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Question & Answer N. 21/2007

Release of information

Status	Public
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QUESTION

In order to submit a valid application for a marketing authorisation for a generic product the applicant needs confirmation that the proposed reference product was authorised following submission of a complete dossier, together with the date of its first authorisation. Furthermore, in order to propose a valid SPC for the generic product, the applicant needs to review the existing SPC for the reference product. The CMD(v) is requested to confirm that the national authority in the Member State where the reference product is authorised is:

1. Obligated to confirm the legal base and date of first authorisation of the proposed reference product on the request of a third party;
2. Obligated to make available the SPC of the reference product on the request of a third party;
3. Not obliged to notify the Holder of the Marketing Authorisation of the proposed reference product of the above requests that have been made by the third party and that any such notification made by the national authority would be considered undesirable.

ANSWER

The release of the above mentioned information is subject to a national decision.

Member states indicated that in general they may inform a third party of the legal base of the authorisation of a reference product and the date of its first authorisation and that they may provide the SPC of reference products. The Marketing Authorisation Holder of the reference product would not be informed of such requests.