

## **GUIDANCE ON CHANGES TO LABELLING AND PATIENT INFORMATION LEAFLETS FOR SELF CERTIFICATION – COMPLIANCE WITH ARTICLE 56(a) – INCLUSION OF BRAILLE ON THE LABELLING**

### **1. Introduction**

Article 56(a) of Council Directive 2001/83/EC [as amended], requires that marketing authorisations are updated to include the name of the medicine in Braille on the labelling. UK legislation requires all marketing authorisation holders (MAH) to comply with these provisions by 30 October 2010.

Detailed guidance has been published by the European Commission and the MHRA has also issued a series of frequently asked questions on this subject. This guidance document should be read in conjunction with these previously published guides.

<http://www.mhra.gov.uk/Howweregulate/Medicines/Labelspatientinformationleaflet sandpackaging/Brailleonlabellingandinpatientinformationleaflets/index.htm>

In certain prescribed circumstances which are set out below MAHs may update the labelling to demonstrate compliance with article 56(a) by means of a notification under the Better Regulation of Medicines Initiative (BROMI) notification scheme. Detailed guidance on this scheme is available from the MHRA website and is complementary to this specific guidance in relation to Braille.

<http://www.mhra.gov.uk/Howweregulate/Medicines/Labelspatientinformationleaflet sandpackaging/Notificationsscheme/index.htm>

Within the provisions of Council Directive 2001/83/EC [as amended] MAHs are required 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 (SPC) [Article 61(3)]. Notwithstanding the need for the applicant to notify the competent authority of the amendment, responsibility for the information presented on the packaging rests solely with the MAH.

### **2. Purpose**

This document sets out the circumstances under which changes to the labelling to reflect the requirements of article 56(a) of the Directive [Braille] can be subject to self-certification by the MAH, requiring only a notification be made to the MHRA.

**This scheme operates from 1 April 2009.**

### 3. General guidance

Where an applicant submits a notification for the changes set out below in respect of including the name of the medicine in Braille on the outer packaging and can meet the prescribed conditions associated with this change which are specified below, such changes will be deemed to be for self certification by the applicant.

Notifications made under article 61(3) for these individual changes will not be subject to formal assessment and approval by MHRA but will be self-certified by the applicant.

**In this case the notification may not make reference to any changes other than the intent to comply with the provisions in respect of Braille placement on the label.**

Notifications made to the MHRA under these provisions will be acknowledged within 14 days of receipt and on receipt of the acceptance correspondence can then be introduced immediately. The fee which applies to such notifications is defined within the relevant statutory instrument. As each notification will cover separate unique changes on each marketing authorisation, bulk fees will not apply.

Applicants intending to self certify the changes submitted must state clearly on the notification form that it is submitted under article 61(3), that the change relates to the inclusion of the registered product name in Braille on the label and that the necessary conditions have been complied with. The following statement must appear on the notification form:

***“Notification submitted to include the full product name as registered in section 1 of the summary of product characteristics in Braille as required by article 56(a) of Council Directive 2001/83/EC.”***

Full colour mock-ups of the proposed final version of the packaging components affected by the change must accompany the notification. Criteria for submission of mock-ups are set out in Special MAIL 5 and must be adhered to for a notification to be deemed valid.

### 4. Audit of submissions

Acceptance of these notifications is based on declarations by the MAH that the prescribed conditions have been fulfilled and the necessary supporting documentation has been submitted. MHRA will be operating a 100% quality audit system of applications submitted as notifications in relation to compliance with article 56(a) to monitor the validity of the submissions.

Notifications which fail to meet the criteria which apply will be rescinded and companies will be notified directly following the audit of any notifications which have been found to be deficient. Full applications to correct any omissions will be required to be submitted subsequently.

Outcome reports from these audits will be published on our website. The audit will be undertaken retrospectively on a quarterly basis.

## 5. Other changes

Changes to packaging not covered by this (or other BROMI) guidance or where the prescribed conditions have not been met must be submitted to the Patient Information Quality unit for formal assessment and approval. Normal timescales for assessment will apply and changes should not be introduced in the absence of a formal letter of approval in these cases.

