

EMA/CMDv/69345/2011
London, 25 January 2011

Question & Answer N. 63/2010
REFERRING TO DATA IN ANOTHER DOSSIER

Status	Public
---------------	---------------

Referring to data in another dossier

Member States receive ongoing queries from industry regarding the possibility of referring to data in another dossier for the purposes of modifying the SPC. CMDv has discussed this extensively and provides the following conclusions to help clarify the current situation:

- Safety (excluding environmental) & residue tests and pre-clinical & clinical data underpinning an MA cannot profit from unlimited protection, regardless of the legal basis used to achieve that authorisation;
- The MAH of a reference product may refer, by means of a variation or extension, to the data generated by the MAH of the generic/hybrid product. However, simply referring to studies conducted by the MAH of the generic product may not be adequate and further data and/or scientific justification may be required to support a change to the originator product e.g. injection site residue data for injectable formulations;
- The MAH of the generic or hybrid product may refer to studies in the dossier of the reference product, which is reflected in the variation classification guideline under C.I.2;
- There is no consensus among the Member States with regard to referring from one originator to another originator dossier by means of a variation. Therefore the MAH would have to submit a new marketing authorisation application as a generic or hybrid;
- It is possible to apply for a marketing authorisation that refers to both the full dossier of a reference product and additional studies in the dossier of a 'variant' of that reference product, where the variant has been authorised under the abridged procedure to a company different from the company holding the initial MA for the reference product.
- Bioequivalence must be demonstrated to each product referred to.