



**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) in formats PDF, DOC, RTF, HTML, TXT. 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.

12 February 2007

PharmDr. Ján Mazag
director