COMPLIANCE WITH ARTICLE 56(a) – PROVISION OF PATIENT INFORMATION LEAFLETS IN FORMATS APPROPRIATE FOR BLIND AND PARTIALLY SIGHTED PATIENTS

The transitional period in relation to the new legislation implementing the provisions in respect of PILs for blind and partially sighted patients [The Medicines (Marketing Authorisations etc) Amendment Regulations 2005 Number 2759 (SI 2005/2759)] came to an end on 30 October 2010. Marketing Authorisation Holders (MAHs) are reminded that to comply with the law they must now be in a position to respond to requests for alternative formats of PILs from patients and their healthcare professionals (HCP) for all medicines which they supply to the UK market. Alternative formats may include Braille, large print, audio tape, CD-rom.

To help with this and to enable patients to easily access the information in a format to suit their needs, the PIL should include details on how to access this information. MAHs may need to make changes to their approved PILs to achieve this and should do this via the notification scheme is open to those applicants who have not yet update their PILs. Alternatively, information directing patients and HCP to the service offered can be added at any forthcoming regulatory intervention which affects the PIL.

ADDITIONAL GUIDANCE CONCERNING GRAPHICAL IMAGES IN PILs

We have recently been in discussion with RNIB (Royal National Institute of Blind People) about difficulties currently being experienced by MAHs when converting some documents to accessible formats for blind and partially sighted patients which contain pictograms or other graphic elements. To help patients with sight loss, it is recommended that information illustrated through graphics in PILs is also described in the text. The following guidance will help those writing the leaflet information to determine what to include and how.

- Establish what information the image is showing and ensure that this information is included in the text. The images are usually instructional and generally demonstrate how to do something, hold something, clean or open something. The text has to reflect what the image is showing.
- If orientation for usage is critical to successful use of the medicine, this must be specifically described in the description. Avoid statements such as “hold upright as shown” without expanding on what is actually being shown. For example if an image shows how to hold an inhaler; state how it is being held “Hold the inhaler as shown in figure one, with thumb on the rounded base and middle finger on the flat top of the canister”.
- Describe any features of medicines which will feel distinctive to enable someone to orientate the medicine correctly by touch, for example words such as wide, narrow, rounded, flat.
• Establish which details are important; for example if packaging has an indicator – avoid saying "open via indicator as shown" – describe where this indicator is on the packaging.

• Ensure that where instructions are presented step by step with an image for each point, that the text reflects its accompanying image. Avoid writing text which implies that the image shows something which is not described.

• The text does not need to reflect what the image looks like, so for example, it is not necessary to describe that it is a black and white picture. It is the information in the image that is significant.

• Images which show a ‘before and after’ or photographs or showing a condition will also need to be described if important; for example, “the photograph shows a foot with a rash covering the entire big toe.”

• The appearance of conditions should be described as well as illustrated, together with an instruction for people to seek professional advice.

Applicants may find that changes are required to PILs which include images to ensure that the information is accessible when converted to an alternative format. Such changes should be made to the PIL in the usual manner by application to the Patient Information Quality Unit.

Further advice can be obtained from RNIB on 01733 37 53 70, businesslink@rnib.org.uk, or from their website at http://www.rnib.org.uk/professionals/solutionsforbusiness/pharmaceutical/Pages/pharmaceutical.aspx or from the Patient Information Quality Unit via email Patient.Information@mhra.gsi.gov.uk

VRMM
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