

Please find below the English version of the table summarising the fees due for the marketing authorisation of veterinary medicinal products in Italy, in order to provide applicants with all the necessary information for the correct calculation of the fees depending on the legal basis supporting the application (full dossier, generic, well established use, etc.) and on the type of product (non immunological, immunological, biological).

The English version of the table has been introduced in order to reduce the frequent request for clarification addressed from MAHs to this ministry.

**Fees with effect from 1 April 2020**

Application type	Fee	Description/notes
Application type Fee Description/notes New MA – full dossier (article 12 and article 13 of Directive 2001/82/EC) implemented in national legislative decree n. 193/2006 (art. 12 and 14)	€ 14.840	A single strength associated with one pharmaceutical form and one presentation
	€ 1.460	For each additional strength and/or pharmaceutical form submitted at the same time as the initial application for authorisation. (The fee covers one additional strength or pharmaceutical form and one presentation).
	€ 740	For each additional presentation of the same strength and pharmaceutical form, submitted at the same time as the initial application for authorisation.
New MA – immunological veterinary medicinal products – full dossier	€ 7.380	A single strength associated with one pharmaceutical form and one presentation
	€ 740	For each additional strength or pharmaceutical form and/or additional presentation
New MA- For applications submitted according to Article 13(1) and (3), and Article 13c of Directive 2001/82/EC) implemented in national legislative decree n. 193/2006 (art.13 commas 2 and 6, and art. 16)	€ 7.380	A single strength associated with one pharmaceutical form and one presentation
	€ 1.460	For each additional strength or pharmaceutical form including one presentation, submitted at the same time as the initial application for authorisation.
	€ 740	For each additional presentation of the same strength and pharmaceutical form, submitted at the same time as the initial application for authorization New MA immunological veterinary medicinal products – abridged dossier
New MA immunological veterinary medicinal products – abridged dossier	€ 3.710	A single strength associated with one pharmaceutical form and one presentation
	€ 740	For each additional strength, pharmaceutical form and/or additional presentation submitted at the same time as the initial application for authorisation.
New MA biological veterinary medicinal products, excluding immunological veterinary medicinal products. (Art 13.4) implemented in national legislative decree n. 193/2006 (art.13 comma 7)	€ 12.530	A single strength associated with one pharmaceutical form and one presentation
	€ 1.460	For each additional strength or pharmaceutical form including one presentation, submitted at the same time as the initial application for authorisation.
	€ 740	For each additional presentation of the same strength and pharmaceutical form, submitted at the same time as the initial application for authorisation.contemporaneamente alla prima domanda di autorizzazione
Extension – according to Annex I to Regulation (EC) No. 1234/2008	€ 3.710	For a single strength/potency associated with one pharmaceutical form and one presentation. This fee shall also cover one or more target species associated with that pharmaceutical form
By derogation	€ 3.350	For all quality extensions (i.e. requiring chemical, pharmaceutical and biological documentation) for which no clinical or non-clinical data are submitted or no cross references to previously submitted clinical or non-clinical data are made by the MAH. This fee covers a single strength/potency associated with one pharmaceutical form and one presentation.
	€ 920	For each additional strength of the same pharmaceutical form of the same extension submitted at the time of the extension application. (This fee shall also cover one or more target species associated with that pharmaceutical form).
Immunological veterinary medicinal products	€ 920	For all quality extensions (i.e. requiring chemical, pharmaceutical and biological documentation) of an immunological veterinary medicinal product for which no clinical or non-clinical data are submitted or no cross references to previously submitted clinical or nonclinical data are made by the MAH. This fee covers a single strength/potency associated with one pharmaceutical form and one presentation.

Application type	Fee	Description/notes
Immunological and nonimmunological veterinary medicinal products	€ 740	For each additional presentation of the same strength/potency of the same pharmaceutical form of the same extension, submitted at the same time of the extension application.
Type IA variation – as defined in article 2(2) of Regulation (EC) No. 1234/2008	€ 330	Applied also to immunological veterinary medicinal products
Type IB variation – as defined in article 2(5) of Regulation (EC) No. 1234/2008	€ 740	Applied also to immunological veterinary medicinal products
Type II variation – as defined in article 2(3) of Regulation (EC) No. 1234/2008	€ 4.440	
By derogation	€ 3.350	For a quality variation (i.e. amendments to the chemical, pharmaceutical and biological documentation) for which no clinical or non-clinical data are submitted or no cross references to previously submitted clinical or non-clinical data are made by the MAH. (Note: bioequivalence data qualifies as clinical data).
Type II variation - immunological veterinary medicinal products	€ 740	
Renewal	€ 740	For each strength associated with a pharmaceutical form.
Transfer of a Marketing Authorisation Holder	€ 740	This fee covers all authorised presentations of a given medicinal product