

Branded generic drug saving

This bulletin focuses on the prescribing of branded generic drugs in primary care. It looks at the possible saving opportunities available and how this could impact on the health economy locally and nationally. It provides some principles to apply if considering branded generics during formulary reviews.

Recommendations

Recommending branded generic prescribing and inclusion of these drugs in local formularies can appear to be a cost saving proposition for Clinical Commissioning Groups (CCGs). Some savings may be possible, however consider these principles before proceeding:

- Branded generic prescribing can undermine Category M by affecting the competition that drives down prices in the generics market and therefore drives up costs to the NHS.
- The companies that manufacture branded generics can be relatively small with limited manufacturing capacity. The impact of including a branded generic in the formulary could create a large demand for the product over a very short period of time, especially if several CCGs switch at the same time; therefore supply could potentially be limited.
- Community pharmacy contractors will need to be informed of the formulary decisions and may need to be provided with information on how to access these branded generics. This may be different from their normal supply routes. They may incur additional expenses obtaining them, which are directly charged back to the NHS by Out of Pocket Expenses claims.
- Check which wholesalers stock the branded generic recommended and if they have the capacity to supply the quantities the CCG might require.
- Check that the bioavailability and the release profiles of the branded generic are interchangeable/ equivalent to the innovator drug (or the drug currently recommended by the CCG). This is because a wide range of branded generics are available as modified or sustained release preparations.
- Check if there is sufficient information available for prescribers relating to the branded generic drug. Is it included in the British National Formulary (BNF)? Does it have a Summary of Product Characteristics (SPC)? Check the branded generic SPC to ensure the indications are equivalent to the innovator drug (or the drug currently recommended by the CCG).
- Check that the branded generic is listed on the prescriber's clinical system to allow the chosen product to be prescribed correctly.
- The prices of branded generic medications are subject to intense competition and change frequently. This could mean a need for regular reviews to ensure the most cost-effective recommendations.

Background

The brand or proprietary name of a drug is the name given it by the pharmaceutical company that originally developed it (the innovator).¹ The use of this brand name is reserved exclusively for the innovator.²

The generic or non-proprietary name is the name given to the active ingredient. This is decided by an expert committee and is understood internationally.¹ A generic drug is usually intended to be interchangeable with an innovator product.² It is manufactured with its own generic licence and marketed after the expiry date of the patent or other exclusive rights of the innovator. Generic drugs are frequently as effective as, but much cheaper than, brand-name drugs.² Many generic medicines are marketed using only the generic name and are not given a brand name.

A branded generic is the brand name given to a drug that is bioequivalent to the original (innovator) brand, but once the original brand has come off patent it is marketed under another company's brand name, not the generic name.^{3,4}

The Drug Tariff outlines what will be paid to pharmacy contractors for NHS services provided. This is for reimbursement of the cost of the drugs, appliances etc. which have been supplied against an NHS prescription or for remuneration. It also sets out what they are paid as part of the dispensing contract for fees/allowances etc.⁵ The price used to reimburse a pharmacy contractor for the medicine or appliance they dispense depends on whether the prescribed product is a branded or generic medicine. Where a medicine has been prescribed by brand name, the reimbursement is based on the manufacturer's list price for the prescribed product. The agreement that controls the prices of branded medicines is known as the Pharmaceutical Price Regulation Scheme (PPRS) <https://www.gov.uk/government/publications/pharmaceutical-price-regulation-scheme-2014>. Although the prices to the NHS of these branded products can be high, pharmacists often make a loss on dispensing them, because the reimbursement price is lower than the purchase price.⁶

Part VIIIA of the Drug Tariff contains the basic NHS reimbursement prices for medicines prescribed generically. It includes most of the commonly prescribed products.⁶ All drugs listed in Part VIIIA have a pack size and price which has been determined by the Secretary of State for Health for England and the Welsh Ministers for Wales⁷ The drugs in this list are divided into categories and payments are based on either generic costs or the cost of a particular brand.

There are a few circumstances when it is appropriate to prescribe a specific manufacturer's product (branded or generic). These include:

- Drugs where there is a difference in bioavailability, particularly those with a narrow therapeutic index.
- Certain modified- or controlled-release drugs.
- Certain administration devices.
- Multiple ingredient products.
- 'Biosimilar' medicines.⁹

Category A

Category A includes popular generic medicines which are widely available. The price is based on a weighted average of list prices from wholesalers and generic manufacturers. Examples of Category A medicines include; isosorbide dinitrate tablets, paracetamol 120mg/5ml oral suspension paediatric and beclometasone 0.025% cream and ointment etc.

