

## Guest editorial

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# Secrecy and drug regulation in Europe: who is being protected?

Over the last eleven years I have been researching medicines regulation in the UK, the US, Germany, the Netherlands, Sweden and the European Union. I have been fortunate because the British Economic and Social Research Council has funded much of this research. A recurring theme in that work is how adequate drug regulatory systems are in *protecting and promoting public health* by preventing unsafe drugs from reaching the market while encouraging the development of drugs which meet genuine therapeutic needs. This raises the question of what provisions there exist for the health professionals and the public, who live with the consequences of drug regulation, to assess such adequacy. The answer is: very few.

For many years British medicines regulation has been the most secretive in the Western industrialised world. The 1911 Official Secrets Act makes it illegal for civil servants, including any member of the British Licensing Authority to divulge any government business without authorisation. On top of this blanket of secrecy is section 118 of the 1968 Medicines Act, which requires the scientific secretariat of the Licensing Authority and all its expert science advisers to treat all information pertaining to product license application and approval with utmost secrecy. Individuals in breach of these laws are liable to criminal prosecution possibly involving a prison sentence.

In a research project (1994–1996), with Ms Julie Sheppard, we examined what seventeen (current or former) expert science advisers to the British regulatory authorities thought about this secrecy. As many as eight opposed the extent of secrecy imposed on them. Three of those eight wanted to reduce secrecy no further than providing the public with summaries of the reasons why products were approved along the lines of the US Summary Basis of Approval. However, some of the others went further and argued that more openness improved regulatory decision-making. One commented:

I believe transparency actually focuses – sharpens people's contribution. . . I think it quite wrong that we do not know the reasons why decisions are taken. . . that everything is out there in the public domain whatever the particular issues, I think that is an important part of democracy.

Another went as far as to say:

I find the lack of openness offensive. I think it is the secrecy of the process which allows them [the British Committee on the Safety of Medicines] to make naff decisions and get away with them. Because they never have to give reasons why they have done *x*, *y* or *z* they can never be challenged. . . and if it were made public they would not be able to defend their decisions.

I am not arguing that the CSM does make poor quality decisions, but it is significant that the secrecy of British drug regulation generates such feelings among some of its own expert science advisers.

What of the arguments in favour of the cloak of secrecy? Very few of the experts mentioned the protection of public health. Virtually all these experts acknowledged that the primary function of the

secrecy under which they operated was to protect the commercial interests of pharmaceutical companies. Some of the experts believed that secrecy improved the quality of regulatory decision-making by protecting the science advisers from industrial pressures. For example, one expert commented:

*Expert:* I think it most important that people on a decision-making body, which is the equivalent of a jury, should make their decision in secret without pressure. Because remember that now a very high proportion of funds for research come from the pharmaceutical industry. It is no good saying that people on the decision-making body must not have any contact with the pharmaceutical industry. . . . So I think the jury [meaning the regulatory committee] must be allowed to discuss in private. Apart from anything else, sometimes you get people “spilling the beans” in the sense of they are somebody who is a consultant to a pharmaceutical company and declares an interest and leaves the room. The Chairman may say to him, “Have you got anything to tell us before you leave?” He might say, “This drug’s no bloody use to you at all. What they [the drug company] have not told you is this, this and this. . . .”

*Interviewer:* And it is important that that individual feels that he has the freedom to say that – even if not in public?

*Expert:* He could not. He would lose his personal consultancy, his department would lose their large grants, the rest of the pharmaceutical industry would blackball him, you know. It is just as you are dealing with a powerful criminal gang, you know you have got to protect the jury. Well, in this case, they are not all criminal, but they are a powerful force, the pharmaceutical industry in general, and that means that, if you want an independent view, you have to protect your jury.

What this reveals, at least, is that some experts *perceive* that their freedom to criticize the pharmaceutical industry is constrained by their financial dependence on the industry. At worst, if that perception is true, this reveals that the British drug regulatory system is not merely secret in order to protect industrial interests, but also that the professional interests of expert medical scientists outside industry are locked into the secret relationship between industry and Licensing Authority.

In 1993 a Private Member’s Medicines Information Bill was put before the British Parliament, which would have established public rights of access to information about medicines licensing. However, it was not supported by the Department of Health and it was defeated. The Government’s excuse for not supporting it was that it was working ‘at the European level’ to secure more transparency across the European Union (EU) with the implication that national legislation would be superseded by EU developments. Thus, one might expect much greater freedom of information within the EU licensing systems. In a project (1994–1997) with Dr Graham Lewis, we examined this issue.

