PRESCRIBING DRUGS USING GENERIC NAMES

The Clinical Commissioning Group (CCG) recognises the equivalence, on grounds of clinical efficacy, of generic drugs approved by Medicines and Healthcare products Regulatory Agency (MHRA) or the European Medicines Agency (EMA). Approval is only granted when a generic product has been proven to meet strict comparison criteria [1]. It is therefore accepted that generic prescribing is appropriate and expected from prescribers in the primary care setting.

In the majority of cases, the generic product is significantly cheaper than the branded equivalent. To ensure the NHS, CCG and practice budgets make best use of limited NHS resource it is highlighted to all prescribers that generic prescribing is considered as normal practice. Variance from this position will only be approved in exceptional circumstances for drugs that need to be continued, which may involve:

- drugs and associated medical conditions where there is known concern around the stability of drug levels and their importance in managing and controlling that medical condition
- the use of generic names may increase the risk of confusion and potentially significant errors
- patients have demonstrable and significant sensitivity to generic products, where it is not possible to:
    - alter the patients drug to an alternative drug from the same class or of similar effect and benefit (ideally in keeping with national guidance)
    - specify a low-cost branded generic product

Any decision to vary from generic prescribing should be made at the discretion of the GP based on clinical evidence and not solely on the preference of the patient. If the GP does not consider there to be genuine clinical need for the item to be prescribed by brand then the case can be referred to Prescribing Advisors at the CCG.

Outside of secondary care settings, other prescribers should refer individual cases for consideration of branded prescribing to the patient's GP.

Approved by:
CCG Prescribing Team November 2012

[1] Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 – amending Directive 2001/83/EC on the Community code relating to medicinal products for human use:

Article 10

2(b) – "generic medicinal product" shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioequivalence studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless the differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.