The European Agency for the Evaluation of Medicinal Products
Executive Director

London, 2 October, 1998
EMEA-D-MH-34849-1998
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An open letter to the Editor of the British Medical Journal

Mr Richard Smith
The Editor
British Medical Journal
BMA House
Tavistock Square
London
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Dear Mr Smith

Editorial 'The European Medicines Evaluation Agency: open to criticism'
(BMJ 1998; 317: 898-900)

The EMEA was set up in 1995 and, as shown on the constantly updated status reports on our Internet website, has now carried out evaluations for 100 medicinal products for human and veterinary use (*http://www.eudra.org/emea.html).*

As pointed out in the editorial, the creation of the EMEA reformed the way both health professionals and patients can obtain information about the medicines they prescribe and use.

The key reform introduced with the creation of the EMEA is the so-called 'EPAR' – the *European public assessment report.* The EPAR is a unique document made available for every medicinal product as soon as it is authorised. The report sets out the scientific assessment carried out by the EMEA, together with the summary of product characteristics and patient leaflet.

The EMEA's commitment to transparency means that all EPARs – as well as much other information – are systematically made available on the EMEA's Internet site.

As you point out in the editorial, most national competent authorities do not currently publish assessment reports. However, the lead taken by the EMEA is being followed as national authorities begin to consider how to implement similar transparency initiatives in their own procedures.

Such a radical concept as the EPAR was bound to be difficult to implement. The EMEA recognises this. The meeting on 26 June 1998 with the International Society of Drug Bulletins – not the first meeting – was just one aspect of the Agency's reflection on how to improve on the transparency of its operations. Indeed a consultation exercise was carried out in early 1997 leading to a workshop on 30 October 1997 with all interested parties representing patients, consumers, health professionals and industry, and the EU institutions. A press release from that meeting is available on the EMEA website.

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The EMEA is currently examining the ISDB analysis of nine early EPARs. It is intended to make public our response before the end of the year, once the scientific committee for human medicines (the CPMP) has been consulted.

As part of the follow-up to the transparency workshop I also took a Decision on rules on access to documents of the EMEA, copies of which are available in all official EU languages on the EMEA website. In line with the recommendation of the international transparency and accountability working group cited in the editorial, the rules provide that refusals to disclose documents are subject to appeal to the EMEA Management Board, made up of representatives of the European Parliament, European Commission and 15 Member States.

The Agency's efforts towards transparency and openness continue. Indeed at its recent meeting on 30 September 1998 the Management Board endorsed my proposals to improve the transparency of opinions adopted by EMEA scientific committees, prior to the grant of marketing authorisations, to be introduced in January 1999. Statistics will also be made available on the number and grounds for withdrawal of applications.

The provision of quality information to health care professionals and patients is of utmost importance to the EMEA. Improving how and what we provide – in consultation with all interested parties – remains one of the Agency's priorities for the future.

Yours faithfully

Fernand Sauer