

CODE OF PRACTICE FOR PACK DESIGN FOR OVER THE COUNTER MEDICINES

Guidance for applicants submitting following pre-approval by the Proprietary Association of Great Britain

INTRODCUTION

Council Directive 2001/83/EC as amended, requires that marketing authorisation holders (MAH) inform the competent authority of all changes to the labelling which are not connected to changes to the Summary of Product Characteristics (SPC) [Article 61(3)]. Notwithstanding the need to notify the competent authority of the amendment, responsibility for the information presented on the packaging rests solely with the MAH.

Article 62 of the Directive permits the inclusion of additional information on the labelling of medicines provided it is compatible with the SPC, useful for the patient and non-promotional. Information of this nature is termed non-statutory and a Code of Practice which deals with this has been developed for use by the over-the-counter (OTC) medicines sector. The code of practice is available from the PAGB.

BACKGROUND

Following the work of the [Better Regulation of Medicines Initiative](#), the Patient Information Quality Unit (PIQU) is offering this scheme in conjunction with the Proprietary Association of Great Britain (PAGB) as a mainstream process. Applications in relation to changes to the design of packs and any non-statutory information included on labelling fall into this category and may be subject to pre-approval by the PAGB.

This scheme introduces a new regulatory model which will include pre-approval of all non-statutory information on the pack by the PAGB in line with the code of practice followed by an expedited assessment by the MHRA. The MHRA will continue to assess and approve all statutory information covered by articles 54, 55 and 59 of Council Directive 2001/83/EC and all non-statutory information in the body of the Patient Information Leaflets (relating to improving patient understanding of the disease and better risk communication) set out in compliance with article 62.

Details of the how the PAGB will operate the pre-approval process and the information they require from MAHs in advance, are available from their website.

The code of practice and the new regulatory model apply only in respect of medicines available over-the-counter as pharmacy (P) or general sales list (GSL) medicines.

HOW TO APPLY

Where the proposed changes include changes to non-statutory information applications can be submitted to the MHRA for an expedited assessment following pre-approval by the PAGB. The usual [application forms](#) should be used and submitted to the MHRA following the instructions in [Special Mail 5](#). For preference submissions should be made electronically. Full colour mock-ups of the proposed final version of all artwork affected by

the application must accompany the submission labelled (and consolidated) according to the instruction provided by the Information Management Division.

All application forms should include the following statement in the “Background” box on the form to ensure the application is appropriately routed on receipt:

“Application submitted for expedited assessment of pack redesign following pre-approval by PAGB according to the published Code of Practice for Pack Design for OTC Medicines.”

In addition you should be clear about the detailed changes being made to the pack by itemising these separately.

Valid applications will be expedited for assessment and you will receive feedback from the assessment area within 30 days. The assessment start date will be notified to you in writing within 10 working days of submission. If you have not received such a letter within the expected timeframe you should contact the Submissions Centre for further information. On conclusion of the procedure you will receive a formal approval letter from the MHRA. As with all other applications you should not print or use new packaging until such time as you have been notified that the application has been concluded successfully.

FEES

The usual fee arrangements will apply to applications submitted under this scheme and the current fee is £544. Bulk fee discounts of one full fee with a 50% reduction in further fees for applications submitted concurrently will apply where identical changes are being made across a range of different strengths of the same dosage form.

MONITORING

Acceptance of applications submitted under this scheme is based on the declaration from the MAH that the principles set out in the code of practice have been adhered to and that prior approval from the PAGB has been received.

A formal audit of 100% of applications made under this scheme will be made to monitor the quality and validity of submissions. Feedback will be provided to the PAGB and to applicants via individual communications and the MHRA website as appropriate.

The MHRA also investigates complaints about the labelling and packaging of medicines made by healthcare professionals, patients or pharmaceutical companies. A complaint may arise about a particular product, a particular pack or an entire product range. The PIQU will consider all complaints received and will report particular complaints received in relation to the code of practice to the PAGB. Details of the [complaints procedure](#) are available from our website.

CONTACT FOR FURTHER INFORMATION

Further information is available from Mrs Jan MacDonald on 020 7084 2267 or via email at patient.information@mhra.gsi.gov.uk