

FEES

for authorization for the marketing of veterinary medicinal products, used by the Institute for Control of Veterinary Biological Products and Medicines

No.	Type of authorization	Fee/Rate (lei)
244	Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by mutual recognition procedure, with Romania acting as reference member state, to which are added, as appropriate:	35607
	a) Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by mutual recognition procedure, with Romania acting as reference member state for each other target species/way of administration, for food producing animals	1.465
	b) Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by mutual recognition procedure, with Romania acting as reference member state for each other target species/way of administration, for animals not intended for human consumption.	1034
245	Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by mutual recognition procedure, with Romania acting as concerned member state, to which are added, as appropriate:	29227
	a) Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by mutual recognition procedure, with Romania acting as concerned member state for each other target species/way of administration, for food producing animals	1465
	b) Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by mutual recognition procedure, with Romania acting as concerned member state for each other target species/way of administration, for animals not intended for human consumption	1034
246	Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by mutual recognition procedure and proposed by “subsequent recognition” procedure, with Romania acting as reference member state, to which are added, as appropriate:	26985
	a) Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by mutual recognition procedure and proposed by “subsequent recognition” procedure, with Romania acting as reference member state for each other target species/way of administration, for food producing animals	1.465
	b) Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by mutual recognition procedure and proposed by “subsequent recognition” procedure, with Romania acting as reference member state for each other target species/way of administration, for animals not intended for human consumption	1034
247	Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by mutual recognition procedure and proposed by “subsequent recognition” procedure, with Romania acting as concerned member state, to which are added, as appropriate:	19744

No.	Type of authorization	Fee/Rate (lei)
	a) Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by mutual recognition procedure and proposed by “subsequent recognition” procedure, with Romania acting as concerned member state for each other target species/way of administration, for food producing animals	1.465
	b) Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by mutual recognition procedure and proposed by “subsequent recognition” procedure, with Romania acting as concerned member state for each other target species/way of administration, for animals not intended for human consumption	1034
248	Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by decentralized procedure, with Romania acting as reference member state, to which are added, as appropriate:	46815
	a) Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by decentralized procedure, with Romania acting as reference member state for each other target species/way of administration, for food producing animals	1.465
	b) Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by decentralized procedure, with Romania acting as reference member state for each other target species/way of administration, for animals not intended for human consumption	1034
249	Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by decentralized procedure, with Romania acting as concerned member state, to which are added, as appropriate:	33710
	a) Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by decentralized procedure, with Romania acting as concerned member state for each other target species/way of administration, for food producing animals	1.465
	b) Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by decentralized procedure, with Romania acting as concerned member state for each other target species/way of administration, for animals not intended for human consumption	1034
250	Authorization of veterinary medicinal products based on bibliographic data, by mutual recognition procedure, with Romania acting as reference member state, to which are added, as appropriate:	33021
	a) Authorization of veterinary medicinal products based on bibliographic data by mutual recognition procedure, with Romania acting as reference member state for each other target species/way of administration, for food producing animals	1465.
	b) Authorization of veterinary medicinal products based on bibliographic data, by mutual recognition procedure, with Romania acting as reference member state for each other target species/way of administration, for animals not intended for human consumption	1034

No.	Type of authorization	Fee/Rate (lei)
251	Authorization of veterinary medicinal products based on bibliographic data, by mutual recognition procedure, with Romania acting as concerned member state, to which are added, as appropriate:	24917
	a) Authorization of veterinary medicinal products based on bibliographic data by mutual recognition procedure, with Romania acting as concerned member state for each other target species/way of administration, for food producing animals	1.465
	b) Authorization of veterinary medicinal products based on bibliographic data, by mutual recognition procedure, with Romania acting as concerned member state for each other target species/way of administration, for animals not intended for human consumption	1034
252	Authorization of veterinary medicinal products based on bibliographic data, by mutual recognition procedure and proposed by “subsequent recognition” procedure, with Romania acting as reference member state, to which are added, as appropriate:	23537
	a) Authorization of veterinary medicinal products based on bibliographic data, by mutual recognition procedure and proposed by “subsequent recognition” procedure, with Romania acting as reference member state for each other target species/way of administration, for food producing animals	1.465
	b) Authorization of veterinary medicinal products based on bibliographic data, by mutual recognition procedure and proposed by “subsequent recognition” procedure, with Romania acting as reference member state for each other target species/way of administration, for animals not intended for human consumption	1034
253	Authorization of veterinary medicinal products based on bibliographic data, by mutual recognition procedure and proposed by “subsequent recognition” procedure, with Romania acting as concerned member state, to which are added, as appropriate:	18881
	a) Authorization of veterinary medicinal products based on bibliographic data, by mutual recognition procedure and proposed by “subsequent recognition” procedure, with Romania acting as concerned member state for each other target species/way of administration, for food producing animals	1.465
	b) Authorization of veterinary medicinal products based on bibliographic data, by mutual recognition procedure and proposed by “subsequent recognition” procedure, with Romania acting as concerned member state for each other target species/way of administration, for animals not intended for human consumption	1034
254	Authorization of veterinary medicinal products based on bibliographic data, by decentralized procedure, with Romania acting as reference member state, to which are added, as appropriate:	42504
	a) Authorization of veterinary medicinal products based on bibliographic data, by decentralized procedure, with Romania acting as reference member state for each other target species/way of administration, for food producing animals	1.465
	b) Authorization of veterinary medicinal products based on bibliographic data, by decentralized procedure, with Romania acting as reference member state for each other target species/way of administration, for animals not intended for human consumption	1034