Despite the rhetoric of the European Commission supporting greater transparency, the European procedures for drug regulation remain opaque to public scrutiny. There is no right of access to either the meetings or minutes of the EU’s expert committee on drug regulation, the Committee for Proprietary Medicinal Products (CPMP). In this sense, EU drug regulation has been modelled much more on the presumption of secrecy approach in the UK than on the presumption of openness operating in the US and to a lesser extent in Sweden.

The EU’s current approach to releasing information is governed by a 1994 Code of Conduct on public access. Under this Code, access is prohibited if disclosure ‘could undermine the protection of commercial and industrial secrecy’ or if ‘confidentiality [is] requested by the source of the information or required by legislation of the Member State supplying that information’ [1]. Hence, statutory bans,

such as that contained in the UK Medicines Act can be used to refuse access to information at the EU level, if the British regulatory authorities are the source of the information. Furthermore, this general provision allows EU drug regulatory bodies, such as the CPMP and the European Medicines Evaluation Agency (EMA) Management Board, to conduct themselves in secret, and prevents access to data provided by the pharmaceutical industry within the regulatory process.

Nevertheless, some attempts to increase the transparency of European drug regulation have been made. The most conspicuous is the publication of the European Public Assessment Report (EPAR) for drug products approved under the centralised procedure. The EPAR usually consists of about 30 pages providing fairly detailed reasons why the CPMP has recommended authorisation of the product, including a summary of scientific discussions about the drug, such as preclinical and clinical assessments. However, EPARs are available only for biotechnological and highly innovative drug products but not for the vast majority of drugs. Moreover, EPARs are not even available for biotechnological or highly innovative drug products that were approved before 1 January 1995.

Significantly, manufacturers are consulted about the contents of draft EPARs on their products prior to publication. Although EMA sources insist that the CPMP decides the contents of EPARs and can ignore industrial objections, it is not obvious that regulators are willing to permit such an adversarial relationship with industry for the sake of public access to information. As one MCA official remarked:

The final say [over the contents of EPARs] is with the regulatory authority, although the regulatory authority would need to consider very carefully that if a company had got a difficulty with something being included, then the regulatory authority would need to be much clearer about the basis for publishing that, otherwise they could expect trouble.

Indeed one representative of a German pharmaceutical trade association told us that in his experience the regulators simply omitted information from the EPAR at the manufacturer's request.

In addition to EPARs, EMA staff have made numerous public statements on the need to make European drug regulation more transparent. Under the decentralised procedure, Member States are obliged by EU law to lodge details of mutual recognition applications with the EMA, such as product name, the Member States involved, submission dates, a copy of any Member State authorisation and the status of any applications submitted to other Member States [2]. However, in practice, we found it impossible to obtain such basic information. The EMA refused to divulge it on the grounds that they did not have the authority to release it. Instead, they referred us to the MRFG, an 'unofficial body' consisting of heads of MS regulatory authorities, whose chairman told us that such information was treated on a 'need to know basis'. We were told that those who need to know are considered to be the industry and regulatory authorities, but evidently not social scientists or the wider scientific and medical communities, let alone patients and the public.

We also elicited the views of scientists and other officials in the pharmaceutical industry, especially regulatory affairs managers. Industrialists varied in their response to EPARs and greater transparency in European drug regulation. The main trade associations did not oppose the EPAR arrangements so long as commercial secrets were protected, but suggestions of further freedom of information met with objections. On the other hand, some industrial toxicologists in Europe thought that the secrecy of the EU licensing systems was at the expense of efficient progress in science because toxicologists could not learn from each other if they were in different companies nor learn from the regulatory reviews done by government scientists on other companies' products.

The current regulatory situation in the UK and the EU is, therefore, one in which the commercial interests of the industry in secrecy are given priority over the interests of patients and health professionals in obtaining adequate access to information about medicines safety assessments. Progress in

establishing greater transparency and public accountability in European drug regulation, except for Sweden, has been pitiful. Regulators defend this situation by arguing that companies have a right to have their commercial secrets protected from unscrupulous industrial competitors. However, the irony of this argument is that, because pharmaceutical companies do not trust each other, drug regulations across Europe have been established in which health professionals, patients and the wider public are expected to trust the entire pharmaceutical industry and its regulators. The worrying consequence is that the medicines licensing systems in place in Europe are deficient in their capacity to accommodate independent scrutiny upon which informed policy development can be based.

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## References

- [1] Anon, Access to Commission documents, *Regulatory Affairs Journal*, June 1994.
- [2] European Commission, *Notice to Applicants: Rules Governing Medicinal Products in the European Union*, Section 3.4, 1996.