

PAGB Briefing Note

The PAGB Code of Practice for Pack Design – How does it work in practice?

Introduction

Article 61(3) of Council Directive 2001/83/EC as amended, requires marketing authorisation holders (MAH) to inform the competent authority of all changes to the labelling and patient information leaflets which are not connected with changes to the Summary of Product Characteristics (SmPC).

Article 62 of Council Directive 2001/83/EC as amended permits the inclusion of non-statutory information on packaging provided it is compatible with the SPC, useful for the patient and non-promotional.

Following the work of the Better Regulation of Medicines Initiative, PAGB is offering this scheme in conjunction with the Patient Information Quality Unit (PIQU) as a mainstream process in relation to changes to the design of previously approved packs and any non-statutory information included on labelling. Applications under the scheme are for those changes to packaging components submitted to the PIQU under article 61(3) of Council Directive 2001/83/EC and which do not include change to the summary of product characteristics. The notification scheme for self certified changes does not apply in these cases.

All non-statutory information on pack will be subject to pre-approval by PAGB in line with the code of practice followed by an expedited assessment by the MHRA. Although PAGB's approval will apply to the non-statutory information only, the statutory information will also be assessed during the pre-vetting process to ensure compliance with current regulatory requirements.

This new mainstream procedure will be available to PAGB member companies as well as non-member companies, on condition that they comply with the conditions set out below.

MHRA will continue to assess and approve all changes to the statutory information required under articles 54, 55 and 59 and any non-statutory information added into patient information leaflets under article 62.

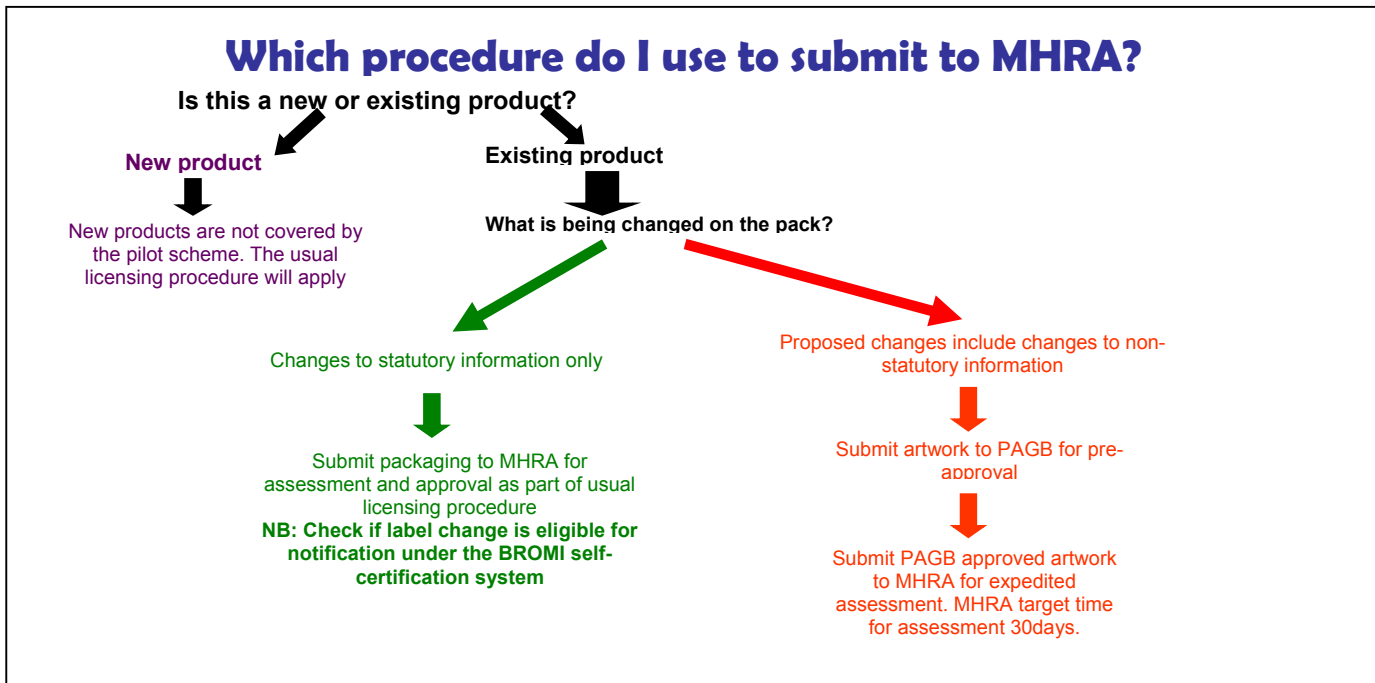
PAGB, with input from MHRA, has developed a Code of Practice for Pack Design to encourage best practice in medicines labelling and provide practical advice to manufacturers designing and amending packaging of over the counter medicines. The Code of Practice provides advice in relation to the provision of the statutory information on packs and contains detailed information on typography and layout and the use of non-promotional symbols and non-statutory information assessed to help consumers identify the product and use it safely and appropriately. Examples are provided to illustrate the various issues. The code of practice is available from the PAGB website.

