South East London Guidance on Prescribing of Branded and Generic Medication

This guidance has been prepared by the South East London Primary Care Medicines Value Group, a sub-group of the SEL Medicines Value Group.

1. Summary

Prescribing medicines by generic name is generally preferred but there are some circumstances when brand-name prescribing is warranted, in line with the British National Formulary (BNF) Guidance on Prescribing and Specialist Pharmacy Service (SPS) recommendations.

South East London Integrated Care System (SEL ICS) does not support the routine prescribing of branded generic medication to generate cost savings.

2. Scope

The scope of this document is to outline the approach within SEL ICS to guide our members and prescribers for the use of generic and branded prescribing within SEL ICS and to detail the basis on which exceptions are considered appropriate.

3. Background

The NHS has an obligation to meet national priorities through effective use of available resources. SEL ICS gives the highest priority to treatments that are known to be most cost effective at improving health, and a low priority to treatments where the cost is high and evidence for health improvement is low.

New medicinal products are covered by a period of intellectual property protection defined by a patent. This period allows the holder to recoup research and development costs and maintain a profit margin. These products will be prescribed under the branded version of the drug.

Once the patent has expired then other companies may manufacture and supply the same product. To do so they must prove that the product supplied contains the same active ingredients and that the same amount is absorbed by an individual taking that medicinal product. Manufacturing must meet the same standard of quality and safety as defined and monitored by the Medicines & Healthcare Products Regulatory Agency (MHRA). This ensures that these competitor products are equivalent and of the highest quality.

The competitor products may be available under the “generic name” of the medicinal product or, alternatively, may be marketed under their own brand name (branded generic). These competitors can be a significantly lower cost to the NHS for an equivalent product.

Approved by SEL Medicines Value Group: February 2024. **Approved by SEL IMOC:** April 2024**. Review date:** April 2026 (or sooner if evidence or practice changes)

South East London Integrated Medicines Optimisation Committee (SEL IMOC). A partnership between NHS organisations in South East London Integrated Care System: NHS South East London (covering the boroughs of Bexley/Bromley/Greenwich/ Lambeth/Lewisham and Southwark) and GSTFT/KCH /SLaM/ Oxleas NHS Foundation Trusts and Lewisham & Greenwich NHS Trust

4. Guidance for prescribers

4.1 Generic Medication

In SEL prescribing medicines by generic name is generally preferred for the following reasons:

1. Generic prescribing offers greater value for NHS money.
2. Generic prescribing reduces the risk of errors as each drug has only one generic name but can have several brand names. Improved familiarity with drug names reduces the risk of confusion by patients, carers and clinicians, especially those in wider access services like Accident and Emergency or Out of Hours.
3. Generic prescribing enables quicker medicines supply because a pharmacy can source and supply any suitable generic product rather than having to source a specific brand.
4. Initiating generic prescribing from the outset removes the need for future review of repeats. When the patent for a brand subsequently expires then the financial benefits of lower cost generics can be realised faster.

4.2 Branded Medication

This is the name given to a pharmaceutical product by the manufacturer who created the medicine. The use of this name is reserved exclusively to the original manufacturer as opposed to the generic name.

While prescribing medicines by generic rather than brand name can improve cost-effectiveness and is encouraged, there are some circumstances in which continuity of the same product is important for patient safety and prescribing a specific manufacturer's product (brand or branded generic) is preferred.

These include:

1. Drugs where there is a difference in bioavailability between brands of the same medicine, particularly if the medicine has a narrow therapeutic index.
2. Where modified-release preparations are not interchangeable.
3. Where there are important differences in formulation between brands of the same medicine.
4. Where administration devices (e.g. inhaler or self-injection) have different instructions for use and patient familiarity with one product is important.
5. Where the product is a biological rather than chemical entity.
6. Where products contain multiple ingredients and brand-name prescribing aids identification.
7. Where there are differences in licensed indications
8. Where there are differences in the excipient content between brands of the same medicine e.g the presence of one particular undesirable excipient e.g. ethanol, or the presence of a greater amount of one particular undesirable excipient, or the presence of multiple undesirable excipients.
9. Intolerance to excipients in a particular product.
10. Patient factors - for some patients, differences in product name, presentation, appearance or taste may lead to anxiety, confusion, dosing errors and reduced adherence.

