Grŵp Strategaeth Meddyginiaethau Cymru Gyfan
All Wales Medicines Strategy Group

Prescribing of branded generics in NHS Wales

Position statement

October 2024

This document has been prepared by the Branded Generics Short Life Working Group, with support from the All Wales Prescribing Advisory Group (AWPAG) and the All Wales Therapeutics and Toxicology Centre (AWTTC), and has subsequently been endorsed by the All Wales Medicines Strategy Group (AWMSG).

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Prescribing of Branded Generics in NHS Wales - Position Statement

The prescribing of branded generics should not routinely be undertaken in NHS Wales unless there is a specific, clinical reason for doing so.

Please see the glossary for definitions of generic, branded and branded generic medicines used.

1.0 Summary

- Prescribers should always use a medicine's generic name when prescribing (referred to as generic prescribing), unless there is a clinical reason to prescribe by brand or branded generic.
- Generic prescribing reduces the risk of prescribing and dispensing errors, facilitates timely supply of medicines, and offers the best value for the NHS in Wales.
- Prescribing policies that encourage the use of branded and branded generic medicines where there is no clinical need to do so can appear to deliver short term cost savings; however, in the longer term, prescribing branded medicines where generics are available may result in increased costs for NHS Wales because:
  - The routine prescribing of branded generics interferes with mechanisms designed to apply downward pressure to the purchase price of generic medicines, which reduce generic medicine reimbursement prices and ultimately save money for the NHS and taxpayers.
  - Widespread use of branded generics undermines the nationally agreed arrangements for reimbursing community pharmacies and may affect their overall financial viability.
  - Switching large numbers of patients from generic to branded generics can result in surges in demand which place unforeseen pressure on supply chains and may lead to patients experiencing difficulty in obtaining their medicines. As well as causing distress for patients, shortages result in increased workload for both pharmacies and GP practices because prescriptions have to be returned to the GP practice and rewritten generically in order for the patient to obtain medicines.
- Prescribing policies should not encourage the use of branded or branded generic medicines where there is no clinical or patient related reason.
- Prescribers must consider professional and regulatory standards when prescribing and ensure that their prescribing decisions are not influenced by incentives or inducements rather than the needs of the patients to whom they prescribe.
- This guidance applies to medicines and is not applicable to products listed in Part IXA (Appliances) of the Drug Tariff.

2.0 Benefits of Generic Prescribing

Generic prescribing – using a medicine's approved International Non-proprietary Name (INN) – tends to be the preferred option[1]. In addition to potential cost savings (prices are typically around 80% lower than the originator medicine[2]), generic prescribing may help to reduce the risk of errors, as each medicine has just one generic name but might have multiple brand names[1].

The British National Formulary (BNF) states that where non-proprietary (generic) titles are given, they should be used in prescribing. This will enable any suitable product to be dispensed, thereby saving delay to the patient and sometimes expense to the health service. The only exception is where there is a demonstrable difference in clinical effect between each manufacturer's version of the formulation, making it important that the patient should always receive the same brand; in such cases, the brand name or the manufacturer should be stated. Non-proprietary titles should not be invented for the purposes of prescribing generically since this can lead to confusion, particularly in the case of compound and modified release preparations[3].

2.1 Reduced risk of prescribing and dispensing errors

The consistent use of the generic name in prescribing may help to reduce the risk of prescribing and dispensing errors[1]. Even if there is only one supplier of a product on the market, prescribing generically supports prescriber understanding of the treatment they are giving and the nature of the product they are prescribing.

It can also create greater certainty amongst patients and healthcare professionals when, for example, patients move between care providers on discharge from hospital, as to the patient's treatment regime.

Prescribing generically can also remind clinicians of the therapeutic action of the drug, meaning they are less likely to prescribe a drug with a similar mechanism of action (unintentionally causing duplication) or to prescribe a second medicine which is incompatible with the first[4].

2.2 Timely supply of medicines

Generic prescribing, using the approved INN, enables any product containing the same active pharmaceutical ingredient in the same formulation and of therapeutic equivalence to be dispensed, potentially avoiding delays for patients and expense to the health service[3]. Multiple suppliers of a generic medicine can protect security of supply for patients. It reduces the need for pharmacies to hold stock of different brands of the same generic medicines and can potentially reduce delays in supplying medicines to a patient, for example, when a particular brand is not stocked in the pharmacy or where there is a shortage[5]. It should be noted however, that a diverse range of generic suppliers does not necessarily protect against shortages and can cause supply chain complexity when suppliers enter and subsequently exit the market.