Responsibility for the information presented on the packaging, and in the patient information leaflet, rests solely with the marketing authorisation holder (MAH). The MAH is responsible for maintaining the marketing authorisations of their products and

for compliance with current regulatory requirements. They are responsible for informing MHRA, using the appropriate application or self certification notification procedure, of any changes to a marketing authorisation (MA) to ensure that the information held by MHRA accurately reflects the current state of the product.

Which procedure applies to my pack change?

The following flow chart details which procedure applies in the various different situations.



How the PAGB pre-vetting procedure will work

The PAGB pack pre-vetting service will operate along the same lines as the existing PAGB copy clearance service. Helen Darracott and Helen Taylor will be responsible for assessing packs submitted to PAGB.

In order to avoid confusion with copy submitted for pre-vetting please submit artwork to the following email address - packs@pagb.co.uk

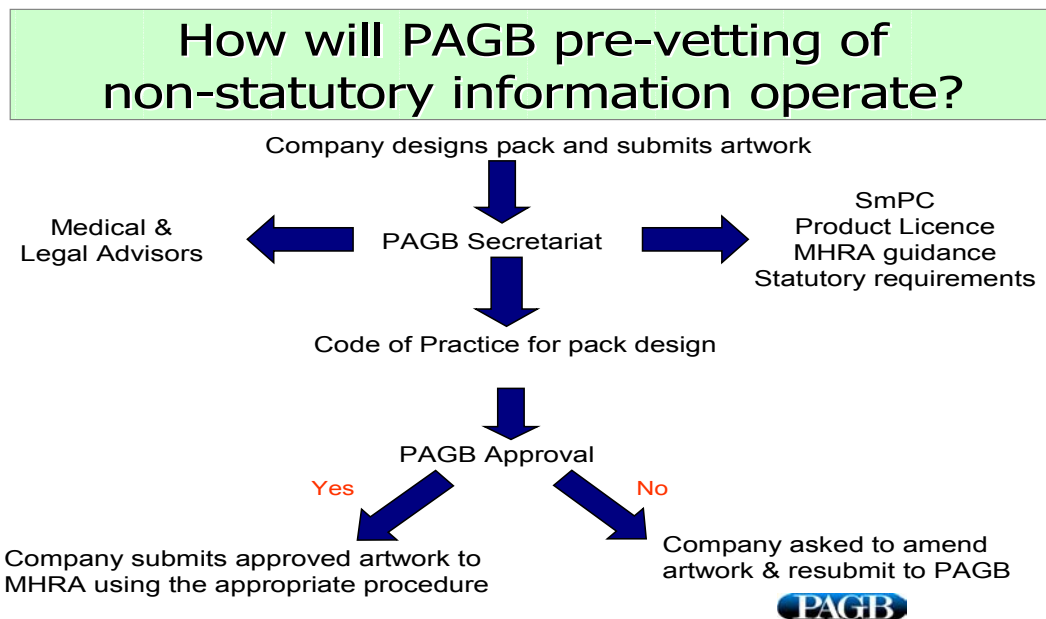
The system will operate as follows:

- 1) Company designs pack and submits the proposed artwork electronically to packs@pagb.co.uk In addition to the proposed artwork, companies are required to submit the currently approved packaging and SmPC. In addition companies are requested to detail the changes being made to the pack by itemising these separately in the email
- 2) PAGB will assess the pack for consistency with the product's SmPC and compliance with MHRA guidance, statutory requirements and the PAGB Code of Practice for Pack Design. If necessary, we will consult our medical and/or legal advisors.

3) If the pack complies with all requirements “PAGB Approved” stamp will be applied to the electronic artwork. The stamped approved artwork may then be submitted to MHRA together with the completed MHRA application form including the signed declaration.

4) If the pack is not approved by PAGB we will tell you why and ask that you make the necessary amendments before resubmitting to packs@pagb.co.uk

5) Our target turn-around time for packs is 5 working days. We will inform you if we are not able to meet this deadline.



MHRA expedited approval system for pack changes

MHRA has issued detailed guidance on the expedited assessment and approval system for pack changes.

- 1) Applications should be made in the usual manner and must include a standard form of words to indicate that Code of Practice principles have been adhered to. All application forms should include the following statement in the “Background” box on the form

“Application submitted for expedited assessment of pack redesign following pre-approval by PAGB”

This declaration will indicate to MHRA that the application is made in accordance with the expedited assessment and approval system and the application will be routed accordingly. The usual fees will apply.

Valid applications will be expedited for assessment and companies should receive feedback from the assessment area within 30 days following validation of the submission. Companies will be notified in writing of the assessment start date usually

within 10 working days of submission. Please refer to the MHRA guidance for further details.

Conditions for using the Code of Practice for Pack Design and expedited approval system

- **Supply to PAGB of electronic copies of SmPC and current packaging**

In order to assess packaging for compliance with the Code of Practice for Pack Design PAGB requires electronic copies of the SmPC and current packaging across the range. These may be supplied at the point of submission of amended packaging artwork or in advance.

Contacts for further information

For further information please contact either Helen Darracott or Lucy Rochford on 020 7242 8331 or via e-mail at packs@pagb.co.uk