Category C

Category C includes medicines that are not readily available as a generic, where the price is based on a particular branded/proprietary product, manufacturer or supplier. Examples of Category C medicines include; calamine lotion (Thornton & Ross Ltd), fluticasone/salmeterol inhalers CFC free (Seretide Evohaler), diltiazem 90mg modified-release capsules (Adizem-SR) etc.

For certain medicines in Category C it is advisable to prescribe by the brand name, for example inhalers. This will ensure patients are supplied the correct inhaler device they are familiar with. Prescribers should specify the brand to be dispensed for certain modified-release preparations, as they may not have the same clinical effect between different brands. As these are in Category C the pharmacy contractors will be paid based on the brand listed.

Category M

Category M includes medicines that are readily available. The Department of Health (DH) calculates the price based on information submitted by manufacturers. Examples of Category M medicines include; ramipril capsules, metformin tablets and amoxicillin capsules etc.^{7,8}

The reimbursement price of all medicines is then reduced by NHS Prescription Services in accordance with a 'discount scale' that reflects the average levels of discounts pharmacies receive from their wholesalers, commonly known as the "clawback". The average discount deduction is up to 9% and for some items, particularly branded and branded generic products that are supplied to the pharmacy with little or no discount, this means the items are reimbursed at less than cost price to the pharmacy.⁶

The potential cost of branded generics for the NHS, pharmacy contractors and patients.

Category M is of the greatest interest to prescribers, CCGs and pharmacy contractors, because it includes the majority of generic medicines that are prescribed in primary care.⁶ It was introduced into the Drug Tariff in April 2005 when the new community pharmacy contractual framework was launched. It is the principal price adjustment mechanism to ensure delivery of the retained margin guaranteed as part of the contractual framework and is used to set the reimbursement prices of over 500 medicines.¹⁰ The retained margin is the profit pharmacies can earn on dispensing drugs through cost effective purchasing.¹⁰ The total funding for the 2014/15 financial year was £2.8 billion, of this; £800 million is to be delivered as the retained buying margin. The DH aim to deliver the £800 million retained margin by adjusting the reimbursement prices of drugs in Category M. If the delivery rate of the retained margin is under or over the £800m target, the DH will re-calibrate Category M Drug Tariff prices to bring the margin delivery rate back on track.¹⁰

Category M prices are set to include an element of purchase profit so reimbursement prices may be higher than manufacturer's list prices.⁴ However the vast majority of generic medicines in Category M are the most cost effective way of prescribing that medicine. Sometimes manufacturers reduce the price of their branded product to one that is cheaper than the equivalent generic product listed in Category M. This is done to promote market share of the branded product.⁶ Therefore to save money, some CCGs may encourage branded prescribing.⁴ However special care has to be taken to avoid taking action that may produce a short term local saving (although the savings are often unsustainable by the manufacturer), while ultimately costing more for the NHS.⁶

When medications are prescribed generically, pharmacies seek to obtain the best available generics prices. This will drive down the prices being charged by wholesalers, manufacturers and in turn the Drug Tariff reimbursement prices and costs for the NHS. Prescribing branded generics profoundly affects the competition that drives down prices in the generics market and acts to drive up costs to the NHS.⁴

Branded generic drug manufacturers sell their brands into the market at prices that include the costs of their marketing efforts with CCGs and prescribers. These costs are not incurred by "true" generic manufacturers. They are able to list prices lower than those of the equivalent generic drug because they are not contributing, or contributing at minimal level, to the delivery of the agreed level of purchase profit that is part of the contractual framework funding. The contribution that is missing is consumed by marketing costs and the branded generic manufacturer's own profits.⁴

When recommending branded generics, pharmacy contractors are required to purchase branded products for which there is little or no discount, but the discount reduction is still applied when the prescription is priced by NHS Prescription Services. Consequently the items may be reimbursed at less than cost price to the pharmacy. This can impact on the financial viability of the pharmacy and put the provision of pharmaceutical care at some risk.⁶

