European Directorate for the Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Certification of Substances Division

Title:	**Packaging information within the certification procedure**
Reference Document:	**PA/PH/CEP (11) 48**

The EDQM wishes to inform CEP users, CEP holders and CEP applicants that the packaging information submitted under section 3.2.S.6 of the dossier will be assessed during the Certification assessment, even if no re-test period is mentioned on the CEP. This will avoid subsequent reassessment at the level of the marketing authorisation application for the relevant medicinal products.

For transparency reasons, the packaging material will be described on all Certificates of Suitability granted or renewed as of 1 September 2011. This change in policy will also apply to revised certificates issued as of the same date, if the revision relates to section 3.2.S.6 of the dossier.