

NORTH EAST LONDON INTEGRATED CARE BOARD POSITION STATEMENT: BRANDED GENERICS

Position Statement Recommendations

- NHS North East London (NEL) does NOT support the routine prescribing of branded generic medicines.
- The primary exceptions to this would be where it is considered appropriate by reason of:
 - (i) clinical need or safety appropriateness to prescribe a drug by a brand name, and/or
 - (ii) demonstrable lower carbon footprint of a particular brand.

Where one or both criteria are met - then an appropriate brand should be prescribed and supplied on the NHS. Clinicians should be familiar with <u>'Example medicines to prescribe by brand name in primary care'</u> published by the Specialist Pharmacy Service (this list is not exhaustive).

- Brand generic prescribing may be considered in other exceptional circumstances, only if the criteria detailed in this position statement are met.
- NHS NEL supports generic prescribing as the preferred option for NHS prescriptions.

Benefits of Generic Prescribing

Better Value: Community pharmacies source generically prescribed medication at competitive prices, fostering a market where wholesalers and manufacturers lower costs to sell their medicines.

Better Supply: Enables quicker patient access to medicines, as generics are more readily available than branded generics. Evidence suggests that some branded generics can quickly become scarce, causing delays in patient access.

Lower Risk: Reduces the risk of prescribing or dispensing errors as each generic medicine has only one approved International Non-Proprietary Name (INN) name, rather than several brand names.

- NHS NEL recognises that some branded generic medicines may be less costly than the equivalent generic or (original) brand medicines. There is, however, the risk that the cheaper prices may not be sustainable by the manufacturer in the long term. Branded generics can also disrupt the funding mechanism that contributes to the financial viability of community pharmacies and can push up the overall cost of medicines to the NHS. Large-scale use of branded generics may also lead to shortages, with consequent impact on access to medicines and health outcomes.
- Where branded medicines are already prescribed, NHS NEL will review with a view to switching to a generic equivalent if clinically appropriate. Any new branded generic recommended for use will be reviewed regularly to ensure that they are being prescribed appropriately, that they are not associated with supply problems and continue to be a clinically and or environmentally appropriate and cost-effective option for NHS NEL. Feedback from prescribers, community pharmacists and the Local Pharmaceutical Committee (LPC), will be reviewed to identify any problems for resolution.

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1 BACKGROUND

- 1.1. A generic medicine is a pharmaceutical product that is produced when the patent on the original medicinal product (the 'originator') has expired. It is bioequivalent to the originator reference product and is labelled with the approved name for the medicine.
- 1.2. Branded generics are generic medicines that have been given a 'brand name' by their manufacturer. Such medicines will have a different brand name to the originator product.
- 1.3. For generically written prescriptions, community pharmacies seek to obtain the best available generic prices, thus driving down the costs being charged by wholesalers and manufacturers. This creates a competitive market. After a medicine is dispensed, pharmacies claim reimbursement from the NHS with prices set in the NHS Drug Tariff.
- 1.4. Category M is the section of the national Drug Tariff, used by the Department of Health & Social Care (DHSC) to set the reimbursement prices of over 600 readily available generic medicines prescribed in primary care. It forms the principal price adjustment mechanism to ensure delivery of the retained margin guaranteed to community pharmacies as part of the community pharmacy contractual framework. It uses information gathered from manufacturers on volumes and prices of products sold plus information from the Pricing Authority on dispensing volumes to set prices each quarter. The DHSC sets Category M prices at levels substantially above the prices notified by

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manufacturers. Prescribing branded generics or off-patent branded medicines limits the competition that drives down prices in the generics market.