4.3 Branded Generics

Brand names may also be used for generic products, they are then often called "branded generics". These brand names are different from original brand names.

A branded generic is the brand name given to a drug that is bioequivalent to the original brand, but once the original brand has come off patent it is marketed under another company's brand name, not the generic name. Branded generics could be a cost effective choice of treatment for products where the brand needs to be specified e.g. modified release products.

Recommending branded generic prescribing can represent cost saving proposition for NHS organisations. However, there are a number of considerations that should be taken into account before recommending a branded generic.

When products are prescribed generically, pharmacies seek to obtain the best available generics prices, driving down the prices being charged by wholesalers and manufacturers and in turn the Drug Tariff reimbursement prices and costs for the NHS. Prescribing branded generics or off-patent branded medicines profoundly affects the competition that drives down prices in the generics market and acts to drive up costs to the NHS. It can also lead to unequal geographical distribution of the funding under the contractual framework.

Branded generic manufacturers sell their brands into the market at prices that, of necessity, include the costs of their marketing efforts with ICS and prescribers; costs 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 are contributing only 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 profits.

For patients already stable on a certain brand then switching to a branded generic should be considered with caution for some medicines. Drug characteristics such as bioavailability, release profile and indication(s) of the branded generic would need to be considered and specialist input and additional monitoring maybe required.

When considering branded generics for use within the ICS, formulary teams and clinicians should follow an assessment process to ensure they would be suitable. Appendix 1 demonstrates some important points to consider.

4.4 Ghost Generics

Branded generics are different to ghost generics. Ghost generics are items prescribed generically with the manufacturers name stated. When an item is prescribed generically, the dispenser is reimbursed at the price in the Drug Tariff; but when a manufacturer is stated, the reimbursement price is usually more expensive. However, this may be warranted for some patients who are allergic or intolerance to specific excipients of generic medicines manufactured by specific manufacturers,

4.5 Biosimilar Products

A biosimilar medicine is a biological medicine that is developed to be similar to an existing biologic (originator) in terms of quality, safety and efficacy.

Biosimilars are not the same as generics, which have simpler chemical structures and are considered to be identical to the reference product; however the active substance of a biosimilar and its reference medicine is essentially the same biological substance.

The only differences should be minor ones due to their complex nature and production methods. Both the biosimilar and the originator will have a degree of natural variability (heterogeneity).

MHRA guidance (2022) states that all biological medicines, including biosimilars, should be prescribed by brand name.

NICE has decided that normally all relevant published guidance that includes the originator molecule will apply to the biosimilar medicinal product at the time it is made available for use in the NHS. A funding direction will apply to a new biosimilar if the active drug substance has already been recommended by NICE.

Biosimilars are subject to the same formulary process as original medication. To determine the SEL IMOC formulary status in SEL refer to SEL Formulary.

5. Advice for patients, carers, and guardians

Generic medicines are generally more readily stocked at community pharmacies compared to branded generic medicines; this helps to reduce delays in obtaining medication.

Prescriptions for generic medicines help to ensure the financial viability of local community pharmacies and reduce costs of medicines in the NHS.
There are certain clinical circumstances where branded or branded generic medicines are prescribed, this will be assessed by your NHS prescriber.

SEL ICS works in partnership with hospitals, GP practices, community providers, community pharmacies and voluntary services to ensure the efficient use of NHS resources. When clinically appropriate it may be recommended that patients are prescribed or switched to a particular brand or branded generic.

References

1. Bulletin 290: Branded generic medicines, PrescQIPP
2. Branded Generics. Pharmaceutical Negotiating Committee
3. Example medicines to prescribe by brand name in primary care. Specialist Pharmacy Service
4. B111. An introduction to biosimilars 2.1 (prescqipp.info)

Appendix 1: Flow chart to illustrate assessment process to consider use of branded generic

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