The European Medicines Evaluation Agency: open to criticism

Transparency must be coupled with greater rigour

The European Medicines Evaluation Agency has been in existence since 1995 and has authorised the marketing of 62 drugs in the European Union.[1] Now fully operational, the agency has furthered its ambition of transparency by starting a public dialogue with the International Society of Drug Bulletins. Rather than quell fears about the agency's activities, however, a recent meeting of the two bodies in London raised a further set of questions about both transparency and rigour.

Although the licensing decisions of national bodies like the Medicines Control Agency in the United Kingdom remain secretive, the European Medicines Evaluation Agency produces a European public assessment report, which attempts to increase openness by outlining the reasons for each licensing decision.[2] Concerns, however, surround the rigour of the agency's appraisal of applications for drug licences and the extent to which it is prepared to withhold information from the public that it has been persuaded to treat as commercially confidential (a notion which remains undefined).[3]

In the European Union drugs may be licensed in three ways under the current, still transitional, system. The centralised procedure allows applications to be made directly to the European Medicines Evaluation Agency so that drugs can be made available throughout the European Union. This approach is mandatory for biotechnology products and optional for new medicinal products. Companies can also apply to national licensing authorities in accordance with a decentralised procedure which ensures that product licences granted in one country receive mutual recognition in other member states. In case of disagreement the European Medicines Evaluation Agency's committee for proprietary medicinal products makes a binding decision. Finally, if a product is to be marketed in a single country an application can be made to the licensing authority of that country under a national procedure.

A recent analysis of European public assessment reports by the International Society of Drug Bulletins, whose members are concerned with disseminating information about new drugs and drug safety to doctors, has echoed worries that the agency's standards of critical appraisal may be less rigorous than they should be.[4] In a draft paper presented to the first joint meeting of the European Medicines Evaluation Agency and the International Society of Drug Bulletins in London in June, the society analysed nine public assessment reports, published in 1997-8, and criticised the variability of presentation styles, lack of clarity, and failure to conform to stated aims (D Bardelay et al).

It found that the information about clinical trials was variable, rarely exhaustive, and without exception based solely on information provided by the applying company. Opinions of experts were not taken into account, and discussions in other licensing bodies, such as the Food and Drug Administration in the United States, were not considered. For example, the public assessment report for riluzole, whose efficacy in treating amyotrophic lateral sclerosis has been questioned,[5] omits to mention the controversy over methodological flaws in riluzole trials. The report for a liposomal formulation of the chemotherapeutic agent doxorubicin gives no details of its cardiotoxicity, though it is claimed to be safer than conventional doxorubicin at the same dose. The society plans to publish the paper when the agency has had time to make a considered response.

The agency excuses such deficiencies by blaming the applicants, whose information it relies on. It should then take action—which it says it can do—to censure those who have supplied misleading data. In addition, the agency needs an independent, and more thorough, system of data collection and appraisal, so that doctors and patients can have greater confidence in the drug licensing system. The present system of withholding information that is deemed to be commercially confidential—so that often as little as 1% of the information about a product that the agency holds is released into the public domain—strengthens the hands of commercial interests at the expense of public confidence.

Nevertheless, in publishing public assessment reports, the European Medicines Evaluation Agency is far ahead of most national licensing authorities—which are still notoriously secretive.[6] Indeed, the agency's continuing dialogue with the International Society of Drug Bulletins and national licensing bodies is likely to produce a more rigorous system. For now, the agency should heed the words of the international working group on transparency and accountability in drug regulation: "In principle information available within regulatory agencies should be freely available to any party requesting it. This basic principle applies at least as strongly here as in other fields of government activity, and exceptions to it must be defined restrictively. There must also be a right of appeal to an independent higher authority if the regulatory authorities initially refuse to disclose."[7]

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1 European Medicines Evaluation Agency status report. www.eudra.org/emea.html (accessed July 1998).
2 Herxheimer A. The European Medicines Evaluation Agency's first year. *BMJ* 1996;312:394.
3 European Medicines Evaluation Agency and the new licensing arrangements. *Drug Therap Bull* 1994;32:89-90.
4 Milner P, Walshe K, Wynyard G, Lipp A, Milne R. Method for rigorously assessing cost effectiveness of new drugs must be set up. *BMJ* 1997;315:953.
5 Riluzole for amyotrophic lateral sclerosis. *Drugs Therap Bull* 1997;35:11-2.
6 Abraham J, Lewis G. Secrecy and transparency of medicines licensing in the EU. *Lancet* 1998;352:480-2.
7 International Working Group on Transparency and Accountability in Drug Regulation. *Statement*. Geneva: Health Action International Europe and Dag Hammerskjold Foundation, 1996.

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