J. Pharm. Pharmacol. 1998, 50 (Supplement): 30

The role of the hospital QA pharmacist in monitoring product quality

ROBERT J. S. SHAW

Academic Pharmacy Practice Unit, University of East Anglia, The Queen's Building, Norwich, Norfolk NR4 7TJ

The majority of products supplied by hospital pharmacists are prescription only medicines. Of these, in East Anglia (EA), there is an approximate 40/60 split by value between branded products and generics. There is a small but significant proportion which are unlicensed 'specials'. These may be prepared in-house under Section 10 exemption of the Medicines Act or, more commonly, manufactured by an NHS manufacturing department with a specials manufacturing licence or a comparable non-NHS commercial unit.

In addition, there will be purchases of a small number of imported medicines, without UK marketing authorisations, for named patients. Pharmacies also procure various medical and surgical items, such as those used in aseptic preparation of injections, surgical dressings and the recently re-categorised medical devices, which are now subject to the CE marking scheme.

Procurement of the mainstream licensed products is mostly by contract (typically at a pharmaceutical purchasing consortium level) or from approved sources via wholesalers. Hospital pharmacists in England work closely with NHS Supplies to negotiate best prices for the purchasing units (typically hospital Trusts). Equivalent national bodies exist for the rest of the UK.

Whilst price is inevitably the key determinant in decision making, the quality assurance/technical services pharmacist will be expected to alert the adjudicating panel to any issues relating to the use of the product, its manufacture and source of supply.

Such issues can include, for example, manufacturer knowledge and past performance, the therapeutic use of the product, results of product testing, reported quality problems, bioequivalence (mainly generics), packaging, labelling and presentation, and proposals to purchase a parallel import.

The NHS Pharmaceutical QC Committee, comprising the Regional Quality Controllers in the UK, liaise closely to network information following manufacturer/supplier visits, results of product testing and defect reports. The latter two of these comprise the Analytical Information Centre (AIC), which is essentially a database administered by the Regional QC laboratory at Torbay hospital. Some product evaluations are collaborative and, where necessary, extensive to address particular issues of equivalence or otherwise justified in terms of overall spend. Metered dose inhalers have been such a product group. Some hospital QC laboratories are equipped to carry out such studies to meet local and agreed national needs. Results of analytical investigations and product defect reports are also promulgated to the Medicines Control Agency (MCA) and contribute to their pharmacovigilance role.

In EA and, latterly, in the Anglia and Oxford health region, we have made a particular effort to encourage users to report on product problems and defects. Ideally, all defective medicines which escape detection during manufacture will subsequently be identified during the various stages of product handling before patient issue. In practice, it is inevitable that some, but hopefully very few, defective products will only become apparent following patient administration. Even so, a large proportion of defects are potentially detectable and intervention is possible before products reach the patient.

When a publicity campaign to stimulate reporting of pharmaceutical product defects was conducted in EA hospitals, the number of reports increased by about 50% compared with control hospitals (Shaw 1992). Furthermore, simple extrapolation of the data suggested that UK hospitals, collectively, would be able to report about 12,000 defects per year. These are mostly minor defects which, by definition, have no important effects on the therapeutic activity of a product and do not otherwise produce a hazard, MCA (1997). Nevertheless, a small number are sufficiently serious to report to the MCA Defective Medicines Report Centre and some of these result in official Drug Alerts.

An analysis of 450 reports (Shaw 1995), in EA, which had all been sent to manufacturers with an invitation to comment, showed that a number of these had resulted in manufacturing process improvements and generally encouraged product development. Some manufacturers were, however, manifestly more positive in their handling of reports than others and it is recommended that the pharmaceutical industry nurture the opportunities for feedback in the interests of improved patient care.

Medicines Control Agency (1997) Guidance on reporting accidents with and defects in, medicinal products

Shaw, R. J. S. (1992) Hosp. Pharm. Pract. 421–425

Shaw, R. J. S. (1995) Pharm. J. 810–813