



**VETERINARY MUTUAL RECOGNITION
FACILITATION GROUP (VMRF)**

QUESTION FROM INDUSTRY

Submission of a single part III for all strengths

Adopted	Status
March 2005	Public

QUESTION

A product with three strengths was submitted in a Member State as three separate full applications. However, the company wish to submit all three strengths for mutual recognition. As Part III is identical for all strengths and because of the number of files involved, is it possible for the company to submit a single combined Part III for all three strengths, instead of three sets of an identical Part III?

ANSWER

The VMRFG agreed that in this particular case, where the part III is identical for all strengths, it would be possible to submit a single combined Part III for all strengths. However a clear cross reference must be provided.