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

**LINE EXTENSIONS
REQUIREMENTS FOR THE CONTENT OF THE DOSSIER –
QUALITY PART**

Adoption	Status
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REQUIREMENTS FOR THE CONTENT OF THE DOSSIER – QUALITY PART**

Regulation 541/95 modified by Regulation 1146/98 specifies what are the changes that can lead to a new application.¹ In any case, an authorisation or a modification to the existing marketing authorisation will have to be issued by the competent national authorities.

The aim of this paper is to define the composition of the dossier that should be provided by the applicant for these so-called 'line extensions'.

For the majority of cases (detailed in Annex 2 of Regulation 541/95) a new updated quality part should be provided.

However, if the following conditions apply:

- the countries involved in the procedure for the line extension are the same as for the parent medicinal product,
- the extension covers a new species or a new claim or a new administration route, a new withdrawal period,
- the quality part is not modified in relation to this extension,
- a modification to the existing marketing authorisation will be issued by the competent national authorities and therefore only **one marketing authorisation** will remain.

No new quality part will be requested. Only a statement that the dossier originally approved has not changed would be required from the applicant. No RMS assessment report will be required; a simple reference to the assessment report of the general procedure will be sufficient.

¹ Dutch legislation requires fees and administrative transfer of the part II (and other relevant) documentation to the one remaining authorisation number (one must be withdrawn) after the procedure. For details contact the Dutch BRD.