No.	Type of authorization	Fee/Rate (lei)
255	Authorization of veterinary medicinal products based on bibliographic data, by decentralized procedure, with Romania acting as concerned member state, to which are added, as appropriate:	29399
	a) Authorization of veterinary medicinal products based on bibliographic data, by decentralized procedure, with Romania acting as concerned member state for each other target species/way of administration, for food producing animals	1465
	b) Authorization of veterinary medicinal products based on bibliographic data, by decentralized procedure, with Romania acting as concerned member state for each other target species/way of administration, for animals not intended for human consumption	1034
256	Authorization of generic veterinary medicinal products, by mutual recognition procedure, with Romania acting as reference member state	26985
257	Authorization of generic veterinary medicinal products, by mutual recognition procedure, with Romania acting as concerned member state	19744
258	Authorization of generic veterinary medicinal products, by mutual recognition procedure and proposed by “subsequent recognition” procedure, with Romania acting as reference member state	20951
259	Authorization of generic veterinary medicinal products, by mutual recognition procedure and proposed by “subsequent recognition” procedure, with Romania acting as concerned member state	17158
260	Authorization of generic veterinary medicinal products, by decentralized procedure, with Romania acting as reference member state	36900
261	Authorization of generic veterinary medicinal products, by decentralized procedure, with Romania acting as concerned member state	26641
262	Authorization of hybrid veterinary medicinal products, by decentralized procedure, with Romania acting as reference member state, to which are added, as appropriate:	37331
	a) Authorization of hybrid veterinary medicinal products by decentralized procedure, with Romania acting as reference member state for each other target species/way of administration, for food producing animals	1.465
	b) Authorization of hybrid veterinary medicinal products by decentralized procedure, with Romania acting as reference member state for each other target species/way of administration, for animals not intended for human consumption	1034
263	Authorization of hybrid veterinary medicinal products, by decentralized procedure, with Romania acting as concerned member state, to which are added, as appropriate:	29399
	a) Authorization of hybrid veterinary medicinal products by decentralized procedure, with Romania acting as concerned member state for each other target species/way of administration, for food producing animals	1.465
	b) Authorization of hybrid veterinary medicinal products by decentralized procedure, with Romania acting as concerned member state for each other target species/way of administration, for animals not intended for human consumption	1034
264	Authorization of hybrid veterinary medicinal products, by mutual recognition procedure, with Romania acting as reference member state, to which are added, as appropriate:	33021

