

Readers' letters : *Generic substitution*

The recent opinion article by Philip Brown, 'The NHS needs a generics policy' (*BJ Clin Pharm* 2009;1:287–8) raises some important issues and shatters a number of widely held beliefs — including mine before I read the article — about the management of generic prescribing and dispensing in the NHS.

The policy of strongly encouraging generic prescribing and dispensing in the interest of reasonable cost containment when brands have lost patent protection is not in dispute. Its acceptance does, however, imply and require effective regulatory control at all levels from manufacturing to dispensing, so that the patient is assured of receiving a generic drug that is bioequivalent to the original brand.

Have I been naïve in believing that the UK and its NHS fulfil these conditions? Dr Brown's personal experience with generic amlodipine, as described in his article, casts doubt on the reliability of regulatory control and assured bioequivalence. His step-by-step 'unveiling' of undisclosed facts raises troubling thoughts: the product dispensed to him had come from a recalled batch; the declared manufacturer had not manufactured the product; it was an unsatisfactory import. Suppose the product in question had not been an antihypertensive but a life-saving medicine with a narrow therapeutic index?

Was this just an isolated slip-up, or is its unhappy mixture of concealment and incompetence a side effect of over-zealous pharmaceutical rationing in the NHS?

I recall the experience of a friend who, not long ago, had an infection that came to light on a Friday night. Searching her medicine cabinet, she found some branded antibiotic capsules and decided to chance it, despite the 1990s expiry date. While this may have been unwise, she was able to report very satisfactory results to her GP the following Monday. Her GP agreed that those particular antibiotics were very effective for the type of infection being treated, and wrote a new prescription for the generic version. However, he commented that they were not the cheapest, and that 'they' were always checking up on his prescribing costs. Enquiring about its actual cost, my friend was told that it was 'a few pounds' for a week's course. When she took the generic prescription to her pharmacy, the pharmacist supplied the original brand, explaining that the product was now so rarely prescribed that only the branded product happened to be in stock!

This appears to be NHS rationing at its most invidious. The question is no longer one of brand versus generic, but one of prescribing the cheapest active substance, with pressure being put on a choice of therapy that rates cheapness above safety or efficacy in treating the individual patient's condition.

In terms of the public policy aspirations of the NHS, such choice appears to be neither evidence-based nor patient-centred. In NICE parlance, it also risks falling short of 'clinical and cost-effectiveness'.

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The recent opinion article on generic substitution (*BJ Clin Pharm* 2009;1:287–8) raises an important point, which is particularly pertinent right now in the case of clopidogrel.

I am sure readers will be aware of the number of generic versions of clopidogrel recently licensed for use in the prevention of atherothrombotic events. These are not licensed in acute coronary syndrome (ACS).

At New Cross Hospital we will be continuing with the branded version (Plavix) simply because it is the only product licensed for use post-ACS. As a tertiary centre performing primary percutaneous coronary interventions, we do not want to risk using a cheap product off-licence when a perfectly good, well-researched, licensed (but more expensive) product is available. Doing so may prove to be risky from a legal viewpoint if there were to be any adverse outcomes.

I am surprised that some acute trusts and primary care trusts appear to have marched headlong into using the generic alternatives simply because the cost savings are apparently so compelling. It may be that the generic versions are bioequivalent to Plavix but, in that case, why do we have drug licensing in place at all?

I have tried to stimulate a debate, or at least gauge some views on this via one of the online pharmacy discussion forums, but few people have commented. I can only assume that they are sitting firmly on the fence. As pharmacists, the drug experts, we should be capable of giving a definitive opinion on this. I have always been in favour of controlling costs by generic substitution, but in this situation I ask myself: "If I had ACS today would I be happy receiving generic clopidogrel?" The answer would have to be no.

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