

Secretive, partisan and unaccountable authorities work against patient welfare

Representatives of medical schools, medicine, regulatory authorities, the medical press and the King's Fund met to explore the theme of "Drug safety — everyone's business". But it was not considered pharmacists' business apparently, for none was among the speakers. **Steven Kayne** reports

The pharmaceutical industry and the regulatory authorities have been strongly criticised by Joe Collier, professor of medicines policy and consultant in clinical pharmacology at St George's Medical School and Hospital, London. Professor Collier said: "Because of commercial interests and political imperatives the industry and the regulatory authorities are secretive, partisan and unaccountable to the public and are prepared to manipulate information for their own ends." He continued: "The over-close relationship inevitably works to the detriment of patient welfare." Professor Collier suggested that more use should be made of senior academics, whose impartiality would be an asset to the assessment process. Speakers from the audience pointed out that pressures associated with research grants from commercial sponsors might affect this impartiality.

Simon Maxwell, senior lecturer in clinical pharmacology at the University of Edinburgh, then described the events leading to the voluntary withdrawal of the Cox-2 selective anti-inflammatory drugs rofecoxib and valdecoxib. Initial studies in 2000 appeared to show decreased gastrointestinal adverse effects and no increase in cardiovascular risk with the coxibs. However a more complete analysis of the results revealed a risk of serious cardiovascular thrombotic events, eg, myocardial infarction. Subsequent work confirmed this effect. Rofecoxib was aggressively marketed and reached total worldwide sales worth \$10m before its removal from the market in 2004.

Angus Mackay, member of the Medicines and Healthcare products Regulatory Agency, outlined the adverse reactions resulting from taking some selective serotonin reuptake inhibitor antidepressants, including tendencies towards suicide, aggression and addiction. He did not believe that there had been any attempt by the regulatory authorities to deliberately mislead over the safety of these drugs by concealment or complacency. However, there was some evidence that the MHRA had failed to communicate its safety concerns effectively, particularly in the case of patients aged under 18 years. It also appeared that product information had not been read carefully enough by some prescribers. A rigorous



Joe Collier: authorities should make more use of senior academics

review by a Committee on Safety of Medicines expert working group set up in 2003 to look at the safety of SSRIs concluded that the balance of risks and benefits in depressive illness in under 18s was unfavourable, with the exception of fluoxetine.

Although acknowledging that industry and the regulators "could do better", Christopher Towler, director of project management at Imperial College London, said there were problems. As companies innovate, their portfolios of products increase and the burden of drug surveillance became enormous. Discontinuing drugs could cause as many problems as keeping them on the market. It was difficult to find a reasonable reference point for estimating safety or benefit within the context of voluntary risks that people took on a daily basis. There were dilemmas for the regulatory authorities too. Their decisions were often complex, being subject to political priorities as well as scientific evidence. Further, it was necessary to establish a balance between denying benefits and ensuring safety. Dr Towler identified a number of paradoxes in modern health care:

- People are healthier but still worry more about health
- The UK is faced with big threats, such as avian influenza, yet seems to be preoccupied with marginal issues
- There is a greater leaning to alternative therapies despite the plethora of proven medicines

- There are more law suits, although health care is better regulated than ever
- Many major advances have been made but many major diseases still prevail

Kent Woods, chief executive of the MHRA, said the agency's aims include protecting public health, providing information and sustaining innovation. There were four key challenges involved in regulating medicines:

- Estimating risk-benefit continuously through the product life cycle
- Consistent and health-focused decisions as risk-benefit changes
- Enabling patients and prescribers to make informed choices
- Maintaining public confidence in the process

Professor Woods emphasised that the clear communication of risk and benefits of medicines was central to the relationship between the medicines regulator and the public. Risk-benefit issues arose in many areas of regulation and of public policy and were generally handled badly by the mass media. The pharmaceutical industry and the MHRA have a shared interest in improving the quality of public engagement in this area.

Helping patients

Melinda Letts, chairman of Committee on Safety of Medicines Patient Information Working Group and non-executive director of Ask About Medicines, discussed two questions:

- How individual patients could be helped to interpret information and make decisions about taking medicines
- How the general level of understanding about drug safety among the population at large could be improved

Ms Letts said there were three overarching principles that should be observed. These were:

- A complete commitment to effective communication between patients, their carers and professionals
- Treating adults as adults
- Considering "patients" and "professionals" as "people" rather than as separate groups

Health professionals should respond to people's individual needs and preferences but

The meeting, entitled "Drug safety — everyone's business" and organised by The Royal College of Physicians of Edinburgh, took place at the RCPE's headquarters in Edinburgh on 25 January

at the same time understand their own limitations. In one of the only references to pharmacy all day, Ms Letts concluded by saying that she fully supported Royal Pharmaceutical Society President Hemant Patel's stated aim of wanting to make Britain the safest place in the world to take medicines.

Some of the reasons for switching patients' prescribed medicines were highlighted by Aberdeen research fellow and Glasgow GP John Haughney. These included:

- Regulatory decisions, eg, the withdrawal of rofecoxib and co-proxamol
- Pharmaceutical company licence extension strategies, eg, loratadine
- Cost containment, as promoted by health authorities — switching soluble preparations to less expensive tablets, eg, co-codamol, and switching proton pump inhibitors to less expensive therapies in the same class, or by dose reduction

Dr Haughney referred to the confusion in patients' minds generated by conflicting messages. It was necessary to promote high quality, accessible information about diseases and their treatments that was not constantly contradicted.

Nicky Britten, professor of applied health care research at Peninsula Medical School, discussed the importance of patient involve-

ment in drug safety. Patients were directly affected both as consumers and taxpayers. She explained that all medicine-taking outside hospital can be considered to be self-medication. Patients' beliefs were central to whether they continued to take their medicines according to the instructions given by the health professional. Some patients showed excellent concordance immediately, some sought further information before accepting instructions and some rejected instructions completely.

The problems of obtaining useful objective information about the safe use of medicines were addressed by Fiona Godlee, editor of the *BMJ*. She said that, on the one hand, members of the public were overwhelmed with information while, on the other hand, they struggle to find the information they need. Available information could be hard to understand, hard to access and hard to trust. The most trusted sources might be the hardest to access and the hardest to understand. Other sources could contain misinformation. This could be due to errors in good faith or, worse still, to manipulated and fabricated data. Dr Godlee accused the press of frequently reporting new advances in drug therapy and adverse episodes in an inappropriate and sensationalist manner.

Niall Dickson, chief executive of the King's Fund, agreed that the provision of accurate information was at the centre of the

debate on drug safety. He acknowledged that the relationship between patient and health care professional was now based on equality. Advice that was once received with complete confidence was now being challenged and patients were making their feelings known. The pressure on the National Institute for Health and Clinical Excellence to fast-track key new cancer drugs and other medicines through a simplified appraisal process was an example.

NICE had been heavily criticised for being too slow in its decision-making, but the new plans mean some breakthrough drugs will be appraised within eight weeks of gaining a licence.

Howard Stoate, MP, told the audience that lapses in patient safety had financial implications for the whole health care system and could result in human tragedy and suffering for the patients and staff involved.

Conclusion

The general theme of communication and trust with regard to the information given about drug safety issues ran throughout the speakers' presentations. It was unfortunate that no pharmacist had been invited to take part. Pharmacists' expertise in providing expert impartial advice to patients in community, primary and secondary health care environments would have contributed positively to the debate.

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