No.	Type of authorization	Fee/Rate (lei)
	a) Authorization of hybrid veterinary medicinal products by mutual recognition procedure, with Romania acting as reference member state for each other target species/way of administration, for food producing animals	1.465
	b) Authorization of hybrid veterinary medicinal products by mutual recognition procedure, with Romania acting as reference member state for each other target species/way of administration, for animals not intended for human consumption	1034
265	Authorization of hybrid veterinary medicinal products, by mutual recognition procedure, with Romania acting as concerned member state, to which are added, as appropriate:	24917
	a) Authorization of hybrid veterinary medicinal products by mutual recognition procedure, with Romania acting as concerned member state for each other target species/way of administration, for food producing animals	1.465
	b) Authorization of hybrid veterinary medicinal products by mutual recognition procedure, with Romania acting as concerned member state for each other target species/way of administration, for animals not intended for human consumption	1034
266	Authorization of hybrid veterinary medicinal products, by mutual recognition procedure and proposed by “subsequent recognition” procedure with Romania acting as reference member state, to which are added, as appropriate:	23537
	a) Authorization of hybrid veterinary medicinal products, by mutual recognition procedure and proposed by “subsequent recognition” procedure, with Romania acting as reference member state for each other target species/way of administration, for food producing animals	1.465
	b) Authorization of hybrid veterinary medicinal products, by mutual recognition procedure and proposed by “subsequent recognition” procedure, with Romania acting as reference member state for each other target species/way of administration, for animals not intended for human consumption	1034
267	Authorization of hybrid veterinary medicinal products, by mutual recognition procedure and proposed by “subsequent recognition” procedure with Romania acting as concerned member state, to which are added, as appropriate	18881
	a) Authorization of hybrid veterinary medicinal products, by mutual recognition procedure and proposed by “subsequent recognition” procedure, with Romania acting as concerned member state for each other target species/way of administration, for food producing animals	1.465
	b) Authorization of hybrid veterinary medicinal products, by mutual recognition procedure and proposed by “subsequent recognition” procedure, with Romania acting as concerned member state for each other target species/way of administration, for animals not intended for human consumption	1034
268	Authorization of veterinary medicinal products containing a known active substance, by mutual recognition procedure, with Romania acting as reference member state, to which are added, as appropriate:	33021
	a) Authorization of veterinary medicinal products containing a known active substance, by mutual recognition procedure, with Romania acting as reference member state for each target species/way of administration, for food producing animals	1.465

No.	Type of authorization	Fee/Rate (lei)
	b) Authorization of veterinary medicinal products containing a known active substance, by mutual recognition procedure, with Romania acting as reference member state for each target species/way of administration, for animals not intended for human consumption	1034
269	Authorization of veterinary medicinal products containing a known active substance, by mutual recognition procedure, with Romania acting as concerned member state, to which are added, as appropriate:	24917
	a) Authorization of veterinary medicinal products containing a known active substance, by mutual recognition procedure, with Romania acting as concerned member state for each target species/way of administration, for food producing animals	1.465
	b) Authorization of veterinary medicinal products containing a known active substance, by mutual recognition procedure, with Romania acting as concerned member state for each target species/way of administration, for animals not intended for human consumption	1034
270	Authorization of veterinary medicinal products containing a known active substance, by mutual recognition procedure and proposed by “subsequent recognition” procedure, with Romania acting as reference member state, to which are added, as appropriate:	23537
	a) Authorization of veterinary medicinal products containing a known active substance, by mutual recognition procedure and proposed by “subsequent recognition” procedure, with Romania acting as reference member state for each target species/way of administration, for food producing animals	1.465
	b) Authorization of veterinary medicinal products containing a known active substance, by mutual recognition procedure and proposed by “subsequent recognition” procedure, with Romania acting as reference member state for each target species/way of administration, for animals not intended for human consumption	1034
271	Authorization of veterinary medicinal products containing a known active substance, by mutual recognition procedure and proposed by “subsequent recognition” procedure, with Romania acting as concerned member state, to which are added, as appropriate:	18838
	a) Authorization of veterinary medicinal products containing a known active substance, by mutual recognition procedure and proposed by “subsequent recognition” procedure, with Romania acting as concerned member state for each target species/way of administration, for food producing animals	1.465
	b) Authorization of veterinary medicinal products containing a known active substance, by mutual recognition procedure and proposed by “subsequent recognition” procedure, with Romania acting as concerned member state for each target species/way of administration, for animals not intended for human consumption	1034
272	Authorization of veterinary medicinal products containing a known active substance, by decentralized procedure, with Romania acting as reference member state, to which are added, as appropriate:	42504
	a) Authorization of veterinary medicinal products containing a known active substance, by decentralized procedure, with Romania acting as reference member state for each target species/way of administration, for food producing animals	1.465