1.5. Rationale

- i. NHSE have stated that branded generics can disrupt the funding mechanism that contributes to the financial viability of community pharmacies and can push up the overall cost of medicines to the NHS.
- ii. Prescribing generically often enables the patient quicker access to medicines, as generics are generally more readily available than branded generic medicines. There is also some evidence that some branded generic products have quickly become short in supply when several organisations have issued guidance to switch to a specific brand generic, leading to delayed access to the medicines for patients and increased workload for community pharmacies and GPs.
- iii. Generic prescribing allows community pharmacists to source medicines from a range of procurement options. Branded generic prescribing restricts these procurement options and potentially leads to reduced access to these drugs for patients prescribed them as fewer wholesalers may stock them. In order to purchase some branded generics, pharmacies may need to set up accounts with additional wholesalers with whom they do not usually transact. Such accounts may present pharmacies with additional costs.
- iv. Generic prescribing can reduce the risk of prescribing or dispensing errors as each medicine has only one approved International Non-Proprietary Name (INN) name, rather than a variety of brand names.

2 SCOPE

- 2.1. This statement outlines the position that NHS NEL will take with regard to branded generics, outlining the limited circumstances under which a brand name will be recommended.
- 2.2. This position statement is applicable to all prescriptions written by primary care prescribers working within NHS NEL, which will include GPs (General Practitioners), other medical prescribers (e.g. those working in dental or community clinics) and NMPs (Non-Medical Prescribers). It is also applicable to all community pharmacies dispensing medicines against an NHS prescription.

3 ROLES AND RESPONSIBILITIES

- 3.1. NHS NEL is responsible for establishing, documenting, and maintaining an effective system to safely manage medicines and prescribing to meet residents' clinical needs.
- 3.2. Members of the NEL System Prescribing and Medicines Optimisation (SyPMO) Board and its subgroups work to provide assurance of good medicines governance. This position statement should be adhered to when reviewing proposals and making prescribing recommendations.

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- 3.3. All healthcare professionals have a responsibility to follow the recommendations made in this position statement to ensure safe and effective prescribing and to support best patient care.
- 3.4. NEL Pharmacy and Medicines Optimisation Team will monitor prescribing data to ensure that branded and branded generic medicines are only prescribed where clinically appropriate. The limited use of branded generics will be monitored to ensure that they are prescribed appropriately and continue to be a clinically, cost-effective option for NHS NEL. Feedback from prescribers and community pharmacists and the LPC will be reviewed to identify any problems for resolution, e.g. supply issues.

4 RECOMMENDATIONS

- 4.1. NHS North East London (NEL) does NOT support the routine prescribing of branded generic medicines. The exception to this would be where it is considered clinically or environmentally appropriate to prescribe a drug as a branded generic. Under these circumstances, then a branded generic can be considered as an option to be prescribed and supplied on the NHS. For clinical appropriateness of prescribing by brand, clinicians should be familiar with Example medicines to prescribe by brand name in primary care published by the NHS Specialist Pharmacy Service (this list is not exhaustive).
- 4.2. NHS NEL supports generic prescribing as the preferred option for NHS prescriptions.

 Benefits of Generic Prescribing

Better Value: Community pharmacies source generically prescribed medication at competitive prices, fostering a market where wholesalers and manufacturers lower costs to sell their medicines.

Better Supply: Enables quicker patient access to medicines, as generics are more readily available than branded generics. Evidence suggests that some branded generics can quickly become scarce, causing delays in patient access.

Lower Risk: Reduces the risk of prescribing or dispensing errors as each generic medicine has only one approved International Non-Proprietary Name (INN) name, rather than several brand names.

- 4.3. A recommendation to routinely prescribe a branded generic will only be considered in circumstances where a medicine should be prescribed by the brand name, as recommended in the BNF (British National Formulary), the NHS NEL Position Statement on Generic and Brand Prescribing, the Specialist Pharmacy Service and this Position Statement.
- 4.4. The Specialist Pharmacy Service website provides guidance on when brand prescribing of a medicine is considered appropriate (<u>Prescribing by generic or brand name in primary care SPS Specialist Pharmacy Service The first stop for professional medicines advice</u>).
- 4.5. Brand name prescribing is **essential** in the following scenarios:
 - **Bioavailability differences:** Where bioavailability differs between brands, especially if a medicine has a narrow therapeutic index. Examples include ciclosporin, lithium, CFC-free beclometasone metered dose inhalers, carbamazepine for epilepsy

