

Guide to Batch-Specific Requests for Veterinary Medicines

Batch-specific requests (~~BSR~~BSRs) are limited in duration and are only accepted for authorised medicines to ensure maintenance of supply, when supply of product in full compliance with its registered marketing authorisation (MA) dossier is temporarily and unavoidably unavailable, or to bring a batch into compliance with its registered marketing authorisation dossier. Marketing authorisation holders (MAHs) are strongly discouraged from applying for a BSR when batch(es) are not in line with the product's finished product specifications. However, in exceptional circumstances non-critical deviations may be considered on a case-by-case basis.

The BSR procedure can be used in situations where an extension to the implementation time for an approved variation or the extension of implementation of changes to labels/leaflet agreed during renewal is required. In such instances, where the variation has been approved and the MAH holder is unable to meet the required timeline for implementation of the change, an extension may be sought via submission of a BSR.

Where the applicant is someone other than the ~~marketing authorisation holder (MAH)~~MAH, a specific letter of consent from the holder is required for the request.

~~Normally one batch may be specified or batches sufficient to supply the market for no longer than three months.~~

When a BSR is intended to assure the continued supply of a product, it is normally limited to the number of packs or batches required to supply the market for no longer than three months. More than one batch of product can be specified on a BSR application. If the BSR is intended to correct a quality defect (to bring a product in line with the registered dossier), this three-month restriction does not apply, i.e. the BSR has indefinite validity.

Applications involving labels and leaflet must be accompanied by copies of the approved and proposed full colour mock-ups with all differences highlighted for review.

Where insertion of the approved leaflet is required or where in exceptional circumstances, over-labelling is required, this must be carried out by a licensed manufacturer who is specifically licensed to carry out such manufacturing operations for veterinary medicinal products. A copy of the manufacturer's licence held by the site which will be performing this packaging activity should be submitted; or its Eudra GMP reference provided. When, in exceptional circumstances, over-labelling is required, it must not obliterate required original text; if placed to cover incorrect text, the over-label should not permit the underlying text to be visible. -The over-label must have permanent adhesive.- A written report on the operation should be prepared and retained at the manufacturing site for review at a subsequent inspection. ~~Where applicable, sample labels should be included with the report.~~

If the HPRA has approved a BSR application for the rubber-banding of documentation (e.g. a package leaflet (PL) or a Caution-in-Use (CIU) letter) to the outer pack of the product, or the insertion of product into a sleeve/plastic bag, etc., with additional information (such as the PL or

CIU letter) in it, the rubber-banding or insertion operation does not need to be carried out by an authorised manufacturer under GMP, as the packs are not being opened or reassembled. However, such an operation should be performed at an authorised wholesaler, and a formal reconciliation of the PLs or CIU letters should be carried out once the operation is completed.

BSRs should not be submitted for batches ~~which have been deemed by~~ with an unexpected deviation during manufacture or distribution; in these cases, the Qualified Person ~~to meet the terms of the 'Reflection paper on a proposed solution for dealing with minor deviations from the detail in the Marketing Authorisation(QP) should deal with the deviation in line with Section 3 of Annex 16 to the 'European Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Medicinal Products (including biological products)'. This reflection paper (document reference EMEA/INS/GMP/227075/2008) is published on the EMA website.~~

~~The BSR procedure-Use' which also provides useful guidance to determine if the batch can be used in situations where an extension to the implementation time for an approved variation is required. In such instances where the variation has been approved and the MAH holder is unable to meet the required timeline for implementation of the change an extension may be sought via submission of a BSR~~still be considered to meet the requirements of the MA and of GMP, and be certified for release.

An application for a batch-specific request should be accompanied by a covering letter and ~~the 'Veterinary medicine fee application form'. It~~proof of payment and can be ~~either~~ submitted either by e-mail to submissions@hpra.ie or by post (one copy) to the address below. The BSR application and fee forms are available from the HPRA website. If the BSR has been discussed with an assessor or a Market Compliance staff member at the HPRA prior its submission, please indicate so accordingly.

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