No.	Type of authorization	Fee/Rate (lei)
	b) Authorization of veterinary medicinal products containing a known active substance, by decentralized procedure, with Romania acting as reference member state for each target species/way of administration, for animals not intended for human consumption	1034
273	Authorization of veterinary medicinal products containing a known active substance, by decentralized procedure, with Romania acting as concerned member state, to which are added, as appropriate:	29399
	a) Authorization of veterinary medicinal products containing a known active substance, by decentralized procedure, with Romania acting as concerned member state for each target species/way of administration, for food producing animals	1.465
	b) Authorization of veterinary medicinal products containing a known active substance, by decentralized procedure, with Romania acting as concerned member state for each target species/way of administration, for animals not intended for human consumption	1034
274	Authorization of veterinary medicinal products by "informed consent", by mutual recognition procedure, with Romania acting as reference member state	33021
275	Authorization of veterinary medicinal products by "informed consent", by mutual recognition procedure, with Romania acting as concerned member state	24917
276	Authorization of veterinary medicinal products by "informed consent", by decentralized procedure, with Romania acting as reference member state	37331
277	Authorization of veterinary medicinal products by "informed consent", by decentralized procedure, with Romania acting as concerned member state	23623
278	Authorization of veterinary medicinal products by "informed consent" procedure, by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as reference member state	23537
279	Authorization of veterinary medicinal products by "informed consent" procedure, by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as concerned member state	18881
280	Authorization of veterinary medicinal products by multiple applications - "duplicate", by mutual recognition procedure, with Romania acting as reference member state	26985
281	Authorization of veterinary medicinal products by multiple applications - "duplicate", by mutual recognition procedure, with Romania acting as concerned member state	17158
282	Authorization of veterinary medicinal products by multiple applications - "duplicate", by decentralized procedure, with Romania acting as reference member state	23796
283	Authorization of veterinary medicinal products by multiple applications - "duplicate", by decentralized procedure, with Romania acting as concerned member state	20175
284	Authorization of veterinary medicinal products by multiple applications - "duplicate", by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as reference member state	23537
285	Authorization of veterinary medicinal products by multiple applications - "duplicate", by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as concerned member state	18881

No.	Type of authorization	Fee/Rate (lei)
286	Authorization of similar biological veterinary medicinal products, by mutual recognition procedure, with Romania acting as concerned member state	24917
287	Authorization of similar biological veterinary medicinal products, by mutual recognition procedure, with Romania acting as reference member state	33021
288	Authorization of similar biological veterinary medicinal products, by decentralized procedure, with Romania acting as reference member state	42504
289	Authorization of similar biological veterinary medicinal products, by decentralized procedure, with Romania acting as concerned member state	29399
290	Authorization of similar biological veterinary medicinal products", by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as reference member state	23537
291	Authorization of similar veterinary biological medicinal products, by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as concerned member state	18881
292	Authorization of veterinary medicinal products with well-established medical use, by national procedure, to which are added, as appropriate:	16166
	a) Authorization of veterinary medicinal products with well-established medical use, for each target species/way of administration, for food producing animals	1.465
	b) Authorization of veterinary medicinal products with well-established medical use, for each target species/way of administration, for animals not intended for human consumption	1034
293	Authorization of veterinary medicinal products based on bibliographic data, by national procedure, with Romania acting as reference member state, to which are added, as appropriate:	16166
	a) Authorization of veterinary medicinal products based on bibliographic data by national procedure, for each other target species/way of administration, for food producing animals	1465
	b) Authorization of veterinary medicinal products based on bibliographic data, by national procedure, for each other target species/way of administration, for animals not intended for human consumption	1034
294	Authorization of generic veterinary medicinal products, by national procedure	12115
295	Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by national procedure, to which are added, as appropriate:	19615
	a) Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), for each target species/way of administration, for food producing animals, by national procedure	1.465
	b) Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), for each target species/way of administration, for animals not intended for human consumption, by national procedure	1034
296	Authorization of hybrid veterinary medicinal products, by national procedure, to which are added, as appropriate:	16166
	a) Authorization of hybrid veterinary medicinal products, for each target species/way of administration, for food producing animals, by national procedure	1.465

