appropriate channels.
- (d) That more information on the organisational structure of the EMEA should be made available, including contact points for specific topics.

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 manufacturing² practice inspections have been performed will also be added.

² The consultation document mistakenly read ‘good *laboratory* practice’. It should have read ‘good *manufacturing* practice’.

Views on this initiative concerning EPARs were mixed. Some contributors supported proposals to include divergent views from Committee members, while others felt that this could impact on confidence in the medicinal product. Other contributors felt that the content of the EPARs provided enough information and that no more details should be provided.

There were comments on the current format of the EPAR, in particular that it is not suitable for non-technical readers and in particular to most patients. The need to update EPARs more regularly was also raised.

A request for inclusion of the names of the Committee members and experts responsible for drawing up the assessment reports ('rapporteurs', 'co-rapporteurs' and their expert teams) was made. This was the practice of the EMEA until 2002 after which the details of experts were removed following concern by some Member States for the safety of experts involved in certain aspects of pharmaceutical evaluation. The names of the experts are known to applicant companies.

There were also requests that more information should be made available for applications that are either withdrawn or receive a negative opinion. These issues are under discussion by the European Parliament and Council as part of the review of Regulation (EEC) No 2309/93 and are therefore not included in the scope of this consultation exercise. Similarly, comments concerning the inclusion of the added therapeutic value of medicines fall outside the mandate of the EMEA and cannot be considered.

Comments were received concerning the Agency's definition of commercially confidential information that is deleted from EPARs and also the process by which EPARs are approved. These issues are covered by a separate standard operating procedure on the preparation of a European public assessment report (EMEA/SOP/H/3003) and are outside the scope of this consultation exercise.

EMEA recommendations:

- (e) That the proposed initiative should be implemented.
- (f) That the EPAR should include references to GCP and GMP inspections conducted.
- (g) That the EMEA/CPMP Working group with patients' organisations should be asked to look at the EPAR and ways of making it more patient-friendly.

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 Committee's opinion, scientific conclusions, summary of conditions (e.g. post-authorisation studies) and amended product information (if relevant), at the moment of the Commission decision

The proposal to improve information on arbitration and Community referrals made to the EMEA is supported by respondents. Comments received included the provision of more explanation for the reasons for the referral and its legal basis.

There was some concern that provision of information on referrals could have a negative impact on the confidence of patients and health care professionals, and also on the companies involved. It was proposed not to publish either the name of the products concerned or the companies.

EMA recommendations:

- (h) That the scientific committees should be consulted on proposals for a more consistent publications policy for referrals made to the EMA.
- (i) This will include the publication of more information on the grounds for referral, on the assessment, any follow-up studies requested as part of the procedure and the amended product information where appropriate. As with EPARs for centrally authorised products, this information should be published once the Commission decision has been taken.
- (j) Information should be made public at the time of the referral itself and should include the name of the product or substance (as appropriate) concerned. The provision of this sort of information has been the practice of the EMA for a number of years and it would be reduction in the level of transparency to stop this. The publications policy should however ensure that this information is provided in a consistent manner for all referrals.

4. Product information for centrally authorised medicinal products

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

There were only four comments made on this particular proposal. The contributions from the consumer organisation and a health care professional association supported the initiative as a means of improving access to information by patients, although it was commented that more effort should be made to improve the readability of patient leaflets.

Comments from two of the industry associations did not support the proposal. One contributor felt that too much information would cause confusion for the end-users of medicines. Provided that the EPARs were more user-friendly and updated more regularly however the other trade association felt able to accept the proposal.

EMA recommendation:

- (k) That the proposal be implemented, but that this should be accompanied by efforts to improve the readability of EPARs and their regular updating.

5. Press releases and meeting reports

- Information on opinions on applications for new indications has been included in CPMP and CVMP 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 EMA 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 continue to be reviewed.

This proposal was supported by contributors.

One contributor from a media organisation requested that the EMEA should provide embargoed information to the press to allow them to prepare their material, in much the same manner as many companies (and indeed some national authorities) currently provide for product approvals, etc. One trade association however requested further consultation on this part of the proposal before proceeding.

It was also questioned why the press releases for the Committee for Orphan Medicinal Products (COMP) do not contain more information on their designation opinions, as is currently the practice for the CPMP and CVMP.

EMEA recommendations:

- (l) That the proposal be implemented, in particular with regard to the provision of information on post-authorisation activities and the working parties and ad hoc groups.
- (m) That work on improvements to the press releases and meeting reports of the each of the committees and Management Board should be continued with a view to improving transparency and to harmonising the information provided, including product-related information.
- (n) That there should be further consultation with relevant interested parties on the provision of embargoed information to the media.

