European Medicines Agency
Evaluation of Medicines for Human Use

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***Operational procedure* on**
Handling of "Consultation with target patient groups" on Package Leaflets (PL) for Centrally Authorised Products for Human Use

1. Introduction

Articles 59(3) and 61(1) of Directive 2001/83, as amended, require that the package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use and that the results of assessments carried out in cooperation with target patient groups shall also be provided to the competent authority.

The articles do not define the precise method to be used. As a consequence, these provisions permit 'user testing' as well as other appropriate forms of consultation.
This is addressed in the draft EU guidance document published on the website of the European Commission for consultation:
(http://ec.europa.eu/health/documents/eudralex/index_en.htm).

To guide applicants/MAH as to how 'consultation with target patient groups' will be handled and reviewed in the centralised procedure, some practical/operational issues are addressed below.

This guidance applies to centralised procedure applications concerning new medicinal products for human use, as of 20 November 2005. For ongoing applications, which are before day 120 on 20 November 2005, the required information needs to be provided by Day 121. For all other ongoing applications for which a marketing authorisation will be granted as of 20 November 2005, submission and review of the required information needs to be discussed with the EMEA on a case-by-case basis.

Where significant changes are made to the package leaflet of authorised medicinal products, 'user consultation' should be considered on a case-by-case basis.

2. Submission and assessment of information on 'target patient group (user) consultation'

Pre-Submission

During the pre-submission phase the applicant may discuss how to address 'user consultation' with EMEA and (Co-) Rapporteur, if necessary. This discussion may indicate whether new 'user consultation' would be necessary or whether a justification for its absence or 'focused' user testing could be acceptable.

DAY 1-120

At the time of the submission of the application the issue of 'user consultation' should be addressed in Module 1.3.4. In the Day 80 Assessment Reports (AR) sent to the CHMP members and to the applicant a comment shall be included on whether 'user consultation' of the PL has been performed or is foreseen, or whether the justification for its absence or 'focused' user testing is acceptable.
In case a 'user consultation' of the PL has been performed and is included in the application, the (Co-)Rapporteur will include the assessment of the results of 'user consultation' in their Day 80 Assessment Reports (AR), as well as a conclusion on the overall readability of the PL and outline possible deficiencies. By Day 100 CHMP members should also review the Rapporteur's position on the requirement for 'user consultation' and his/her assessment of the 'user consultation' results

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or justification, and PL readability. It will be up to the (Co-)Rapporteur to involve the relevant experts for the assessment of the 'user consultation' information and PL readability.

DAY 120-121

Within the clock-stop time, the applicant may undertake initial or further 'user consultation' to take account of questions on the 'user consultation' performed or on the readability of the package leaflet included in the CHMP List of Questions (LoQ).

DAY 121-150

If not included in the initial submission the results of 'user consultation' or any further clarification, as requested, will be submitted as part of the answers to the LoQ at Day 121.

In the Day 150 Joint AR the (Co-)Rapporteur will include the assessment of the results of 'user consultation' or of any further clarification submitted, as well as a conclusion on the overall readability of the PL and forward it to the applicant and to the CHMP members.

Module 1.3.4 'user consultation' results and the (Co-)Rapporteur's assessment of the results and the PL readability will also be forwarded to the QRD Group, as useful information when reviewing the draft product information around Day 160.

DAY 180

By Day 180 CHMP may identify outstanding issues, which may include remarks on the PL and 'user consultation' carried out.