No.	Type of authorization	Fee/Rate (lei)
	b) Authorization of veterinary medicinal products, for each target species/way of administration, for animals not intended for human consumption, by national procedure	1034
297	National authorization of veterinary medicinal products by "informed consent"	16166
298	Authorization of homeopathic veterinary medicinal products with therapeutic indications, by national procedure	16166
299	Authorization of veterinary medicinal products by parallel comert, procedure	3.494
300	Limited marketing authorization for veterinary medicinal products	6.770
301	Marketing notification for veterinary medicinal products	2.937
302	Authorization of similar veterinary biological medicinal products, by national procedure	16166
303	Authorization of veterinary medicinal products by multiple applications - "duplicate", by national procedure	15562
304	Authorization of homeopathic veterinary medicinal products	3174
305	Variations not requiring assessment but require checking the Summary of Product Characteristics/Package leaflet/Labelling	678
306	Variation requiring assessment by national procedures, reduced timetables, administrative changes	678
307	Variation requiring assessment by mutual/decentralized/subsequent recognition procedures, with Romania as concerned member state, reduced timetables, administrative changes	716
308	Variation requiring assessment by mutual/decentralized/subsequent recognition procedures, with Romania as reference member state, reduced timetables, administrative changes	953
309	Variation requiring assessment by national procedures, reduced timetables, related to quality, safety, efficacy, pharmacovigilance changes	1545
310	Variation requiring assessment by mutual/decentralized/subsequent recognition procedures, with Romania as concerned member state, reduced timetables related to quality, safety, efficacy, pharmacovigilance changes	1663
311	Variation requiring assessment by mutual/decentralized/subsequent recognition procedures, with Romania as reference member state, reduced timetables related to quality, safety, efficacy, pharmacovigilance changes	2137
312	Variation requiring assessment by national procedures, standard timetables, related to quality, safety, efficacy, pharmacovigilance changes	3911
313	Variation requiring assessment by mutual/decentralized/subsequent recognition procedures, with Romania as concerned member state, standard timetables, related to quality, safety, efficacy, pharmacovigilance changes	4030
314	Variation requiring assessment by mutual/decentralized/subsequent recognition procedures, with Romania as reference member state, standard timetables, related to quality, safety, efficacy, pharmacovigilance changes	4266
315	Variation requiring assessment by national procedures, extended timetables, related to safety, efficacy, pharmacovigilance changes	5883
316	Variation requiring assessment by mutual/decentralized/subsequent recognition procedures, with Romania as concerned member state, extended timetables, related to safety, efficacy, pharmacovigilance changes	6001

No.	Type of authorization	Fee/Rate (lei)
317	Variation requiring assessment by mutual/decentralized/subsequent recognition procedures, with Romania as reference member state, extended timetables, related to safety, efficacy, pharmacovigilance changes	6238
318	Variation requiring assessment by national procedures, extended timetables, related to active substance, concentration, pharmaceutical form, route of administration, target food-producing species changes	10837
319	Variation requiring assessment by mutual/decentralized/subsequent recognition procedures, with Romania as concerned member state, extended timetables, related to active substance, concentration, pharmaceutical form, route of administration, target food-producing species changes	10955
320	Variation requiring assessment by mutual/decentralized/subsequent recognition procedures, with Romania as reference member state, extended timetables, related to active substance, concentration, pharmaceutical form, route of administration, target food-producing species changes	11191
321	Emission of a duplicate of the marketing authorization, by national procedure	263
322	Approval of advertising material for veterinary medicinal products	1.481
323	Consultancy in the field of veterinary medicinal products /hour	187
324	Consolidated notification for the completion of the technical documentations for the products in course of authorization, by national procedure*****	1.407
325	Annual fee to maintain on the market the marketing authorization for veterinary medicinal products	357
326	Transfer of the marketing authorization	5.820
327	Assessment of technical documentation for nutritional supplements, cosmetics and other veterinary products for notification	877
336	Variation requiring emergencies assessment by national procedures	1273
337	Variation requiring emergencies e assessment by mutual/decentralized/subsequent recognition procedures, with Romania as concerned member state	1511
338	Variation requiring emergencies assessment by mutual/decentralized/subsequent recognition procedures, with Romania as reference member state	2064

***** For the subsequent notifications the tariff will be 50% of the initial value.

NOTES:

a) Emission of a duplicate of the marketing authorization is made only upon request, based on the documents attesting the loss of the document by publishing in the Official Gazette of Romania, Part III,

b) In case of grouped variations, the tariff is calculated for each marketing authorization, by summing the appropriate tariff of the variation that defines the group and 75 % of the tariff of the variation included in the group, other than the variation that defines the group,

c) For type I, II or group of variations, requested by “Equitable distribution of tasks” (worksharing), the same tariff established for variations of type I, II or group of variation depending on the type of procedure applies,

d) The annual tariff for maintaining on the market the marketing authorization for veterinary medicinal products will be paid within first 6 months of the current year for all marketing authorizations valid at 31 December of the previous year.