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PRESS RELEASE

The EMEA and the CMD(h) review Europe-wide experience with user consultation in the readability testing of package leaflets

On 23 October 2006, the European Medicines Agency (EMEA) and the Coordination Group for mutual recognition and decentralised procedures (human) (CMD(h)) organised a workshop on user consultation in the context of readability testing of package leaflets for medicines. The aim of the workshop, titled "User testing and how to review the data", was to review and bring together experience and expertise of European regulators with readability testing of the package leaflets by target patient groups.

Consultation of target patient groups to demonstrate readability and usability of the package leaflet is a mandatory element of marketing authorisation applications for medicinal products. Introduced by the revised pharmaceutical legislation in November 2005, the aim of this new provision is to improve the information provided in the package leaflet and make it more suitable to the needs of the patients concerned.

The participants of the workshop, chaired by Truus Janse de Hoog, the chairperson of the CMD(h), looked in particular at the layout and design of a good package leaflet, the review of user testing reports and the assessment of the justification for not performing user testing. Based on the results of the discussion, participants from the EMEA and the CMD(h) concluded that further experience was necessary in order to develop guidance for assessors involved in the assessment of user consultations and for industry.

During this process, which will eventually lead to a harmonised European approach to user consultation in readability testing, the EMEA and the national competent authorities will make efforts to clarify those areas where different views have been expressed, in a step-by-step approach.

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Notes:

1. The legal basis for user consultation in readability testing is Article 59 (3) of Directive 2001/83/EC on the Community Code relating to medicinal products for human use as amended. The text of the Directive can be found here.
2. Until November 2005 readability testing of the package leaflet was optional for pharmaceutical companies and all reports submitted by companies were reviewed by experts of the Quality Review of Documents (QRD) group. During that period of voluntary participation, the QRD experts made an effort to standardise their assessment reports on the readability testing.
3. This press release, together with other information about the work of the EMEA, may be found on the EMEA website: http://www.emea.europa.eu.

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