

Pros and cons of generic substitution

Richard Hough, a practitioner in pharmacy law, looks at the practical and legal aspects of generic substitution



The Department of Health launched a consultation paper on January 5 on the issue of generic substitution in England, setting out proposals further to the Pharmaceutical Price Regulation Scheme 2009. The PPRS is a mechanism used to control the prices of branded medicines sold to the NHS by regulating the profits pharmaceutical companies can make on medicines sales.

The PPRS 2009 includes measures aimed at reducing NHS expenditure on branded medicines (currently about £9bn per year) by an average of 5 per cent a year over the lifetime of the scheme through a combination of price cuts and the introduction of generic substitution. It states: "Subject to discussion with affected parties, the DH will introduce generic substitution in primary care. This will enable pharmacists and other dispensers to fulfil a prescription for a branded medicine by dispensing an equivalent generic medicine. Provision will be made to allow the prescriber to opt out of substitution where, in his clinical judgement, it is appropriate for the patient to receive a specific branded medicine. In these circumstances, the named brand must be dispensed. Provision may also be made to exclude certain categories of medicines for clinical reasons in the interests of patient safety."

Consultation

The DH is consulting on three options for the implementation of generic substitution of drugs (not appliances) dispensed by pharmacies (not dispensing doctors):

1. Do nothing (and maintain the existing inflexible dispensing arrangements);
2. Introduce dispensing flexibility but with specific exclusions, so that the generic substitution arrangements would not apply to a selected group of products on an exempt list; or
3. Introduce dispensing flexibility but limiting the scheme in such a way that the generic substitution arrangements would only apply to a selected group of products on a select list.

Prescribers concerned at the erosion of their autonomy could still maintain control by either "opting in" or "opting out" of the arrangements, which could be implemented by either a tick-box system or an endorsement applied by the prescriber to the prescription. Whether this facility would prove to be administratively practical or have a detrimental impact on patient safety remains to be seen.

The DH's preferred approach is option 3, with a prescriber "opt out" endorsement. A pharmacist would, therefore, be able to dispense an equivalent generic version of the medicine when a brand had been prescribed, unless the prescriber has opted out.

Savings claim

In England in 2008 (in primary care) 83 per cent of prescription items were prescribed generically. The remaining 17 per cent were prescribed and dispensed by brand name, the majority of which were available only as a branded product. However, 5 per cent of prescription items were prescribed by brand where a generic version was available. The DH claims that generic substitution would save the NHS between £73m and £237m per year. However, it also recognises that, for clinical reasons, there will be occasions when generic substitution would be inappropriate.

The supply of medicines in the NHS in England is governed by a combination of the Medicines Act 1968 and the NHS Act 2006. Section 58(2) of the Medicines Act 1968 requires that, where a prescription only medicine is prescribed, the medicine must be dispensed in accordance with the prescription. This has generally been interpreted as meaning that what is dispensed by or under the supervision of a pharmacist should be exactly what is written on the prescription. Currently, where a branded product is prescribed, the substitution of that brand by an equivalent generic product is not permitted without the prior agreement of the prescriber.

The NHS (Pharmaceutical Services)

Regulations 2005 and the NHS (Local Pharmaceutical Services etc.) Regulations 2006, the regulations setting out a pharmacist's terms of service, made under the NHS Act 2006, require the dispensing of the medicine ordered by the prescriber and this obligation has similarly been interpreted as requiring the dispensing of a branded medicine where a branded medicine has been prescribed.

The DH is not looking to change primary legislation to achieve generic substitution and changes to secondary legislation would be made, namely to the NHS Pharmaceutical Services Regulations and NHS Local Pharmaceutical Services Regulations, making generic substitution part of the pharmacist's terms of service. Such changes would need to outline the scope of allowable dispensing flexibility, including making provision for opt out arrangements. The amended regulations would also need to give the Secretary of State the power to establish and maintain the list of drugs for which generic substitution is permitted, which would initially be quite restrictive (suggested as being approximately 40).

The legal definition of "generic equivalent" for the purposes of implementing generic substitution would also have to be robust and scientifically sound. The DH proposes that drugs on the list would be referred to by their Recommended International Non-proprietary Name (rINN) or by the British Approved Name (BAN) and, when prescribed as such, the "generic equivalent" could be supplied.

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It is proposed that "generic equivalent" would be defined as a drug that is of the same pharmaceutical form and strength as the reference product and:

- its active substance has the same rINN or BAN as the reference product; or
- its active substance is a salt of the reference product and is a permitted alternative salt included in the select list

There is an element of "pip squeezing" about the proposals, as the generic prescribing rate is already laudably high and it is doubtful whether the savings to be achieved in practice

will be as high as predicted and whether they would outweigh the costs of the scheme's implementation. The consultation is also certain to raise concern amongst pharmacists, who might view the DH's preferred option as a further burden to their workload — when the duty to ensure that cheaper generic medicines are supplied should more correctly be placed upon the prescriber prescribing appropriately — and as adding an unwelcome complication to the dispensing process.

Flexibility

The wording of the consultation document mentions the introduction of "dispensing flexibility", which implies that, if implemented, generic substitution would be discretionary rather than mandatory. However, careful consideration will need to be given to the final wording of the implementing legislation so that binding obligations are not created where discretions are envisaged and proprietors are not financially penalised for any failure to substitute when called upon to do so.

Notwithstanding these reservations, my gut feeling is that this is a positive development which pharmacists should embrace as an opportunity to throw off the shackles of dispensing passivity and assert their pre-eminence amongst healthcare professionals as pharmaceutical experts. Another potential positive benefit from the proposals is that proprietors would also doubtless welcome any savings that would be made from reduced stock holdings.

However, two final concerns which need to be addressed are those of liability and public confidence. Pharmacists need reassurance that, on the occasion when a generic substitution is made and a patient suffers an adverse reaction to the substituted generic equivalent, no additional liability attaches to the pharmacist. Perhaps of greater concern is that it is not inconceivable that generic substitution could undermine public confidence if the erroneous perception exists that the pharmacist has swapped the prescriber's choice of a more expensive drug for a cheaper one solely for commercial gain. This issue must also be addressed from the outset.

The DH is consulting on the implementation of generic substitution in England only. Implementation in Northern Ireland, Scotland and Wales is a matter for the devolved administrations. Views are sought and the consultation runs to March 30, 2010.

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