Community pharmacy contractors may have to order the branded generics from a different supplier than normal. This may incur additional expenses obtaining the drug, appliance or chemical reagent which can be claimed back by the pharmacy as Out of Pocket Expenses. Out of Pocket Expenses

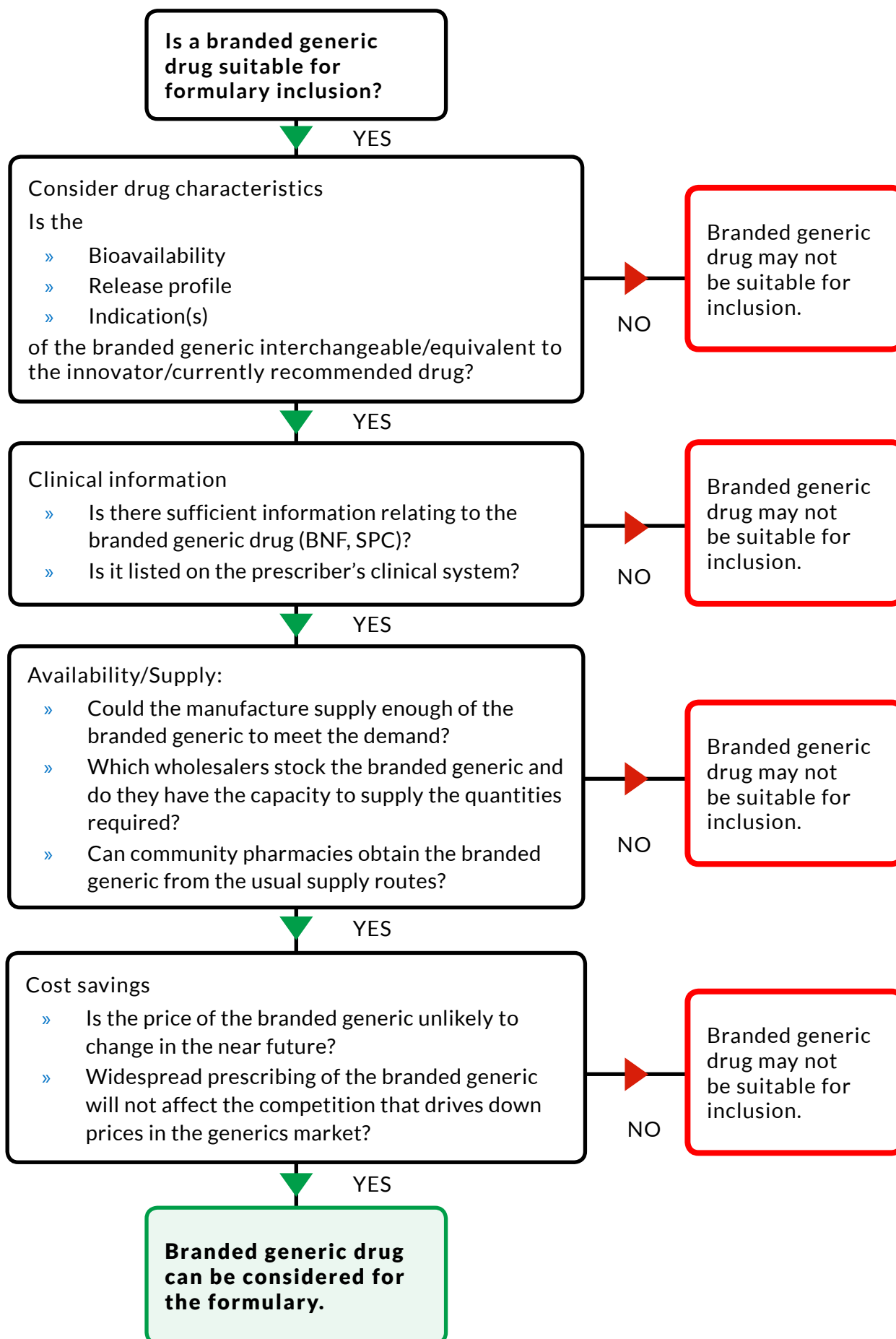
includes costs such as postage and packaging, handling and the cost of phone calls to manufacturers or suppliers to order products.¹¹

Frequent changes to prescribing could also be detrimental to patient care. Continually changing brands (due to price changes or supply issues) can create confusion for patients and can undermine their confidence in their medicines. There is also evidence that some branded generic products that have been subject to switching have quickly become short in supply, leading to delayed access to the medicines for the patient.⁶ Continually changing brands could also lead to pharmacy contractors being left with old stock they cannot dispense against prescriptions.

