CMDh
Co-ordination Group for Mutual Recognition
and Decentralised Procedures – Human

**MEMBER STATES RECOMMENDATION ON THE COVER LETTER
FOR NEW APPLICATIONS SUBMITTED THROUGH THE MRP/DCP**

*July 2007*
***Rev.2, April 2008***

With every MA application, the applicant is required to provide a cover letter with appropriate regulatory information. The cover letter however does not reduce the applicant's responsibility to submit an application in accordance with the requirements in the current legislation.

The purpose of the recommendation is to highlight which information the CMD(h) advises to be included in the cover letter, to support the validation of the application. We would also recommend the applicants to seek advice on published guidance papers on MSs websites prior to submission.

The following information is highly recommended to be included in the Cover Letter:

- Name of the medicinal product
- Name of the active substance(s) and the ATC code
- The allocated MRP/DCP procedure number
- Legal basis of the application
- Use of European reference medicinal product (when appropriate)
- Indicate if the strength(s) and/or the pharmaceutical form(s) and/or the indication(s) of the reference medicinal product differs between RMS/CMS (when appropriate)
- Confirmation of identical dossiers in the RMS and CMS concerned
- Information whether multiple/duplicate applications are submitted, also in cases where the duplicates are not submitted simultaneously. When submitted later, a reference to the first application should be given.
- A clear description of the enclosures
- Indication whether a transfer of ownership(MAH) for the medicinal product is to take place in the national step after finalization of the procedure (applicant should seek advice on MSs websites as transfer during this step is not possible in all MSs)
- Fees paid (when appropriate as some MSs send invoice after receipt of the application).
- In case an electronic copy of the paper original application is provided, it should be clearly stated that the copy is identical (most MS do not allow differences but if a MS due to their national practice allows differences they will have to be explained )

Further information to electronic component(s) of the submission, if relevant (Member States would like to mention that eCTD is the preferred format):

- Number of media units per application (full set) and number of copies
- Index (content) of each media unit
- Statement that the submission is checked with an up-to-date and state-of-the-art virus-checker (name and version of the anti-virus programme should be mentioned)

For eCTD applications also:

- An annex document with the history of the sequences (Sequence Tracking Table).
- Specify the use of the "Comprehensive Model" or the "Parallel National Model"