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- Release profile variations: Where modified-release (MR) preparations are not interchangeable, e.g. methylphenidate
- **Specific device directions:** Where administration devices have different instructions for use and patients require training to use them. Examples include adrenaline auto-injectors, dry powder inhalers, insulin injection devices
- **Licence variations:** Where branded and generic products have different licensed indications, they should be prescribed by the brand name. Examples include valproic acid, buprenorphine patches and sublingual tablets
- 4.6. Brand name prescribing may also be *considered* in the following scenarios:
 - Multi-ingredient preparations: Where products contain more than one active
 ingredient, brand name prescribing may aid selection of the correct product.
 Examples include combination inhalers, hormone replacement therapy,
 combined oral contraceptives, pancreatin supplements, skin or scalp
 preparations.
 - **Biologics and biosimilars:** While brand name prescribing of biologics and biosimilars is no longer considered essential by the MHRA (Medicines and Healthcare products Regulatory Agency), it may be considered in limited circumstances where patients prefer a particular brand (see patient factors below). Examples include insulins and erythropoietin.
 - Patient factors: It may be appropriate to prescribe by brand name for some patients, where differences in product name, presentation, appearance or taste may lead to anxiety, confusion, dosing errors and reduced adherence. Some patients may also require specific brands of a medicine due to inclusion of certain excipients which they may be intolerant of or wish to avoid due to personal beliefs, e.g. lactose, alcohol, or animal-based gelatines.
 - **Drug shortages:** It may occasionally be appropriate to temporarily recommend prescribing by brand name if there is a supply issue with generic medicines. Prescribers should consult with their Pharmacy team and Community Pharmacies.
 - **Appliances**: It will often be necessary to prescribe products defined as appliances in section IX of the Drug Tariff by brand. Such products include blood glucose test strips, needles, emollients, woundcare products, stoma products and incontinence products.
 - Cost savings: NEL ICB has a responsibility to ensure that expenditure on medicines continues to deliver value for money. There are some rare instances where the cost of prescriptions for a small number of patients contributes disproportionately to a significantly high cost for that medicine, due to price differences between brands. In these cases, it is appropriate to consider recommending a specific brand/branded generic, if the impact on access, funding mechanisms etc can be demonstrated to be minimal. The inclusion of a branded generic cost-saving initiative will be subject to the same governance process of all NEL ICB prescribing efficiency schemes, including the requirement to consult with partners and stakeholders, and a risk and quality assessment.

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Any such decisions will be reviewed regularly to ensure continuing appropriateness.

A case in point is Glycopyrronium1mg and 2mg tablets: Twelve (12) month data reviewed in 2024 showed glycopyrronium prescribed as a recommended brand cost at the time £800 per patient vs glycopyrronium prescribed generically at £4,700 per patient. Savings of over £220K would be realised if the 58 patients were prescribed a recommended brand of glycopyrronium.

4.7. Sustainable Prescribing

In common with the Greener NHS agenda, NHS NEL is committed to reaching net zero carbon by 2040 and have an Integrated Care System (ICS) Green Plan. Part of this plan includes utilising low carbon options within work programmes where possible to enable the ICS to achieve its carbon reduction targets. Medicines account for 25% of emissions within the NHS. NHS NEL may therefore recommend a specific brand, where if a significantly lower environmental impact can be demonstrated without compromising clinical efficacy. As part of discussions on brands that offer lower environmental impact, consideration will be given to wider aspects of carbon footprint for example potential waste from reduced adherence or impact on frequency of patient journeys required to access particular products. This will also be aligned with national recommendations.

