

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)
1.	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:	32.902
	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	1.354
	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.	956
2.	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:	27.007
	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	1.354
	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	956
3.	Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as reference member state, to which are added, as appropriate:	24.935
	a) Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as reference member state for each other target species/way of administration, for food producing animals	1.354
	b) Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as reference member state for each other target species/way of administration, for animals not intended for human consumption	956

No.	Type of authorization	Fee/Rate (lei)
4.	Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as concerned member state, to which are added, as appropriate:	18.244
	a) Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as concerned member state for each other target species/way of administration, for food producing animals	1.354
	b) Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as concerned member state for each other target species/way of administration, for animals not intended for human consumption	956
5.	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:	43.258
6.	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	1.354
7.	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	956
8.	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:	31.149
9.	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	1.354
10.	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	956
11.	Authorization of veterinary medicinal products with well-established use, by mutual recognition procedure, with Romania acting as reference member state, to which are added, as appropriate:	30.512
	a) Authorization of veterinary medicinal products with well-established use by mutual recognition procedure, with Romania acting as reference member state for each other target species/way of administration, for food producing animals	1.354
	b) Authorization of veterinary medicinal products with well-established use, 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	956

No.	Type of authorization	Fee/Rate (lei)
12.	Authorization of veterinary medicinal products with well-established use, by mutual recognition procedure, with Romania acting as concerned member state, to which are added, as appropriate:	23.024
	a) Authorization of veterinary medicinal products with well-established use by mutual recognition procedure, with Romania acting as concerned member state for each other target species/way of administration, for food producing animals	1.354
	b) Authorization of veterinary medicinal products with well-established use, 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	956
13.	Authorization of veterinary medicinal products with well-established use, by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as reference member state, to which are added, as appropriate:	21.749
14.	a) Authorization of veterinary medicinal products with well-established use, by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as reference member state for each other target species/way of administration, for food producing animals	1.354
15.	b) Authorization of veterinary medicinal products with well-established use, by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as reference member state for each other target species/way of administration, for animals not intended for human consumption	956
16.	Authorization of veterinary medicinal products with well-established use, by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as concerned member state, to which are added, as appropriate:	17.447
17.	a) Authorization of veterinary medicinal products with well-established use, by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as concerned member state for each other target species/way of administration, for food producing animals	1.354
18.	b) Authorization of veterinary medicinal products with well-established use, by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as concerned member state for each other target species/way of administration, for animals not intended for human consumption	956
19.	Authorization of veterinary medicinal products with well-established use, by decentralized procedure, with Romania acting as reference member state, to which are added, as appropriate:	39.275
20.	a) Authorization of veterinary medicinal products with well-established use, by decentralized procedure, with Romania acting as reference member state for each other target species/way of administration, for food producing animals	1.354
21.	b) Authorization of veterinary medicinal products with well-established use, 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	956
22.	Authorization of veterinary medicinal products with well-established use, by decentralized procedure, with Romania acting as concerned member state, to which are added, as appropriate:	27.166

No.	Type of authorization	Fee/Rate (lei)
23.	a) Authorization of veterinary medicinal products with well-established use, by decentralized procedure, with Romania acting as concerned member state for each other target species/way of administration, for food producing animals	1.354
24.	b) Authorization of veterinary medicinal products with well-established use, 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	956
25.	Authorization of generic veterinary medicinal products, by mutual recognition procedure, with Romania acting as reference member state	24.935
26.	Authorization of generic veterinary medicinal products, by mutual recognition procedure, with Romania acting as concerned member state	18.244
27.	Authorization of generic veterinary medicinal products, by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as reference member state	19.359
28.	Authorization of generic veterinary medicinal products, by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as concerned member state	15.854
29.	Authorization of generic veterinary medicinal products, by decentralized procedure, with Romania acting as reference member state	34.097
30.	Authorization of generic veterinary medicinal products, by decentralized procedure, with Romania acting as concerned member state	24.617
31.	Authorization of hybrid veterinary medicinal products, by decentralized procedure, with Romania acting as reference member state, to which are added, as appropriate:	34.495
	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	1.354
	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	956
32.	Authorization of hybrid veterinary medicinal products, by decentralized procedure, with Romania acting as concerned member state, to which are added, as appropriate:	27.166
	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	1.354
	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	956
33.	Authorization of hybrid veterinary medicinal products, by mutual recognition procedure, with Romania acting as reference member state, to which are added, as appropriate:	30.512
	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	1.354

