New arrangements for the Medicines and Healthcare products Regulatory Agency

Offer lay involvement, fewer competing interests, and better decision making

Major changes are occurring at the Medicines and Healthcare products Regulatory Agency (MHRA) and these hold promise for real advance. The events of the last weeks and months give important insights into the changes now underway.

On 5 April the House of Commons health select committee in its report on the influence of the pharmaceutical industry found that the agency was complacent, lacking the competence to act as a licensing authority. It recommended that the agency be subject to an independent review. On 7 April, government laid before parliament the Medicines (Advisory Bodies) Regulations,[1] presaging the abolition of the agency's two key advisory bodies—the Medicines Commission and the Committee on the Safety of Medicines—both essentially unchanged since the early 1970s. On 13 April the national press carried advertisements inviting senior professionals and representatives of patients and consumers to fill posts in the new system.

To these recent events one must add the National Audit Office's critical report on the MHRA in 2003[2]; the appointment to the MHRA of a communications director on 31 January; the increased openness about data from yellow cards and the promise made by the MHRA to the health select committee to make public the basis for each decision to award a licence. The last development, that affects the advisory system, is probably the most fundamental, and warrants particular scrutiny.

The Medicines Commission (which never really served its purpose) and the Committee on the Safety of Medicines are to be replaced by the Commission on Human Medicines (CHM). This new committee will only deal with drugs for use in humans and will have four functions. It will advise ministers on licensing policy in general and on the licensing of individual drugs in particular; have overall responsibility for drug safety issues; advise on the appointment of members of the other professional bodies serving the MHRA; and hear initial appeals from drug companies when a licence application has been rejected. These appeals will be heard within six months of the original rejection, and if this appeal fails the applicant will have the right to a final appeal to a small panel of specialists appointed by the minister.

The CHM will have 19 members including a chair, who will be a clinician or from a profession allied to medicine, and two lay members. The remaining members will be senior professionals in fields such as general medicine, paediatrics, clinical pharmacology, analytical chemistry, biological science, and herbal medicine. All members and their close families will be barred from having any personal interests such as shares in the pharmaceutical industry or earnings from it.

The new commission will be advised by three standing committees and around 15 expert advisory groups (EAGs) all of which will include at least two lay members. The standing committees will deal with biologicals and vaccines, pharmacovigilance, and pharmacy and standards. The expert advisory groups will be constituted for each application, will probably have a dozen or so members, including four or five specialists, and will call on advisers from other expert advisory groups or from outside as required. Some members, such as statisticians, lay representatives, and industry experts, will be drawn from pools held by the MHRA. The job of these expert advisory groups will be to scrutinise the licence application and ultimately recommend to the CHM whether a licence should be awarded.

The MHRA will also have three statutory committees and a new advisory committee on herbal medicines. Like the CHM these will advise ministers directly.

Chairs of the standing committees and expert advisory groups will also not be permitted to have personal interests in the pharmaceutical industry. Others may have interests but these must be declared and may sometimes bar them from taking part in discussion.

We should welcome the greater involvement of lay persons, the removal of those with conflicts of interests from the senior decision making bodies, the better use of expertise with the separation of technical and policy skills, the greater fluidity of the assessment procedures with expert advisory groups especially constituted for each application, and the accelerated arrangements for appeals.

However, some caution is needed. With the fragmentation that the new process brings there is a risk that standards across the licensing process might vary. To avoid this, meticulous training of participants and quality control checks on decision making will be needed. An independent review of the new procedures in, say, three years would be worthwhile. These safeguards will require time, money, and a preparedness for honest self criticism—commodities rather rare in the regulatory authority so far.

Joe Collier *professor of medicines policy*

St George's, University of London, London SW17 0RE (jcollier@sghms.ac.uk)

Competing interests: JC is a member of the UK Medicines Commission and the committee on the safety of medicines paediatric medicines working group. He was a specialist adviser to the House of Commons health select committee in its enquiry into the influence of the pharmaceutical industry.

1 The Medicines (Advisory Bodies) Regulations 2005. Statutory Instrument 2005 No. 1094. www.hmso.gov.uk/si/si2005/20051094.htm (accessed 14 Apr 2005).
2 National Audit Office. Safety, quality, efficacy: regulating medicines in the UK. 2003. www.nao.org.uk/publications/nao_reports/02-03/0203255.pdf (accessed 14 Apr 2005).

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