

Non-proprietary names for medicinal products: procedure for constructing names by the BNF

Background

- 1.1 This procedure sets out the process by which the British National Formulary, under the authority of the Joint Formulary Committee, may introduce a non-proprietary name for a medicinal product.
- 1.2 A non-proprietary name for a product containing one or more active ingredients may need to be constructed because:
 - A patent of a proprietary product has expired (or is about to expire)
 - A new generic formulation which has the same composition as a proprietary product has been introduced
 - A requirement is identified to prescribe the product by a non-proprietary name

Name construction process

- 2.1 The BNF will process the construction of non-proprietary titles once a year beginning in early March.
 - 2.1.1 Applications should be sent in writing to, Executive Secretary, Joint Formulary Committee, British National Formulary, 1 Lambeth High Street, London SE1 7JN.
- 2.2 The BP Commission will be contacted to confirm that it is not minded to introduce a monograph for the product.
- 2.3 The BNF will apply the conventions set out in Supplementary Chapter IIB of the British Pharmacopoeia in order to construct non-proprietary titles. These will include the use of Standard Terms as published by the Council of Europe (*Pharmeuropa*, Special Issue, December 2002) and as may be subsequently amended. The BP Commission will be consulted for guidance on constructing particular names.

Consultation

- 3.1 For each product, the following will be consulted on the proposal to construct a non-proprietary name and on the non-proprietary name being considered:
 - Known manufacturers
 - Medicines and Healthcare products Regulatory Agency
 - BP Commission
 - Department of Health, Medicines Pharmacy and Industry Division
 - Scottish Executive Health Department
 - NHS Wales
 - Northern Ireland Department of Health, Social Services & Public Safety

- 3.2 To ensure that all interested parties are consulted, The Association of the British Pharmaceutical Industry and the Proprietary Association of Great Britain will be notified and a notice of the proposal will be placed on the BNF website, in the *Pharmaceutical Journal* and on the MHRA website.
- 3.3 Interested parties shall have a period of 6 weeks from the date the BNF's consultation notice is published to comment in writing.
- 3.4 The BNF will respond to comments from interested parties within 14 working days of receiving the comments and, if necessary, instigate a second consultation.
- 3.5 A second consultation will be initiated if, in the light of the first consultation, either
- (a) significant changes are required to the proposal; or
 - (b) there are significant objections and/or significant suggested amendments to the proposal which the BNF is not minded to accept
- 3.6 In the case of (a) above, all parties listed in paragraphs 3.1 and 3.2, and all consultees who have made representations in the first consultation, will be notified of the amended proposal and notice of the proposal will be placed on the BNF website, in the *Pharmaceutical Journal* and on the MHRA website.
- 3.7 In the case of (b) above, consultees who communicated significant objections and/or significant suggested amendments to the proposal which the BNF is minded not to accept shall be notified of the BNF's decision and given the opportunity to make further representations.
- 3.8 In both (a) and (b) of paragraph 3.5, the parties notified in accordance with paragraphs 3.6 and 3.7 shall have a further period of 6 weeks from the date the BNF's second consultation notice is published to comment in writing.
- 3.9 The BNF will respond to comments from interested parties within 14 working days of receiving them.

Decision and announcement

- 4.1 At the end of the consultation period, the BNF will make a final decision on the title to be coined within a further 4 weeks. This will include a simultaneous (as near as practically possible) announcement of the title on the BNF website, in the *Pharmaceutical Journal* and on the MHRA website.
- 4.2 The new non-proprietary title will be shown in the next available edition of the BNF.