## SPECIFIC GUIDANCE

### Braille alphabets

Both the Royal National Institute for the Blind (RNIB) in the UK and the European Blind Union (EBU) have published the Braille alphabets which are commonly understood by UK Braille readers. All applicants must use these recognised alphabets as a condition of notification. The alphabets are available from the MHRA website.

<http://www.mhra.gov.uk/Howweregulate/Medicines/Labelspatientinformationleaflet sandpackaging/Brailleonlabellingandinpatientinformationleaflets/index.htm>

### Information required to appear in Braille on the pack

The name of the medicine as set out in section 1 of the SPC **in its entirety** must appear in Braille on the label.

However, where only one strength or form of the medicine is available in the market place, the strength or form may be omitted. Where different pharmaceutical forms of the same medicine are available in the market place the pharmaceutical form must be included.

### Location of Braille text

It is preferable for the Braille text to appear on the front of the pack but this is not required. Braille text, if placed over other statutory information must not impair readability of the statutory information for sighted patients. Care will also be needed where non-statutory information is used for robotic picking systems to ensure that such information is not rendered useless by the placement of Braille.

Separately the Braille information must not be placed over the space set aside for the dispensing label to be applied to POM medicines.

Each applicant will need to make an assessment of the effect the addition of Braille will have on the readability of the statutory text in a general manner and this will depend on the means used to apply the information in Braille. It is likely that once a particular means of applying Braille has been researched the effect it will have on readability of typed text will not change. Nevertheless, use of a suitable “white space” on the packaging where available, is considered preferable for the application of Braille text.

### **Application of Braille to the immediate primary packaging of medicines**

The application of Braille should be to the labelling for the packaging component which meets the full labelling provisions of article 54. Blister strips for example will not be affected by these new provisions. However, if a bottle is presented with only a paper label applied to the container surface and no outer carton, the Braille should be applied to the bottle label.

### **Braille font to be used**

The guidance published by the European Commission recommends the use of Marburg Medium but there are other spacing standards available for Braille in use in other member states. Nevertheless the use of Marburg Medium is recommended and encouraged. Separately the British Standards Institute and European Centre for Normalisation are developing a standard for the application of Braille to medicines labelling and packaging and other fonts are recognised as being acceptable.

### **Use of contracted Braille and abbreviations**

Contracted Braille is a form of abbreviation and the information which has to be placed on a medicines label is not easily abbreviated. The full text should be used when applying Braille to medicines labels and packs.

### **Sample packs**

Sample packs are not intended for use by patients and therefore will not need the application of Braille. Sample packs are intended for prescribers to familiarise themselves with the product and are not for patient use in pursuance of a prescription.

### **Medicines administered by a healthcare professional**

Those medicines normally handled by healthcare professionals will not be required to include Braille on the packaging. However, where injectable products such as anti-diabetic medicines are handled by patients in the home these will need to include Braille on the pack to aid identification by the patient.

### **Applying Braille to more than one face of the carton**

Many registered product names are too long to fit in one line of Braille text on a carton or paper label. To accommodate the full registered name the following solutions should be considered:

- The full name can be accommodated on more than one line of Braille text on the packaging.
- More than one face of the carton may be used to enable the full registered product name to appear on the label. Ordering of different aspects of the registered name on different faces of the carton should be logical.
- Hyphenation of words may be used. However, hyphenation should be applied logically and should be carried out in Braille in the same way as when hyphenation is used for printed text for sighted patients.
- Braille text may be applied vertically to a carton where portrait labels make horizontal placement difficult.

Further information on the technical application of this guidance is available from the Patient Information Quality Unit at [patient.information@mhra.gsi.gov.uk](mailto:patient.information@mhra.gsi.gov.uk)

Further information on how to submit notifications under the BROMI scheme in relation to labelling and patient information leaflets is available on the MHRA website

<http://www.mhra.gov.uk/Howweregulate/Medicines/Labelspatientinformationleaflet sandpackaging/Notificationsscheme/index.htm> or from the regulatory information service at [variations@mhra.gsi.gov.uk](mailto:variations@mhra.gsi.gov.uk)

**Vigilance and Risk Management of Medicines Division**  
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