2.3 Value and sustainability for NHS Wales

Generic prescribing, using the approved INN, usually facilitates lower prescribing costs, with generic medicine prices typically around 80% lower than the originator medicine's price[2]. When prescriptions are written generically, any cost savings associated with the loss of originator exclusivity will automatically be realised.

In primary care, when a prescription for a medicine is dispensed, the dispenser (e.g. community pharmacy or dispensing doctor) will be reimbursed for the medicine according to the price listed in the Drug Tariff. In general, Drug Tariff prices of generic medicines are calculated to reflect the volume-weighted, average price, and are informed by pricing and volume data provided to the UK Department of Health and Social Care (DHSC) every three months by manufactures and wholesalers. Where generic medicines are commonly available from a range of suppliers, their Drug Tariff price is determined by competition between manufacturers and wholesalers. The Category M mechanism is used to determine reimbursement prices which reflect the weighted average price from all suppliers plus a profit margin which can be retained by dispensers (e.g. community pharmacies and dispensing doctors). This is intended to encourage dispensers to purchase from suppliers offering the largest difference between the NHS reimbursement price and the actual selling price. Where medicines are prescribed generically, dispensers can purchase at the best available purchase price, with a choice of dispensing generic or proprietary products. This promotes competition and drives down selling prices as dispensers seek to maximise their retained purchase profit.

The DHSC monitors medicine prices based on sales data they receive and as selling prices fall (or rise), it decreases (or increases) NHS reimbursement prices to reflect the updated volume-weighted, average price charged by suppliers and to maintain a fixed overall level of retained purchase profit for community pharmacies. This works effectively to reduce average selling prices and ensure the NHS pays the lowest possible prices for medicines overall.

Proprietary medicine prices, including branded generic prices, are determined by manufacturers. The DHSC does not set reimbursement prices for these medicines and the NHS reimburses dispensing contractors the manufacturer’s list price less a sliding scale discount as described in the Drug Tariff.

Reflecting the intended competition expected, manufacturers of branded and branded generic medicines sometimes set their list price at a level below the NHS reimbursement price for the generic version of the same medicine. This provides an ‘opportunity’ for a health board to reduce the amount it spends on that medicine when it promotes prescribing the medicine by its brand rather than generic name. However, this approach may compromise the retained purchase profit which is intended to be available to community pharmacies as part of core contractual funding.

Prescribing a branded or branded generic medicine may not support value-based prescribing in the long term because it disrupts the mechanisms in place to deliver agreed retained community pharmacy purchase profit and to control medicine expenditure overall. It can instead potentially lead to higher generic medicine prices both for the generic medicines prescribed by brand, because of reduced price competition, and for other generic medicines in general, because the DHSC is required to increase prices to maintain an agreed level of retained purchase profit. Widespread use of branded generics ultimately undermines the core contractual funding for community pharmacies and may affect their overall financial viability (and the viability of supply chains generally) as it changes the distribution of profit in the supply chain, moving it from wholesalers and dispensing contractors to manufacturers. The net effect of prescribing branded generics can therefore increase costs for the NHS overall even when an individual organisation may appear to be reducing its own costs.

Prescribing a branded or branded generic medicine also means that longer term efficiencies are not fully realised when Drug Tariff prices fall. This is both because it takes time for health boards and prescribers to revert to generic prescribing of the same or alternative product, and because there is less price competition between suppliers with branded prescribing acting as a disincentive for generic suppliers to enter the market.

The new UK wide Voluntary Scheme for Branded Medicines Pricing, Access and Growth (VPAG) has been agreed for sales of branded medicines between 2024–2028, whereby older branded medicines will pay a lower VPAG payment percentage if they reduce their selling prices than those older branded medicines which do not reduce selling prices[6]. This is anticipated by the UK Government to encourage lower prices for older branded medicines including branded generics and in time, may help in time to provide more pricing and supply stability in primary care.

2.4 Impact on patient care

Frequent changes to medication can be detrimental to patient care. For example, switching between brands and generic presentations can create confusion for patients, and can undermine their confidence in their medicines if changes are not explained at the point of dispensing by a member of the team.