4.8. Identification of Suitable Medicines

Before a branded generic is recommended for routine prescribing, the Pharmacy and Medicines Optimisation team will ensure that all of the following criteria are met: and confer with the NEL-Position-statement-for-generic-and-brand-prescribing-V1_06.2023.pdf (icb.nhs.uk)

- The medicine should be prescribed by brand name according to the reasons set out in sections 4.5, 4.6 and 4.7
- The branded generic product is listed on prescribers' clinical systems
- There is sufficient information on the branded generic product in the British National Formulary (BNF) or the Summary of Product Characteristics data sheet for the medicine (accessed via: Home - electronic medicines compendium (emc))
- There are no future changes in practice/guidance identified through horizon scanning that might impact on the future preferred medicines and decision to recommend a specific branded generic.

4.9. Implementation and Communication of Recommended Branded Generics

i. Appropriate steps must be undertaken to ensure that the Pharmacy and Medicines Optimisation team communicate, newly approved and existing recommendations for branded generics, in a timely and effective manner, to all relevant stakeholders. This may include consulting with the Local Pharmaceutical Committee for the most costeffective branded generics, updating all relevant medicines formularies and GP

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- prescribing decision support systems (e.g. OptimiseRx), and any other relevant ICB documents (e.g. position statements, newsletters).
- ii. The Pharmacy and Medicines Optimisation team must also ensure that local community pharmacists, who are likely to be impacted by a recommendation, and the LPC are consulted as partners so that they can inform any final decisions and order in the appropriate product while reducing the stockholding of other brands they may have in stock. Where relevant, community pharmacists, and the Local Pharmaceutical Committee will also be informed of any specific suppliers or ordering mechanisms for recommended branded generics.

4.10. Review and Audit

- i. The Pharmacy and Medicines Optimisation team will regularly review prescribing data to ensure the appropriate use of brand and branded generics in line with this position statement and resources outlined.
- ii. Any new branded generics recommended for use by NHS NEL must be reviewed regularly to ensure that they are being prescribed appropriately and to identify any particular problems for escalation, e.g. supply issues. Prescribing usage and expenditure data on ePACT2 will be analysed, as well as review of feedback from prescribers and community pharmacists and the LPC.

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5 INTERNAL AND EXTERNAL REFERENCES

- Area Drug and Therapeutics Committee Position Statement: Prescribing of Branded Generics. NHS Lothian. V3.0. December 2019 <u>ADTC Position Statement Prescribing</u> <u>Branded Generics Dec 2019 v3 (nhslothian.scot)</u>
- Branded Generic Prescribing: Process for Considering Branded Generic Prescribing.
 NHS North Central London Joint Formulary Committee. Draft document (undated).
- Bulletin 290: Attachment 1. Branded generics QIPP savings. PrescQIPP. V2.0. July 2021 Bulletin 290: Branded generic medicines | PrescQIPP C.I.C
- Bulletin 290: Branded generic medicines. PrescQIPP. V2.0. July 2021 <u>290. Branded generic medicines 2.0 (prescqipp.info)</u>
- Example medicines to prescribe by brand name in primary care. NHS Specialist Pharmacy Service. June 2023 <u>Example medicines to prescribe by brand name in primary care – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice</u>
- Position Statement on Generic and Brand Prescribing. NHS North East London. V1. June 2023 <u>NEL-Position-statement-for-generic-and-brand-prescribing-V1 06.2023.pdf (icb.nhs.uk)</u>
- Prescribing by generic or brand name in primary care. NHS Specialist Pharmacy Service. September 2022 <u>Prescribing by generic or brand name in primary care – SPS</u>
 Specialist Pharmacy Service – The first stop for professional medicines advice
- Prescribing of Branded Generic Medication Position Statement. NHS South West London. V1.0. June 2023 <u>SWL-Prescribing-of-Branded-Generic-Medication-Position-Statement.pdf</u> (icb.nhs.uk)
- Position Statement on the Prescribing of Branded Generics. NHS North East and North Cumbria Feb 2024 <u>NENC-Position-statement-on-Branded-Generics-v2-approved-Feb-2024.pdf</u> (ntag.nhs.uk)

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