

## Overhaul 'made-to-order' drugs, which cost NHS millions, urges DTB

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The provision of made-to-order drugs ("specials") in primary care is expensive, often unnecessary, and associated with legal pitfalls, says the *Drug and Therapeutics Bulletin (DTB)*.

It calls for a major overhaul of the practice, in a review of the evidence in this month's issue.

Bespoke drugs or "specials" are medicines made specifically to meet the needs of individual patients, so may be prepared in formulations and strengths which differ from those of standard licensed medicines.

They might be prescribed, for example, when a patient can't or won't swallow tablets or is allergic to a particular non-active ingredient in a readily available drug. And they are sometimes used when a particular medicine has been discontinued or is out of stock, or when a non-standard dose is required.

Although made by a licensed manufacturer, these drugs are not themselves licensed. They are therefore not assessed for safety, quality, or effectiveness, warns *DTB*.

Unwanted effects caused by a licensed medicine, used as intended, are the manufacturer's responsibility. By contrast, prescribers, and potentially, supplying pharmacists, are legally liable for harmful effects caused by a special, unless it can be proved the product is defective, says *DTB*.

Specials are also expensive. In 2008 the total spend on specials in primary care in England was £63 million. By 2009, this had risen 68% to £109 million - equivalent to 1.4% of the total prescribing budget in primary care.

The cost of an individual special depends on the ingredients and the complexity of the processes involved in its manufacture, to which can be added levies charged by distributors and/or "out of pocket expenses" claimed by pharmacists.

The review provides some examples of prices charged for specials. These include liquid formulations of the painkiller paracetamol, costing £67 for a 100 ml bottle, and topiramate, used to treat epilepsy and prevent migraine, costing over £3,400 for one prescription.

And in 2009, there were over 15,000 prescriptions for special liquid formulations of the indigestion drug omeprazole - costing an average of £250 - despite there being a licensed soluble version of the drug.

In August this year, the legislation was changed to permit manufacturers to produce price lists of unlicensed medicines, including specials. But the bespoke nature of the products means that it will be difficult to include all of them on price lists, suggests *DTB*.

"This lack of information on pricing means that at the point of prescribing, prescribers are often unable to judge whether a particular product represents value for money," it says, urging doctors to prescribe specials only when there are no suitable licensed or off label alternatives that meet the patient's needs.

"On occasion it may be necessary to meet a particular need through the use of an unlicensed special ... However, this should be a matter of last resort once all the options using licensed products have been explored,"

it says.

And it concludes: "We believe that the use of specials in [primary care](#) requires a major overhaul and much closer scrutiny than it has had to date."

Provided by British Medical Journal

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