6. Guidance documents

The layout of guidelines³ 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 the document.

In addition, the current consultation process should be made more transparent by disclosing the list of consulted parties⁴ 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.

This proposal was widely supported by contributors. A number of comments were also made concerning the process surrounding the development of guidelines, which while outside the scope of this consultation exercise will be looked at by the EMEA as part of an ongoing project to revise the so-called 'guideline on guidelines'.

An additional comment concerned the regular updating of the work programmes of the working parties, in particular to update interested parties on expected completion dates.

EMEA recommendations:

- (o) That the proposal be implemented as part of the EMEA revision of the 'guideline on guidelines'.
- (p) Other contributions concerning the guideline development process should be looked at as part of this revision, in particular the need for systematic consultation on concept papers prior to commencing work on new guidelines.

³ The term 'guideline' is used in accordance with EU pharmaceutical legislation in preference to the less specific term 'guidance documents'.

⁴ This should be understood as meaning the list of parties who responded to the consultation.

7. Interaction with EMEA stakeholders

- 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.

This proposal had wide support and there were many suggestions on specific ways of developing EMEA interaction with stakeholders. Proposals ranged from provision of information to parallel distributors, to more info days with interested parties, more interaction with media and public, more involvement of healthcare professionals and more communication between the EMEA and industry during procedures.

EMEA recommendation:

- (q) That the proposal be implemented and that the suggestions from contributors be looked at in further developing interaction.
- (r) The proposals relating to relations with the media and financial analysts should be looked at as part of the specific consultation set out in recommendation (n).

Part II – New initiatives

8. Publication of 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, and species in the case of veterinary medicines. Other sections may be considered on a case-by-case basis, e.g. pregnancy.

This proposal was supported. Two industry associations stressed that post-marketing communication should only be done where there is a public health added value. A health care professional association requested that divergent positions of committee members should be included. This is not currently the practice of the EMEA for summaries of opinion for initial applications, but will be retained as a proposal in any future review of the Agency's policy concerning summaries of opinion.

EMEA recommendation:

- (s) That the proposal be implemented.

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).

This proposal was supported, but it was stressed by a number of parties that the 'question and answer' documents should be prepared in consultation with the marketing authorisation holder. There were also some presentational comments and an offer from a health care professional association to use their network to disseminate the information.

EMEA recommendation:

- (t) That the proposal be implemented, together with a procedure for the preparation of 'question and answer' document, including appropriate consultation.

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.

There was a cautious approach to this proposal by contributors. While acknowledging the potential usefulness of a safety bulletin from the EMEA, it was generally felt that the target audience and content needed to be carefully researched in particular not to duplicate efforts already made at Member State level. As an alternative to a bulletin publication, it was also suggested that the EMEA should work towards creating a single web site portal to handle safety enquiries regardless of authorisation route.

EMEA recommendation:

- (u) That further examination of the scope of the publication of safety information should be made before proceeding with the implementation of this proposal.

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.

There was strong support for this proposal from industry trade associations. There were specific requests for more transparency in the way the Ad hoc meeting of good manufacturing practice inspectors operates and prepares its guidance to industry, and also for publication of the main weak points observed in inspection to help guide industry.

EMA recommendation:

- (v) That this proposal should be implemented, taking into account the comments made by contributors.

12. Orphan medicinal products

This proposal was not included in the public consultation document. It was supported by the Management Board and a separate consultation exercise will be held on the question.

The proposal relates to a recommendation contained in the *Communication from the Commission on Regulation (EC) No 141/2000 of the European Parliament and of the Council on orphan medicinal products*⁵ for the publication of the name of designated orphan drugs when an application is submitted for marketing authorisation,

“1.4. Transparency regarding Marketing Authorisation applications for designated orphan medicinal products

In order to aid transparency, when a sponsor of a designated orphan medicinal product submits an application for a marketing authorisation to the EMA or to a national competent authority, it is recommended that the competent authority publish the name (INN) of the active substance of the designated orphan medicinal product.”

- (w) The EMA supports this recommendation from the European Commission and, with the approval of the Management Board, intends to consult with interested parties on the wider proposal that the EMA should publish the name of the active substance of a designated orphan medicinal product when the sponsor submits an application for marketing authorisation, together with the indication applied for.

⁵ OJ C 178, 29.07.2003, p. 2