



**Announcement for applicants/ marketing authorization holders
regarding a submission of an application for a marketing authorization, variation
or renewal
on electronic media (CDs)**

Modules 3, 4 and 5 (quality, non- clinical and clinical data) for above mentioned applications may be submitted to the SIDC / Registration Unit as of **1 March 2007** on electronic media (CD), resp. in a eCTD format. This applies for national as well as EU procedures.

In case that an applicant submits above mentioned documentation on **an electronic media (CDs) only**, a **declaration** stating that the applicant/ MAH shall submit **a paper version upon SIDC request within 48 hours** is requested.

Number of electronic **copies** requested is **1 or 2**:
Modul 3 has to be provided either separately or as an additional copy.

More details about eCTD format can be found on the web site:
<http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev2.htm>

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director