Generic Prescribing Position Statement

Summary

- Prescribers are encouraged to prescribe medicines by their generic name using the approved WHO International Nonproprietary Name (INN)[1] that is as described in the latest British National Formulary (BNF)[2]

- Generic medicines are usually as effective as the branded versions, but can cost the NHS up to 80% less[3]

- The Department of Health continues to support the increased use of generic medicines, recognising that there are still some more cost savings to be made in this area

- There are some circumstances in which continuity of the same brand is important for clinical reasons

Background

The INN (International Nonproprietary Name) is a drug's real name. Created by the World Health Organization (WHO), the standardised INN system is used throughout the world.[1] It allows healthcare professionals and patients to identify a drug precisely and with confidence, and to avoid potentially serious adverse effects due to confusion between drugs. Every drug has its own INN, but not all drugs have generics.

Generic drugs are copies of brand-name drugs that have exactly the same dosage, intended use, effects, side-effects, route of administration, risks, safety, and strength as the original drug. Their pharmacological effects are exactly the same as those of their brand-name counterparts that originally received marketing authorisation (i.e. the reference or innovator medicine). If a generic medicine is granted a licence, 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. Many medicines are available in both generic and branded forms, with the former generally, but not exclusively so, being overall less expensive to the NHS.[3]

Benefits

Generic prescribing can reduce the risk of prescribing or dispensing error as each drug has only one approved name, rather than many brand names.[3] It allows patients recognise the INN of their medications on their prescription, thereby reducing the expectation that a particular brand will be used should a different product need to be supplied, for example when there is a patent expiry, brand unavailability or the need to obtain an alternative supply from abroad, a hospital or a different pharmacy to the patient's usual one. As generic prescribing allows any suitable generic (or equivalent branded product) to be dispensed it reduces the number of items to be stocked by a pharmacy and thus can potentially reduce delays in supplying medicines to the patient (e.g. when a particular brand is not stocked). 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 specified.[3]

Cost Savings

The Department of Health supports the increased use of generic medicines and recognises that there are still some more cost savings to be made in this area but mindful that it should be achieved in a way that is acceptable to patients.[1] Nonetheless, the appropriate use of generic prescribing instead of branded medicines can deliver considerable cost savings. Average NHS levels of generic prescribing for the period 1976 to 2013 have increased from 20% to 84%, respectively. This has resulted in saving the NHS around £7.1 billion and allowed 490 million more items to be prescribed without an increase in spending. Consequently, the NHS is now getting much more value for every pound it spends on prescribing.[4]

With the generic prescribing rate across Blackpool CCG practices averaging at 89%, further improvements would be harder to attain. However, a proportion of medicines, although prescribed generically, are still dispensed as proprietary; on average these medicines cost nearly seven times more than those prescribed and dispensed generically. Of the total NHS prescribing spend, these medicines dispensed as proprietary products now account for around 29% of the total NHS prescribing spend (compared to nearly half in 2004/5) so there is potential for further savings.[4]

Significantly, despite high average rates of generic prescribing, there remains variation between general practices, suggesting some scope for increasing generic prescribing rates for some practices. In Blackpool for the last quarter of 2015-16 there were potential savings of approximately £25k from generic prescribing. In reality, only around 50% of this is likely to be achievable.

When should a Specific Manufacturer's Product be Prescribed? [3,5,6]

There are some circumstances in which continuity of the same brand is important for patient safety and brand-name prescribing is preferred. These include:

- A specific manufacturer's product could be either branded or generic

- When specifically advised to do so as part of a CCG prescribing initiative

- Where there is a difference in bioavailability between brands of the same medicine, particularly if the medicine has a narrow therapeutic index

  There is no good quality evidence for any clinically significant difference between bioequivalent medicines containing drugs with a narrow therapeutic index. However, in view of the concerns and potentially serious consequences of losing therapeutic control, patients should be maintained on the same manufacturer's product for drugs with a narrow therapeutic index.

- Where modified release preparations are not interchangeable

  Drug release and bioavailability profiles may differ considerably between modified-release or extended-release formulations of drugs, primarily because of different formulation approaches taken by manufacturers. The MHRA recommends that all modified-release preparations should be prescribed by their brand name. The BNF warns against changing brands only where there is the possibility of significant clinical impact (e.g. loss of clinical control or increased risk of adverse effects).

- Where modified release preparations are not interchangeable (cont/d.)

  In many instances, variation that results from non-bioequivalence is likely to have a smaller effect than other factors that determine absorption and distribution of the drug, for example not taking the medicine exactly on time and varying the time of taking the medicine with respect to food. For these reasons the BNF does not highlight the need to keep to the same brand for every modified-release drug.[2]

- Where there are important differences in formulation between brands of the same medicine

- Where products contain multiple ingredients and brand name prescribing aids identification

- Where administration devices (e.g. inhaler or self-injection) have different instructions for use and patient familiarity with one product is important.

- Where the product is a biological rather than chemical entity.

Patient Requests for Specific Brands

Some patients wish to continue to be prescribed their preferred branded medication even though there is not a clinical requirement to do so. The GP NHS terms of service require that a patient receives an NHS prescription where a treatment is deemed clinically necessary. Accordingly, unless there is a clear clinical justification for prescribing a particular brand, for example intolerance to a specific excipient, then a generic prescription must be issued. If a patient requests a particular branded product, despite local NHS policy to prescribe generically, it is not appropriate to issue a private prescription. The GPC has issued advice regarding the issuing of a private prescription forms alongside or as an alternative to a FP10, for example in circumstances where this is a cheaper option for the patient than paying the NHS prescription charge or patient preference for as a particular brand. Thus, in any case where a GP is obliged to issue an FP10, the concurrent issue of a private prescription will be a breach of obligation. Additionally, in any case where a GP is obliged or entitled to issue an FP10 the concurrent issue of a private prescription will be conduct calculated to deprive the NHS of a small amount of money and will on that account also be wrongful.

The advice is therefore that GPs do not issue private prescriptions under these circumstances.[7]

References

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4. The King's Fund. Better value in the NHS. The role of changes in clinical practice July 2015 http://www.kingsfund.org.uk/publications/better-value-nhs

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