



## Certification Unit

### CERTIFICATES OF SUITABILITY TO MONOGRAPHS OF THE EUROPEAN PHARMACOPOEIA

#### Implementation of the amendments to the Directives 2001/83/EC and 2001/82/EC: Renewal of certificates of suitability

#### Introduction

The revised Directives 2001/83/EC and 2001/82/EC state that 'a marketing authorisation should be renewed once five years after the granting. Thereafter, the MA should normally be of unlimited validity.' (17, directive 2001/83 amended).

The same requirements will be implemented on 1<sup>st</sup> January 2006 for certificates of suitability (CEPs) under the conditions described below.

#### Impact and procedures

The CEPs will be renewed after a 5-year period on the basis of a re-evaluation of an updated dossier.

Once renewed, the CEPs will be valid for an unlimited period, unless it is decided by EDQM for justified grounds to proceed with one additional renewal (as foreseen in the Directives 2004/27/EC and 2004/28/EC). That could occur in case of commitments to be taken by the manufacturer/applicant to introduce specific actions, in particular regarding the safety of the substance or implementation of new or revised requirements.

This policy will be implemented for all CEPs for which the date of renewal is from **1 January 2006**. For the CEPs which have already been renewed, a new renewal is normally not necessary, provided the dossier is in compliance with the current legislation.

In this context the layout of the CEPs will be changed and the end of validity date will no longer appear on the CEPs once they have been renewed. For the CEPs which have already been renewed, the new layout will be applied to the next revision of the CEP.

It is reminded that in any case, the CEP holder has to declare, through a request for revision sent to EDQM, any changes made to the content of the dossier during the validity period of the CEP and has to implement any changes related to the specific and general Ph. Eur. monographs and to any legal text.

For any question about the new policy for renewal of CEPs please contact us at: [ceprevision@pheur.org](mailto:ceprevision@pheur.org)