Summary

- The prescribing of branded generics may produce a short term local saving for CCGs however a number of points need to be considered before they are recommended. Despite initial savings the prescribing of branded generics can result in increased costs to the NHS by undermining Category M. The prices can change frequently so regular reviews are required to ensure the most cost-effective drugs are recommended. Continually changing the recommendations can confuse patients and undermine their confidence in their medicines.
- The companies that manufacture branded generics are often small and recommending a branded generic can create a large demand where supplies could be limited. It is wise to check which wholesalers stock the branded generic recommended and if they have the capacity to supply the quantities required. Pharmacy contractors should be informed about how to access the recommended branded generic as this might not be from their usual supplier. This can result in extra charges obtaining the product which is charged to the NHS as Out of Pocket expenses.
- Finally you should ensure there is sufficient information available for prescribers on the recommended branded generic. Many branded generic drugs are modified or sustained release medications therefore is the bioavailability and the release profiles interchangeable/equivalent to the innovator drug or the drug currently recommended. Is the branded generic in the BNF? Does it have a SPC? Is it listed on the prescribers clinical system? It is important that prescribers have access to enough information, to satisfy themselves that the chosen product is prescribed correctly and appropriately.

Figure 1: Flow chart to illustrate an assessment process of branded generic drugs for inclusion in formularies.



References

1. NHS Choices. Why do medications have brand names and generic names? Last reviewed December 2014. Accessed 31/08/2015. Available online at: <http://www.nhs.uk/chq/pages/1003.aspx?categoryid=73>
2. World Health Organization. Generic Drugs. Accessed 31/08/2015. Available online at: <apps.who.int/medicinedocs/en/d/Jh2993e/8.html#Jh2993e.8>
3. Valeant Pharmaceuticals International Inc. Branded generics. Accessed 31/08/2015. Available online at: <http://www.valeant.com/branded-generics>
4. The Pharmaceutical Services Negotiating Committee. Branded generics. Accessed 31/08/2015. Available online at: <http://psnc.org.uk/funding-and-statistics/funding-distribution/branded-generics/>
5. NHS Business Services Authority. Drug Tariff. Accessed 07/09/2015. Available online at: <http://www.nhsbsa.nhs.uk/924.aspx>
6. NHS Employers organisation, the British Medical Association's General Practitioners Committee (GPC) and the Pharmaceutical Services Negotiating Committee (PSNC). The community pharmacy. A guide for general practitioners and practice staff. July 2013. Accessed 07/09/2015. Available online at: <http://www.nhsemployers.org/~media/Employers/Documents/Primary%20care%20contracts/Pharmacy/Guide%20to%20community%20pharmacy%20for%20GPs%20and%20practice%20staff.pdf>
7. Drug Tariff. September 2015. Accessed 03/09/2015. Available online at: <http://www.nhsbsa.nhs.uk/PrescriptionServices/4940.aspx>
8. The Pharmaceutical Services Negotiating Committee. Dispensing Factsheet – Using the Drug Tariff. January 2015. Accessed 07/09/2015. Available online at: <http://psnc.org.uk/dispensing-supply/psnc-briefings-dispensing-and-supply/psnc-briefing-01315-dispensing-factsheet-using-the-drug-tariff-january-2015-2/>
9. UKMI. Medicines Q&A 247.3 Which medicines should be considered for brand-name prescribing in primary care? July 2013, partial update December 2013. Accessed via <https://www.evidence.nhs.uk/Search?q=%22Which+medicines+should+be+considered+for+brand%22>
10. The Pharmaceutical Services Negotiating Committee. Retained margin (Category M). Accessed 07/09/2015. Available online at: <http://psnc.org.uk/funding-and-statistics/funding-distribution/retained-margin-category-m/>
11. The Pharmaceutical Services Negotiating Committee. Out of pocket expenses. Accessed 07/09/2015. Available online at: <http://psnc.org.uk/dispensing-supply/endorsement/fees-allowances/oop/>

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