

## FAO all PLPI Regulatory Staff and Qualified Persons

### User Testing – Additional Information

As you are aware, Parallel Import companies have always had the option of meeting the requirement for consultation with target patient groups introduced by Directive 2004/27 by producing a leaflet which was identical to the UK leaflet except for product specific particulars, such as PL number and licence holder details.

Having gained experience from leaflets received, the Agency considers that this condition can be modified and PI leaflets can be judged to have met the requirement for consultation with target patient groups if they are sufficiently similar to the UK leaflet. The conditions which must be met are described below.

Companies wishing to follow this route should provide the information detailed below in the 'Statement of Compliance' for consideration and approval of their proposed leaflets.

For further information please contact:

[nicola.wilson@mhra.gsi.gov.uk](mailto:nicola.wilson@mhra.gsi.gov.uk).

**PLPI Units**  
**MHRA**  
**Mar 2009**

## Statement of compliance

The patient leaflet for the parallel import licence detailed below can be regarded as satisfying the requirement for consultation with target patient groups by virtue of its similarity to the UK leaflet.

PLPI No:

Size of finished leaflet:

Font and size used for body text:

Leaflet will be printed single / double sided (delete as appropriate)

Finished format: flat sheet / booklet / other -

The text of the leaflet exactly follows the text of the UK leaflet except for product specific differences. Yes/No (delete as appropriate)

A 100% scale mock-up (i.e. exact replica of the leaflet which will be inserted into patient packs) of the leaflet has been provided.

Other previously approved leaflets for **this** product satisfying the consultation requirement by similarity to the UK leaflet (PL numbers):

Signed:

Name:

## Conditions for the PI leaflet to be regarded as sufficiently similar to the UK leaflet

A PI leaflet can be considered to reflect consultation with target patient groups if it is sufficiently similar to the UK leaflet. The leaflet can be judged as sufficiently similar if the following conditions are met.

**Text:** The PI leaflet must use the full text of the UK leaflet apart from product specific particulars.

**Colour:** We encourage PI leaflets to adopt a colour scheme which, if not the same, should at least be a similar shade to that used in the UK leaflet. It is however recognised that the colour portions of the UK leaflet may be replaced by grey scale or black & white equivalents provided the overall presentation remains clear. Any portion of the UK leaflet highlighted by means of colour should be appropriately highlighted also using the adopted colour scheme in the PI leaflet.

**Column format:** The column dimensions of the PI leaflet should give a line length (number of characters) similar to that of the UK leaflet. The PI leaflet will be expected to have the same number of columns as the UK leaflet though this may be different in exceptional cases, if satisfactory justification is provided. The text justification should be the same as the UK leaflet, i.e. left or fully justified. The gap between columns should preferably be at least 10mm and not less than 6mm. A vertical line may assist visual separation of columns where the gap is small.

**Font:** The font and font size used in the PI leaflet does not have to be the same as that used in the UK leaflet. The font chosen should have a readability at least equal to that of 8pt Arial (normal width) though it is preferable if a larger font is used, e.g. Arial 9pt.

**Line spacing:** This should normally be the same as that used by the UK leaflet and in any event should not be reduced to less than that which is normal for the font chosen.

**Headings:** These should be clearly emphasised, preferably in the same way as the UK leaflet, for example by use of a larger font size, bold text and/or reverse printed text.

**Sub-headings:** Should be distinguished from both headings and other emphasised text and should be similar in placement and design to the UK leaflet.

**Emphasis:** Emphasised sections of the UK leaflet (e.g. bold or boxed) should be appropriately emphasised in the PI leaflet. Inappropriate emphasis (e.g. product name in bold throughout the leaflet) is not allowed.

**Graphics:** The PI leaflet should include all graphics present in the UK leaflet. The UK leaflet graphics may be replaced by grey scale or line drawing versions providing that the content of the image is the same. The graphics should be at least 95% of the size of the equivalent graphic in the UK leaflet. The aspect ratio of the original graphic must be maintained and the relative sizes of multiple graphics should be maintained. They must be clearly legible.

**White space:** There should be good use of white space, e.g. to break up large sections of text. For example, there should be a small space between paragraphs and sections of the text. The general pattern of white space in the UK leaflet should be followed in the PI leaflet but large areas of white space in the body of the leaflet should be avoided if possible.

**Paragraphs:** These should be used appropriately to avoid large blocks of continuous text.

**Column breaks:** These should be in appropriate places in the text. Important paragraphs should not be split across columns unless unavoidable and appropriately justified.

**Page dimensions:** The page size and aspect ratio should normally be similar to the UK leaflet though they can be different in exceptional cases, if satisfactory justification is provided.

**Page margins:** Preferably 10mm and not less than 7mm.

If the leaflet is not in line with the above requirements, a full user test may be required.