will come to be seen as professionally backward. Competition may stimulate action and response by practices, but the agenda for action has to be set by professional commitment rather than by the crude economic forces which operated to lower standards under the panel system.

Finally, the panel system has lessons about the dangers of a two tier system divided between NHS and private patients. Standards were planned to be lower for panel patients and they were forced down further as the system developed. Under a two-tier system there is bound to be a diversion of energy to the paying customers: then general practice will be trying to resolve problems of access as well as of quality.

NICK BOSANQUET
Professor of health policy, Royal Holloway and Bedford New College, University of London

References

1. Digby A, Bosanquet N. Doctors and patients in an era of national health insurance and private practice 1913–38. *Economic History Review* 1988; 2nd series XCI: 74-94.
2. Bosanquet N, Leese B. Family doctors and innovation in general practice. *Br Med J* 1988; **276:** 1576-1580.
3. Secretaries of State for Social Services, Wales, Northern Ireland and Scotland. *Promoting better health (Cm 249).* London: HMSO, 1987.
4. Bosanquet N. GPs as firms: creating an internal market for primary care. *Public Money* 1986; **5:** 45-48.

Drug defect reporting

ADVICE on the reporting of adverse drug reactions is readily available to health care professionals in the *British national formulary* and the *ABPI data sheet compendium.* The Committee on Safety of Medicines recommends that all adverse reactions should be reported for new drugs, but that for established drugs only serious suspected reactions should be reported.[1] Serious reactions are those which are fatal, life threatening, disabling, incapacitating, or which result in prolonged hospitalization. Administratively, the reporting of adverse reactions is easy, using the yellow card which is found in the back of the *British national formulary,* the FP10 prescription pad and the *ABPI data sheet compendium* or by dialling 100 and asking for CSM freephone.

It is right that prescribing doctors should be acutely aware of the possibility of adverse reactions to recently introduced drugs. Experience with thalidomide and benoxaprofen has shown that a rapid and effective reporting system is vital. It is also important that all doctors should bear in mind that, apart from having adverse reactions, drugs may be relatively inactive therapeutically, which is just as serious to the patient. Advice for the doctor wishing to report a possible drug defect is not readily available. The agreed procedure when a drug defect is suspected is to inform the local chief administrative pharmaceutical officer in Scotland and Northern Ireland, or the regional pharmaceutical officer in England and Wales, who passes the complaint to the defect centre at the Department of Health and Social Security medicines division, who are responsible for investigating the possible defect (Medicines Testing Laboratory, personal communication). Investigations are usually performed by the medicines testing laboratory of the Pharmaceutical Society of Great Britain. Information can be difficult to extract from this system. An alternative method of reporting suspected defects is to inform the manufacturer of the drug directly.

A major concern in this area relates to generic prescribing. This assumes greater importance with the implementation of part 1 of the consumer protection act 1987. The *Drug and Therapeutics Bulletin*[2] has listed the advantages of generic prescribing — the generic name indicates the chemical class to which the drug belongs, the use of a single name reduces confusion and facilitates teaching, pharmacists can reduce stocks, and prescribing costs can be reduced. The disadvantages are also listed — brand names are simpler, the quality of the generic drug is less predictable than the proprietary drug, the appearance and the excipients used may differ between different generic preparations of the same drug, and the source of the generic product may not be known. The concerns about the quality and the uncertain source of generic drugs are important and now have particular relevance to general practitioners because of the new laws on product liability. Reports by Levy[3] and Wyllie and colleagues[4] show that the therapeutic risks involved in switching between different brands of the same drug are real and perhaps occur more frequently than is usually recognized.

The new laws on product liability impose a considerable burden of record keeping if doctors are not to find themselves legally liable for the supply of a defective drug or other medical product.[5] Unless the supplier of a drug is able to identify accurately the producer, together with batch numbers, the supplier is liable. If accurate records are not kept, general practitioners could be liable for any defect in a drug directly dispensed or administered to a patient.

The General Medical Services Committee advises that doctors are unlikely to be at risk if they adhere strictly to labelling regulations, which apply to all dispensed medicines, and ensure that every instance of supply is recorded in the patient's records. The medical defence societies have said that members will be indemnified in the usual way, providing the goods are supplied in connection with the doctor's professional activities[6] and that accurate records of sources and supply are retained for 11 years.

Generic drugs are supposed to be subject to the same rigorous scrutiny as branded products, but if the medical profession is to continue to prescribe generically with confidence we need more information about the sources of generic products and the routine tests which are carried out to ensure their consistently high standards. As part of this process, it is essential that the DHSS publicizes more widely the procedure for reporting drug defects and the details of those defects which have been found, whether they are in proprietary or generic drugs.

DAVID MCBRIDE
General practitioner, Kilmacolm

References

1. Committee on Safety of Medicines. *Current problems no. 22.* London: CSM, May 1988.
2. Consumers Association. For and against generic prescribing. *Drug Ther Bull* 1987; **25:** 93-95.
3. Levy RA. Therapeutic risks associated with substitution of pharmaceutical alternatives. *N Engl J Med* 1985; **313:** 755-756.
4. Wyllie E, Pippenger CE, Rothner AD. Increased seizure frequency with generic primidone. *JAMA* 1987; **258:** 1216-1217.
5. Dyer C. Strict product liability arrives: implications for doctors. *Br Med J* 1988; **296:** 635.
6. Beecham L. From the CCNMS. *Br Med J* 1988; **296:** 1479.