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Points to consider for an EMEA communication policy

Background

As an illustration of the principles of transparency, accountability and good administration, public authorities are under increasing pressure from the public at large towards greater openness and communication.

At the workshop on transparency and access to documents held on 30 October 1997, its social and institutional partners welcomed the level of transparency achieved by the EMEA.

In principle, the Agency only releases information on medicinal products once a Community marketing authorisation has been granted by the European Commission. The EPAR is then placed on the Agency's Internet site.

At its December 1997 meeting, the Board gave delegation to the Executive Director to explore specific initiatives for further improvements to transparency. On that basis and with growing experience in the centralised procedure, new orientations could be explored in relation to communication issues in particular during evaluation and immediate post-opinion stages.

Since the EMEA is only part of a global European system, Community and national practices on this matter should converge as far as possible.

I – APPLICATIONS UNDERGOING EVALUATION

In principle, the Agency does not release any information on applications undergoing evaluation. Similar practices are noted at national level as shown in the EMACOLEX survey on public access circulated by Denmark on 11 May 1998.

Withdrawal of applications in general

As a point of principle, consideration should be given on whether applicants should continue to have, under Community law, the possibility to withdraw centralised or decentralised applications. This option is currently available. Prof. Benzi raised the issue of whether a certain level of transparency should be introduced.

So far, the withdrawal rate under the centralised procedure is 10% (14 withdrawals out of the 148 applications submitted since 1995).

Under the mutual recognition procedure, a recent MRFG survey shows that, during the 90-day period, the overall withdrawal rate for all applications is 12%. The rate of partial withdrawal, i.e. withdrawals in at least one concerned Member State during the 90-day period is 46%. No information is available on withdrawals occurring during the initial evaluation by the Reference Member State.

Under the centralised procedure, decisions to withdraw appear to be based on the risk of negative public image for the company. The procedure, if completed, would lead to a negative CPMP opinion, which the Agency would have to make public.

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Out of the 14 cases, scientific and technical grounds for withdrawals can be categorised as follows:

(a) Lack of evidence of efficacy (11 withdrawals)
(b) Clinical safety risks (1 withdrawal)
(c) Poor quality of data (1 withdrawal)
(d) Data not validated (1 withdrawal)

Given the potential significant damages to the company's interests, disclosure of withdrawal should not be recommended unless in fully justified and exceptional circumstances.

Release of information in exceptional circumstances
As a matter of principle, the EMEA cannot take a valid public position before the CPMP has formulated a final opinion. It would therefore not be normal EMEA practice to release any information prior to the opinion adoption.

However, in exceptional circumstances, the Agency might be required to make public statements where
(a) Detailed information about the application is already in the public domain
(b) Misleading information might have to be corrected by means of factual clarification

The EMEA recently experienced this in relation to the extensive press coverage of British Biotech alleged violation of shareholders' interests. The EMEA felt appropriate to issue a press release, the content of which had been previously agreed with the company (see attachment). In this specific instance, the press release concentrated on procedural rather than substantive points.

II - POST-OPINION PHASE

Release of information at the initiative of the company
Companies might be very keen to make as soon as possible a public announcement on a positive CPMP opinion on their product. This has frequently been the case in relation to products subject to wide media coverage, e.g. anti-HIV products, Viagra. The EMEA would in principle have no objection to this providing that:
(a) The information is cleared by the EMEA so as to ensure conformity of the public message with the CPMP opinion, in particular the summary of product characteristics and patient information, and
(b) A statement is introduced that the CPMP recommendation is without prejudice to the final Commission decision.

Systematic release of information by the EMEA
Consideration could be given on whether the EMEA should systematically provide certain information, after an opinion, either positive or negative, has been formulated by CPMP. Whilst companies may be keen to announce positive outcomes prematurely, it is in the interest of the public (e.g. shareholders) to also be aware of the "bad news". The EMEA would therefore serve the public interest in providing systematic and neutral information, in line with the orientations given by the European Ombudsman.

In practical terms, information would normally be released by the EMEA 60 days after the CPMP opinion so as to ensure
(a) That the CPMP opinion becomes final, i.e. that the company will not appeal against the opinion.
(b) That the opinion is already available to the relevant European Commission services and national authorities.