

# Use of specials in the NHS

## — managing the risks

By Tim Root, BSc, MRPharmS

**A** recent article in the *Pharmaceutical Journal* and subsequent correspondence regarding “specials” in the NHS, have highlighted a number of issues of importance to pharmacists involved in their use and manufacture.

It seems that management of specials is sometimes seen as an issue mainly for technical services pharmacists, centred on “what product do we want and where can we get it from?” Clinical governance must, however, start at the point of prescribing.

Clinical pharmacists must satisfy themselves that a special is essential and prescribers must be reminded that an unlicensed medicine will never carry the same level of assurance of quality, safety or efficacy as a licensed medicine. Only after a thorough exploration of all possible options should the prescription for an unlicensed product be agreed and written.

Hospital and community pharmacists should remember that while the prescriber takes overall responsibility for patient safety, the pharmacist who buys the special is responsible for its quality. Further guidance on this is available from the Medicines and Healthcare products Regulatory Agency<sup>2</sup> and the NHS QC Committee.<sup>3</sup>

In 1976, the Breckenridge report recommended that all intravenous drug doses should be prepared in pharmacies.<sup>4</sup> However, 25 years later in 2001, the Audit Commission found

evidence that high-risk injectable medicines were commonly being prepared in near-patient areas in English hospitals.<sup>5</sup> The scale of use and complexity of intravenous drug therapy has increased faster than pharmacy service capacity, and risk-potential has increased concomitantly.

Today’s pharmacy managers must take a holistic view of the demands on technical service resources. Products for manufacture or preparation in pharmacy should be prioritised primarily by clinical risk. Senior pharmacists must consider the opportunity costs of continuing to make specials with low risk-potential if alternative sources of supply are available. NHS resources should be directed first at high-risk medicines identified by local risk assessment as being made in clinical areas.

All manufacturers licensed by the MHRA to produce specials should be working to the same standards of good manufacturing practice. Choice of manufacturer may depend on factors including lead time and product availability, labelling and packaging, formulation and price. It must be explicit for every product whether it has been manufactured and subject to retrospective quality assurance or dispensed under section 10 exemption of the Medicines Act 1968.

We must also challenge the perception that non-NHS manufacture is always “expensive”. Before drawing conclusions, we must be sure that our own costings are realistic and accurate and our prices account for all relevant costs and the need to generate income for reinvestment in the services and facilities. Failure to do this in the past may have

generated misleading cost comparisons. The proposed inclusion of some specials in the Drug Tariff is an opportunity to review prices.

### — Rationalisation

The scale of use and manufacture of specials can be considered as a spectrum. At one end are those rarely-used products, made in very small quantities, to rudimentary formulae supported by little, if any, stability or shelf-life data. There is probably only anecdotal evidence of efficacy and safety for these products. At the other end of the spectrum are products which have been widely used for years and are made by several manufacturers to validated formulae. In between these extremes lies a plethora of products. Work done by the Department of Health in 2000 produced a list of over 6,000 items made by NHS hospital pharmacies, and there was evidence of considerable product duplication.

Rationalisation is a key step towards development of a core of products justified by defined clinical need, supported by evidence of safety and efficacy and made to validated formulae.

If such rationalisation is to be acceptable to clinicians, they must be involved in the process. By virtue of their proximity to patients, clinical pharmacist colleagues and prescribers, managers of NHS manufacturing units are in a unique position to facilitate rationalisation. NHS capacity alone will never be sufficient to meet demand and the NHS and non-NHS sectors should collaborate and play to their individual strengths rather than compete.

### — The future

Doctors and pharmacists need access to comprehensive, accurate and objective information about specials and manufacturers yet, historically, there has been no single source of such information. The National Implementation Board for modernisation of NHS medicines manufacturing and preparation services, has developed Pro-File, a web-based decision-support tool to provide NHS staff with detailed information about all specials made in the NHS. Pro-File will be available to registered NHS pharmacy staff in secondary care in the second quarter of this year. It will support decision-making to identify and source specials and opportunities for product rationalisation. Once the utility of Pro-File has been established, it is hoped to expand access to community pharmacists.

### — References

1. Gross Z. Why specials manufacturing units are needed now as much as they ever were. *The Pharmaceutical Journal* 2005;275:743-6.
2. Medicines and Healthcare products Regulatory Agency. Guidance Note 14. The supply of unlicensed medicinal products for individual patients. London: MHRA; 2005.
3. NHS QC Committee. Guidance for purchase and supply of unlicensed medicinal products — notes for prescribers and pharmacists, 3rd Edition. The committee; 2004.
4. Breckenridge A. Report of the working party on the addition of drugs to intravenous infusion fluids [HC9769]. London. Department of Health and Social Security; 1976.
5. Audit Commission. A spoonful of sugar: medicines management in NHS Hospitals. London: the commission; 2001.

**Tim Root** is specialist pharmacist, clinical governance and technical services for London East and South East specialist pharmacy services, based at the Chelsea and Westminster Hospital, London.