

2 April 2008

Dear Marketing Authorisation Holder

Patient Information Leaflets: compliance with legal requirements on consultation with target patient groups: 30 June 2008 deadline for applications

A significant minority of MA holders have failed to submit applications to update marketing authorisations (MAs) with an approved patient information leaflet to comply with the new legal requirements in articles 59(1) [information to be shown] and 59(3) [consultation with target patient groups] of Council Directive 2001/83/EC. It is a legal requirement that all products have an updated MA by 1 July 2008.

MA holders must submit an approvable application (see Annex A overleaf) by 30 June 2008 or a notification that the product will not be marketed if they are to be considered compliant with the requirements. Enforcement action, as foreseen in the Directive, will be considered in relation to those MAs which have not been the subject of an approvable application or notification of non marketing by that time. The Agency had hoped to avoid a peak of work in the run up to the deadline – for industry and the Agency - but despite a three year transition period and guidance calling for submissions by the end of December 2007 at the latest, there is now a significant risk that compliance action will need to be taken.

Guidance on quality information, user testing and bridging studies and a series of FAQs to help you meet the requirements of article 59(3) are available on the MHRA website [<http://www.mhra.gov.uk/Howweregulate/Medicines/Labelspatientinformationleafletsandpackaging/Usertestingofpatientinformationleaflets/index.htm>].

Every marketing authorisation will need data in module m-1-3-4 of the eCTD which demonstrates compliance with article 59(3) of the directive [consultation with target patient groups]. Some MAs will include a full report for that leaflet based on a specific user test. In line with previous guidance, however, many applications will be based on bridging from other approved PILs. Where a leaflet for a different strength of product, for example, is being submitted, the supporting data necessary will be less. In addition, related applications which are submitted together will benefit from the bulk fee arrangements and will be handled by the same assessor. Applicants should bear in mind that we approve the PIL and the user test should be seen as a tool for the improvement of the leaflet and not an end in itself.

For further information please contact Jan MacDonald on 020 7084 2267 or via email at patient.information@mhra.gsi.gov.uk.

Jeremy Mean
Group Manager
Information for public Health
Vigilance and Risk Management of Medicines