

EMA/CMDv/11566/2010
London, 20 May 2010

Question & Answer N. 118/2010

ERA data submission

Status	Public
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QUESTION

1. Is it possible to submit the Environmental Risk Assessment (ERA) data in the same way as for documentation on the active substance (Active Substance Master File), with a closed part containing the proprietary ERA data owned by a company different from the applicant for the Marketing Authorisation procedure?
2. The applicant of a generic product has sought and been granted permission to refer to the ERA data of another MAH in order to share scientific data and avoid duplication of previously conducted studies. The ERA data to which the applicant has been granted permission to refer to has previously been subject to a referral and subsequent arbitration to CVMP and for which a positive opinion was adopted.

ANSWER

1. According to Annex I of Directive EC/2001/82, as amended, the CMDv concludes that this is not currently acceptable. The environmental risk assessment (ERA) documentation should be submitted solely by the applicant within the Marketing Authorisation application.
2. To refer to ERA data without the applicant having access to the data is not acceptable.

From a legal point of view an environmental risk assessment have to be provided with each application, except for informed consent application. However, consent to refer to the ERA package of a different applicant can only be accepted providing **the applicant and the competent authority** have access to the data.