

Rethinking transparency and accountability in medicines regulation in the United Kingdom

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Rethinking transparency and accountability in medicines regulation in the United Kingdom

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As the Labour government in the United Kingdom introduces its plans for British freedom of information legislation in a white paper, it is important to consider the issues raised by this for the regulation of medicines. In the United Kingdom, the regulation of medicines is governed currently by the 1911 Official Secrets Act and 1968 Medicines Act. These require all information on drug product licence applications to be treated with the utmost secrecy by the Department of Health's regulatory authority, the Medicines Control Agency, and all its expert advisory committees. Until May 1997, the official position of the British government was that confidentiality about regulation of medicines was needed to protect drug companies' commercially sensitive trade secrets so that the pharmaceutical industry continued to invest and to make medicines available in the United Kingdom.¹

Open government?

The existing secrecy sits uneasily with the rhetoric of the Conservative government's 1993 white paper on open government, which espoused the following principles:

Open government is part of an effective democracy. Citizens must have adequate access to the information and analysis on which government business is based. Ministers and public servants have a duty to explain their policies to the public... The Government believes that people should have the freedom to make their own choices on the important matters which affect their lives. Information is a condition of choice and provides a measure of quality... The provision of full, accurate information in plain language about public services, what they cost, who is in charge and what standards they offer is a fundamental principle of the Citizen's Charter.

Ironically, this white paper was published in the same year that the Department of Health refused to support the Medicines Information Bill, which had the backing of the British Medical Association and the Patients' Association. That bill sought to establish public access to data on:

- Why drug product licenses are approved, revoked, or withdrawn
- Expert scientific advice given to the Department of Health
- Broader concerns about the quality, safety, and efficacy of medicines, subject to ministerial approval.²

The pharmaceutical industry opposed the bill, arguing that the wider rights of public access to data could contravene European Union legislation on intellectual property rights.³ The Department of Health subsequently adopted the industry's perspective by refusing to support the bill because it would have put the United Kingdom out of step with the rest of the European Union.^{4,5}

Summary points

Proposals for freedom of information legislation in the United Kingdom raise issues for regulation of medicines

Under current law all information on applications for licences of drug products is treated with utmost secrecy

Medicines regulators and their expert advisors are closely identified with the interests of the pharmaceutical industry in Britain

Existing secrecy may not protect public health

If legislation includes a "harm test" the commercial interests of pharmaceutical companies may take priority over providing the public with adequate information

Divided loyalties

The close identification of regulators and their expert advisers with the interests of the pharmaceutical industry is evident in other respects. In 1984, the head of the British medicines regulatory authority returned to industry as director of the Association of the British Pharmaceutical Industry. He revealed that all his deputies, principal medical officers, and superintendent pharmacists at the Department of Health had come from industry and that many returned to industry after working as regulators.^{6,7} Moreover, in 1989, only a fifth of the expert advisers on the Committee on Safety of Medicines or the Medicines Commission had neither personal nor non-personal financial interests in the industry.⁸ In 1996, the figure remained as low as a quarter (table). Of the 23 members of the Committee on Safety of Medicines with financial interests in 1996, three had interests in at least 20 companies, seven had interests in at least 10 companies, and 20 members had interests in at least five companies.⁹

Harm test

New Labour's white paper promises to release more information about medicines regulation. However, it also implies that there will be a "harm test" for disclosure of information "which could affect share prices" of pharmaceutical companies. If such a test becomes law, the commercial interests of pharmaceutical companies might take priority over the provision of adequate information to the public. Indeed, the Medicines Control Agency intends to consult with industry about what information might be exempted on the grounds of harm to pharmaceutical firms. Therein lies the reason for reducing the presence of

Industrial interests of expert scientific advisers on medicines regulation in 1989 and 1996^a

Regulatory body	No of advisers		Personal interests*		Non-personal interests†		No interests	
	1989	1996	1989	1996	1989	1996	1989	1996
Medicines Commission	24	19	17	11	7	7	5	6
Committee on Safety of Medicines	21	29	14	18	15	22	4	6
Total	45	48	31	29	22	29	9	12

*Defined as consultancies, fee paid work, and shareholding.

†Defined as payments that benefit the department for which member is responsible but are not received by member personally.

industrial interests within the regulatory process and increasing the presence of wider public health interests.

Risky omissions

The marketing of a number of drugs that have been withdrawn because their risks outweighed their benefit would probably have been challenged earlier if there had been greater transparency and public accountability.¹⁰ Only a few examples can be mentioned here. In the case of Opren, the lack of experimental testing for photosensitivity before approval in the United Kingdom and the omission of clear estimates of risks of photosensitivity from the United Kingdom product data sheet might well have been questioned.¹⁰ Hundreds of patients who had taken Opren subsequently complained of persistent photosensitivity. Similarly, Zomax was approved in the United Kingdom

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for the chronic treatment of arthritis without any warning on the product data sheet, despite positive carcinogenicity findings in animal tests before marketing. After the drug had been withdrawn, the Medicines Commission described the findings on carcinogenicity as a cause for concern when justifying its recommendation that Zomax should not be returned to the market. Had those findings been public before the drug had been approved, fewer patients would probably have been prescribed Zomax.¹⁰ More recently, Halcion was finally banned in the United Kingdom in 1993. It had been approved in 1978, but suspended since 1991. On banning Halcion, the British regulatory authorities said that if they had known in 1978 what they knew in 1991, they would never have approved the drug in the first place. However, with greater transparency the regulatory authorities might have been warned sooner by the wider medical community of potential problems with the quality of Halcion data, in terms of inadequate summaries and disqualified investigators.¹¹

An opportunity to lead

Our focus on the United Kingdom freedom of information white paper does not imply that the context of the European Union should be ignored, but we should not use a desire to stay in line with Europe as an excuse for adopting the lowest common denominator of openness. Rather, the British regulatory authorities should take the opportunity in forthcoming

legislation to show leadership in Europe with regard to transparency and democratic accountability of medicines control.

More specifically, there should be public rights of access to all biochemical, clinical, pharmacological, statistical, and toxicological assessment reports by regulators, as well as to transcripts of expert advisory meetings, including appeals procedures. Clinical data supporting the labelling for a medicine (that is, the summary of product characteristics) should also be available for public inspection. The identities of individual patients should be kept confidential, and companies' intellectual property rights could extend to confidentiality for manufacturing techniques and formulation technology. However, the fact that pharmaceutical companies do not trust each other not to use data unscrupulously should not override the need of health professionals, patients, and the wider medical community for adequate information about medicines safety and effectiveness. Furthermore, the negative impact on pharmaceutical companies of greater freedom of information is often overstated. The American practices of releasing the internal scientific reviews by regulators and holding expert advisory committee meetings in public does not prevent its pharmaceutical industry from being the most prosperous in the world.

Conflict of interest: None.

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Endpiece Useful remedy

In cases where patients are distressed and ill, and want to hang themselves, administer mandragora root to drink in the morning, in a smaller dose than would cause delirium.

Hippocrates, *Places in Man*, edited and translated by Elizabeth M Craik, 1998

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