The proposed new European Medicines Evaluation Agency may decide to publish in outline its reasons for granting licences, which would match long established practice in the United States and elsewhere. Yet there has been no suggestion that this agency should say why licences are refused (as in Norway) or hold public inquiries when unsafe drugs are withdrawn (as in the United States). Despite a series of drug disasters no public inquiry has ever been held in Britain. Why is openness reserved for disasters involving trains, stadiums, boats, and planes?

The main reason is to protect the commercial interests of pharmaceutical companies, but in Britain (and many countries of the European Community) this has led to blanket secrecy because of the failure to distinguish between legitimate trade secrets (such as manufacturing processes useful to a competitor) and commercially sensitive information (including data on drug safety and problems with efficacy).

Officials believe that the public tends to make impossible demands[7] and would be alarmed by disclosure. For example, a senior drugs regulator said that the recent scare over human insulin had led to 100 or so patients stopping their drugs, with predictably disastrous results. If this is true, and evidence for it is hard to come by, we must find better ways of avoiding such problems. Perhaps it is the aura of secrecy, rather than the disclosure, that causes most difficulties.

But there are now stirrings for more openness[8] and increasing awareness that secrecy is a problem, even from the Medicines Control Agency.[9] At the agency's recent annual meeting the Nobel laureate Sir James Black urged that the drug regulatory process should become an integral part of drug development—which it could be if the authorities opened up. In the meantime, he complained of the waste of experimental data that were locked away and the emphasis on compliance rather than scientific inquiry. "The main enemy in drug development is ignorance," said Black, and more openness is needed to overcome it.

Openness is a tough discipline but essential to the development of trust. In the long run, therefore, it should make business sense and may be the only thing that brings peace of mind.

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GMC in the dock again

The council should investigate unscientific treatments

"The jury is still out on whether self regulation by doctors is adequate," says Ian Kennedy, a professor of law and a member of the General Medical Council (GMC).[1] The approval last year of a mechanism to deal with doctors whose performance is consistently poor[2] was greeted by most observers as a step likely to sustain self regulation (although at least one former member of the GMC disagreed[3]). But a paper we publish today will not help the council's case (p 122).[4] Professor Barry Kay describes a case in which the council avoided investigating what many would have expected to be the central issue—was the accused doctor offering a treatment that could undoubtedly do harm but for which there was no scientific evidence of benefit?

Dr Keith Mumby, a clinical ecologist, faced five charges when he appeared before the GMC last summer, but the charges did not include practising an unscientific form of medicine. Indeed, the chairman of the professional conduct committee instructed it that the hearing was not a trial of alternative medicine or the provocation-neutralisation test, which lies at the centre of clinical ecology. Yet clinical ecology has been severely criticised in the High Court[5] and castigated by the Royal College of Physicians[6] and the American College of Physicians[7]; and the provocation testing used by clinical ecologists has been argued in a paper in the *New England Journal of Medicine* to be unscientific.[8]

The GMC was founded to protect the public against quacks. Its contract is to guarantee that the doctors consulted by members of the public are properly qualified and will give competent treatment. If a doctor offers a treatment which may be risky and has not yet been scientifically proved to be beneficial the GMC surely owes it to the public either to stop the doctor offering that treatment (outside scientifically valid trials) or to stop the doctor practising at all.

The council may demur for two reasons. Firstly, it might argue that so much of what doctors do lacks solid scientific support that it would be ludicrous to try to insist that all doctors practise scientifically valid medicine all the time. But surely there may be a whole order of difference between inserting grommets for glue ear (a much criticised treatment[9]) and injecting people with extracts of gas and petrol fumes. Secondly, the council may balk at the costs of determining whether a treatment is scientifically valid. The courts often sit for months over scientific questions—for example, whether whooping cough vaccine caused brain damage—and the GMC may fear cases lasting months and costing millions. But doctors may be able to make swifter judgments than a lay jury, and anyway self regulation cannot be bought on the cheap.

To protect the public, to uphold the standing of the medical profession, and to safeguard self regulation the GMC needs to be willing to investigate treatments offered by doctors that may be risky and whose value has not been scientifically proved.

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