East Surrey CCG
Guildford & Waverley CCG
North West Surrey CCG
Surrey Downs CCG
Surrey Heath CCG
Crawley CCG
Horsham & Mid Sussex CCG

Recommendations for appropriate prescribing of generic and branded medicines

1. Executive Summary

A generic medicine contains the same quantity of active substance(s) as the proprietary medicine that originally received marketing authorisation (i.e. the reference medicine). If a generic medicine is granted a license, the regulatory authority has considered it equally safe and clinically equivalent to the reference branded medicine when used at the same dose to treat the same condition. There is little clinical evidence to suggest that interchanging branded and generic medicines causes any adverse clinical consequences[1].

As such, prescribers are encouraged to prescribe medicines by their generic name as they are generally considerably less expensive, thereby freeing up NHS resources to pay for other treatments.

It is good practice to prescribe drugs generically using their approved, International Non-proprietary Name (INN) (i.e. as described in the BNF) and not specify the manufacturer or supplier, except where a change to a different manufacturer's product may compromise efficacy or safety.

There are some circumstances in which continuity of the same brand is important for clinical reasons, when it is appropriate to prescribe a specific manufacturer's product (branded or generic).

Recommendations as to how healthcare professionals can support patients adhere to their prescribed medicine can be found in NICE clinical guideline 76: *Medicines adherence: involving patients in decisions about prescribed medicines and supporting adherence*.

This document provides a background on why generic drugs should be prescribed and the circumstances when this may not be appropriate.

The recommendations within this document may be utilised by individual CCGs to support further development of local policy.

2. Background

The switch from branded to generic medicines in appropriate patients has been identified as a potential prescribing efficiency by many CCGs. Data from the NHS Information Services Portal indicates that this could release over £1 million of annual savings across the MCG member CCGs if 100% of possible switches from brands to generic occurred.

Information on these potential efficiencies has been made available to GP practices for some years, but there has been some reluctance to change certain patients. In order to support practices in making these changes, CCGs have developed policies supporting the advice in the British National Formulary (BNF)[2].

The British National Formulary (BNF) guidance 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.*"

3. Benefits of Generic Prescribing[1]

- Many medicines are available in both generic and branded forms. However, generic medicines are, overall, much less expensive to the NHS.
- Generic prescribing can reduce the risk of prescribing or dispensing error as each drug has only one approved name, rather than many brand names.
- Generic prescribing allows patients to recognise the medicine International Non-proprietary Name (INN) on their prescription. This will reduce expectation that a particular brand should be used when a situation occurs where a different product needs to be supplied. Examples of these situations could be patent expiry or a brand becoming unavailable or obtaining supply from abroad or a hospital or different dispensary than the patient's usual one.
- Generic prescribing allows any suitable generic (or equivalent branded product) to be dispensed, reduces the number of items to be stocked in the pharmacy and can potentially reduce delays in supplying medicines to the patient (e.g. when a particular brand is not stocked).

4. Situations where prescribing by brand name is appropriate[3]

The UK Medicines Information (UKMI) service have published a document entitled "*Which medicines should be considered for brand-name prescribing in primary care?"*. This was updated in November 2017 and is available on the Prescribing Advisory Database (PAD; http://pad.res360.net/Content/Documents/Enc%20B%20-%20UKMi_QA_Brand-name_prescribing_Update_Nov2017.pdf

The document identifies those circumstances when it is appropriate to prescribe a specific manufacturer's product. Specific circumstances are described below:

◆ **Where there is a difference in bioavailability** between brands of the same medicine, particularly if the medicine has a narrow therapeutic index. In these circumstances, lack of clarity over which preparation is intended when prescribing can lead to the patient receiving a sub-therapeutic or toxic dose. Examples include ciclosporin, lithium, CFC-free beclometasone metered dose inhalers and some antiepileptic medicines.
◆ **Where modified release preparations are not interchangeable**, particularly if the medicine has a narrow therapeutic index. This avoids confusion between formulations with different release characteristics. Examples include aminophylline, diltiazem and morphine.
◆ **Where there are important differences in formulation** between brands of the same medicine. For example, fentanyl patches are available as matrix formulations and reservoir formulations. Reservoir patches must not be cut because damage to the rate-limiting membrane can lead to a rapid release of fentanyl resulting in overdose. If the prescriber intends the patch to be cut (although this is unlicensed and not recommended by the MHRA) then the prescription must specify a brand of matrix formulation patch.
◆ **Where products contain more than one ingredient** and brand name prescribing aids identification. This is useful when prescribing products with multiple ingredients (e.g. pancreatin supplements, skin and scalp preparations) and to differentiate between similar products where patient familiarity with a brand is important (e.g. hormone replacement therapy and oral contraceptives).
◆ **Where administration devices** have different instructions for use and patient familiarity with one product is important. For example salbutamol dry powder inhalers, combination inhalers and adrenaline pre-filled syringes.
◆ **Where the product is a biological** rather than chemical entity. Such agents are licensed as 'biosimilar' medicines. Examples include somatropin (growth hormone) and insulin preparations

- **In exceptional circumstances, where the cost of the generic product is considered to be disproportionately excessive**
  In circumstances where a generic product price is significantly more costly than a branded product, the MCG or PCN may make a recommendation to prescribe a branded product. In making such a recommendation, the following factors will be considered:
  - Consideration of the cost-benefit versus the impact on patient care if recommending a switch from one product to another
  - The impact on prescriber time
  - The likelihood of price fluctuations that would alter the recommendation
  - Product availability through usual pharmaceutical wholesalers
  - Impact on community pharmacy

In addition to the situations above, the following circumstances may necessitate the prescribing of a specific product:

- **Different excipients -** Inactive formulation ingredients (excipients) may differ between products (branded and generic). Where an individual patient is experiencing intolerable side effects and, in the clinical opinion of the prescriber, the side effect is consistent with reported intolerances of an excipient, it may be reasonable to prescribe a specific brand or generic product that does not contain the troublesome component.

- **Following guidance from NHS England –** in February 2015 NHS England issued guidance recommending that the drug pregabalin should be prescribed by its brand name Lyrica® for the treatment of neuropathic pain. This guidance was issued due to the potential infringement of the manufacturer's patent for this indication. At the time of writing this is the only drug affected.

References

1. Greater Manchester Medicines Management Group (GMMMG) Guidance - Generic Prescribing Guidelines; version 1.0, December 2013.

2. BNF Guidance on Prescribing, Non-proprietary title. https://bnf.nice.org.uk/guidance/guidance-on-prescribing.html

3. Which Medicines should be considered for brand name prescribing in Primary Care? UKMI; Medicines Q&A. February 2009, updated November 2017. Available at https://www.sps.nhs.uk/wp-content/uploads/2017/12/UKMi_QA_Brand-name_prescribing_Update_Nov2017.pdf