There is also some evidence that switching to branded generic products can lead to shortages in supply[7]. The British Generic Manufacturers Association (BGMA) analysis of medicines supply issues identified supply issues affecting branded generic and biosimilar lines as disproportionate to the relatively small number of these medicines when compared with generic medicines. They concluded that supply issues are exacerbated by fewer suppliers and less competition, and can result in the NHS paying more; in addition, they are a drain on limited NHS and pharmacy capacity, with staff focused on mitigating shortages[8]. However, it should be recognised that the causes of medicines shortages are multi-factorial and their root-cause best considered on a case by case basis. Suppliers of branded generics may be particularly exposed and quickly impacted (as they are only supplied by single manufactures) if the supply of the generic version of the same medicine is disrupted.

Within primary care, if a medicine is prescribed as a branded or branded generic medicine, the pharmacist may dispense only the specified brand and cannot substitute an alternative equivalent generic medicine when the prescribed medicine is not available, unless the UK government agrees there is a shortage of the medicine in the UK and has put a Serious Shortage Protocol (SSP) in place. Where a pharmacist is unable to obtain a medicine prescribed by brand or as a branded generic, patients may have to travel to different pharmacies to obtain a supply of their medication. In the event that large numbers of patients are switched from generic to branded generic products a surge in demand may result. This can place unforeseen pressure on supply chains while also exacerbating patient difficulty in obtaining medicines. Alternatively, the pharmacy may send the prescription back to the GP practice to ask that it is amended and rewritten using the medicine's generic name, however this results in additional unnecessary workload for both the pharmacy and the GP practice (therefore increasing costs for the NHS overall) and will regardless lead to delays for patients in receiving their medicines.

3.0 Guidance for Prescribers

This guidance relates to all prescribers, both medical and non-medical prescribers. In its guidance for non-medical prescribers, the BNF highlights that non-medical prescribers are recommended to prescribe generically except where this would not be clinically appropriate or where there is no approved non-proprietary name[9]. The Royal Pharmaceutical Society *Prescribing Competency Framework* includes a common set of competencies that inform the basis for prescribing, regardless of professional background[10]. The competencies have been developed to help healthcare professionals to be safe and effective prescribers. The framework highlights that prescribers should prescribe generic medicines where practical and safe for the patient, in addition to highlighting that prescribers are expected to know when medicines should be prescribed by brand[10].

3.1 When to prescribe by brand or branded generic

Prescribing by brand or branded generic restricts the dispenser to supplying only that brand or branded generic. In some circumstances, continuation of the same brand or branded generic, is clinically important. Prescribers should use their clinical judgement and consult the latest information when deciding whether to prescribe by brand or branded generic.

The Medicines and Healthcare products Regulatory Agency (MHRA) provides examples of where prescribing by brand name is required/suggested for clinical reasons. The Specialist Pharmacy Service also provides information on situations where prescribing by brand, or branded generic, is necessary, and circumstances where it should be considered.

Prescribers should ensure they practice in accordance with the principles, values, and standards of care and professional behaviour expected and refer to professional frameworks, which support professionals to deliver safe care to a good standard, in the interests of patients. Prescribers are reminded that people of different race and ethnicities can have varying responses to medicines. Prescribers must ensure that any incentive payments, inducements, or targets do not compromise their professional judgement and ensure the care they provide reflects the needs of the person and does not compromise the health, safety and wellbeing of patients and the public[11-13]. Prescribers should refer to current clinical guidance to support them in making decisions regarding the appropriate prescribing of brands or branded generics.

Glossary

Branded generic: Branded generic medicines (branded generics) are generic medicines licensed and marketed under a brand name. Branded generics are brought to market after the patent protection on the originator medicine has expired. In some cases, the use of a brand name is required by a medicines' regulator for reasons of patient safety. In other cases, the decision to apply a brand name is a commercial one, where the brand is used to differentiate a manufacturer's product from competitors[14].

Generic medicine: A generic medicine contains the same active ingredient as the equivalent originator medicine and is marketed only after the originator's patent protection has expired[15]. Generic medicines can be produced by many different manufacturers, but all must meet the standards for the reference medicine defined in the UK, by the Medicines and Healthcare products Regulatory Agency (MHRA). Every generic medicine has an associated International Non-proprietary Name (INN) that facilitates the identification of pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognised[16].

Branded (proprietary) medicine: When a medicinal product comprising a new active substance or a novel presentation of a pre-existing active substance is authorised, in general, it will be protected by a patent which prevents anyone other than the patent holder from producing an equivalent product. Such medicines are referred to as originator or reference products and are usually given a proprietary (or brand) name by the manufacturer for marketing purposes.

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