Fees with effect from 4 April 2024

Please find below the English version of the table of fees payable to Italian Competent Authority for the marketing authorisation and for variations of VMPs.

This table provides applicants with all the necessary information to correctly calculate the fees according to the legal basis supporting the application and to the type of product (non-immunological, immunological, biological etc.).

Application type	Fee (in euro)	Description/notes
New MA – full dossier (article 8, 20, 22, 25 of Regulation 2019/6)	17 890,00	A single strength associated with one pharmaceutical form and one presentation
Additional fee	1 760,00	For each additional strength 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).
Additional fee	890,00	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	8 890,00	For a single strength associated with one pharmaceutical form and one presentation
Additional fee	890,00	For each additional strength or pharmaceutical form including one presentation submitted at the same time as the initial application for authorisation.
Additional fee	890,00	For each additional presentation of the same strength and pharmaceutical form, submitted at the same time as the initial application for authorisation.
New MA- For applications for marketing authorisation pursuant to Article 18, 19 (except for similar biological products) 21 and 23 of the Regulation (EU) 2019/6	8 890,00	For a single strength associated with one pharmaceutical form and one presentation.
Additional fee	1 760,00	For each additional strength or pharmaceutical form including one presentation submitted at the same time as the initial application for authorization.
Additional fee	890,00	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– abridged dossier	4 480,00	This fee is for a single strength associated with one pharmaceutical form and one presentation.
Additional fee	890,00	For each additional strength or pharmaceutical form including one presentation submitted at the same time as the initial application for authorisation.
Additional fee	890,00	For each additional presentation of the same strength and pharmaceutical form submitted at the same time as the initial application for authorisation.
New MA - For applications for a marketing authorisation for similar biological products authorised pursuant to Article 19 of Regulation (EU) 2019/6	15 120,00	This fee is for a single strength associated with one pharmaceutical form and one presentation.
Additional fee	1 760,00	For each additional strength or pharmaceutical form including one presentation submitted at the same time as the initial application for authorisation.
Additional fee	890,00	For each additional presentation of the same strength and pharmaceutical form, submitted at the same time as the initial application for authorisation.

Application type	Fee (in euro)	Description/notes
Variation to a marketing authorisation requiring assessment (VRA)		
<u>Level 1</u> Variation requiring assessment introducing changes of active substance(s), strength, pharmaceutical form, route of administration or food-producing target species	4 480,00	For a variation requiring assessment that introduces changes of route of administration or food-producing target species
	4 040,00	For a variation requiring assessment that introduces changes of active substance(s), strength or pharmaceutical form, i.e. 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 marketing authorisation holder.
	1110,00	For immunological veterinary medicinal products for a variation requiring assessment that introduces changes of active substance(s), strength or pharmaceutical form, i.e. 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 marketing authorization holder.
	1110,00	For each additional strength/potency of the same pharmaceutical form of the same variation application including one presentation submitted at the time of the variation application. This fee shall also cover one or more target species associated with that pharmaceutical form.
	890,00	For each additional presentation of the same strength/potency of the same pharmaceutical form of the same variation application submitted at the same time of the variation application.
<u>Level 2</u> Variation requiring assessment introducing safety, efficacy or pharmacovigilance changes	5 360,00	For variations requiring assessment that introduce changes to safety, efficacy or pharmacovigilance, which follow an extended (90 day) or a standard (60 days) timetable.
	890,00	For immunological veterinary medicinal products for variations requiring assessment that introduce changes to safety, efficacy or pharmacovigilance, which follow an extended (90 days) or a standard (60 days) timetable.
	890,00	For variations requirement assessment with scope G.I.18 referred to in the guidance on the details of the classification of variations requiring assessment according to Article 62 of Regulation (EU) 2019/6 for veterinary medicinal products and on the documentation to be submitted pursuant to those variations*
<u>Level 3</u> Variation requiring assessment introducing quality changes	4 040,00	For variations requiring assessment introducing quality changes only, which follow a standard (60 days) timetable, i.e. all 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 marketing authorisation holder.
	890,00	For immunological veterinary medicinal products for variations requiring assessment introducing quality changes only, which follow a standard (60 days) timetable, i.e. all 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 marketing authorisation holder.
<u>Level 4</u> Variation requiring assessment reduced timetable	890,00	For all variations requiring assessment which follow a reduced (30 days) timetable.
Variation to a marketing authorisation not requiring assessment (VNRA)	400,00	For variations not requiring assessment reported in the list established by the Regulation (EU) 2021/17 of 8 January 2021.

Application type	Fee (in euro)	Description/notes
Changes to the pharmacovigilance part of the dossier (VNRA)	400,00	C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV): Single fee for one or more medicinal products of the same marketing authorization holder presented at the same time
	400,00	C5 - Change in the pharmacovigilance system master file (PSMF) location. Single fee for one or more medicinal products of the same marketing authorization holder presented at the same time
	400,00	C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. Single fee for one or more medicinal products of the same marketing authorization holder presented at the same time
Transfer of a Marketing Authorisation Holder	890,00	This fee covers all authorised presentations of a given medicinal product.

*Note: In accordance with Regulation (EU) 2022/839, this variation should be submitted so that the variation is finalised and implemented on the printed labelling and package leaflet before 29 January 2027. Grouping with other variations in chapter G affecting the product information texts for the same product is recommended