No.	Type of authorization	Fee/Rate (lei)
	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	956
34.	Authorization of hybrid veterinary medicinal products, by mutual recognition procedure, with Romania acting as concerned member state, to which are added, as appropriate:	23.024
	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	1.354
	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	956
35.	Authorization of hybrid veterinary medicinal products, by mutual recognition procedure and proposed by "repeat use" procedure with Romania acting as reference member state, to which are added, as appropriate:	21.749
	a) Authorization of hybrid veterinary medicinal products, by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as reference member state for each other target species/way of administration, for food producing animals	1.354
	b) Authorization of hybrid veterinary medicinal products, by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as reference member state for each other target species/way of administration, for animals not intended for human consumption	956
36.	Authorization of hybrid veterinary medicinal products, by mutual recognition procedure and proposed by "repeat use" procedure with Romania acting as concerned member state, to which are added, as appropriate	17.447
37.	a) Authorization of hybrid veterinary medicinal products, by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as concerned member state for each other target species/way of administration, for food producing animals	1.354
38.	b) Authorization of hybrid veterinary medicinal products, by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as concerned member state for each other target species/way of administration, for animals not intended for human consumption	956
39.	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:	30.512
40.	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	1.354
41.	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	956
42.	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:	23.024

No.	Type of authorization	Fee/Rate (lei)
43.	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	1.354
44.	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	956
45.	Authorization of veterinary medicinal products containing a known active substance, by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as reference member state, to which are added, as appropriate:	21.749
46.	a) Authorization of veterinary medicinal products containing a known active substance, by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as reference member state for each target species/way of administration, for food producing animals	1.354
47.	b) Authorization of veterinary medicinal products containing a known active substance, by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as reference member state for each target species/way of administration, for animals not intended for human consumption	956
48.	Authorization of veterinary medicinal products containing a known active substance, by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as concerned member state, to which are added, as appropriate:	17.407
49.	a) Authorization of veterinary medicinal products containing a known active substance, by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as concerned member state for each target species/way of administration, for food producing animals	1.354
50.	b) Authorization of veterinary medicinal products containing a known active substance, by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as concerned member state for each target species/way of administration, for animals not intended for human consumption	956
51.	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:	39.275
52.	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	1.354
53.	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	956
54.	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:	27.166

No.	Type of authorization	Fee/Rate (lei)
55.	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	1.354
56.	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	956
57.	Authorization of veterinary medicinal products by "informed consent", by mutual recognition procedure, with Romania acting as reference member state	30.512
58.	Authorization of veterinary medicinal products by "informed consent", by mutual recognition procedure, with Romania acting as concerned member state	23.024
59.	Authorization of veterinary medicinal products by "informed consent", by decentralized procedure, with Romania acting as reference member state	34.495
60.	Authorization of veterinary medicinal products by "informed consent", by decentralized procedure, with Romania acting as concerned member state	21.829
61.	Authorization of veterinary medicinal products by "informed consent" procedure, by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as reference member state	21.749
62.	Authorization of veterinary medicinal products by "informed consent" procedure, by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as concerned member state	17.447
63.	Authorization of VMPs containing a new active substance, by mutual recognition procedure, with Romania acting as reference member state	30.512
64.	Authorization of VMPs containing a new active substance, by mutual recognition procedure, with Romania acting as concerned member state	29.396
65.	Authorization of VMPs containing a new active substance, by decentralized procedure, with Romania acting as reference member state	39.275
66.	Authorization of VMPs containing a new active substance, by decentralized procedure, with Romania acting as concerned member state	29.556
67.	Authorization of veterinary medicinal products containing a new active substance by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as reference member state	21.749
68.	Authorization of veterinary medicinal products containing a new active substance by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as concerned member state	18.244
69.	Authorization of veterinary medicinal products by multiple applications - "duplicate", by mutual recognition procedure, with Romania acting as reference member state	24.935
70.	Authorization of veterinary medicinal products by multiple applications - "duplicate", by mutual recognition procedure, with Romania acting as concerned member state	15.854
71.	Authorization of veterinary medicinal products by multiple applications - "duplicate", by decentralized procedure, with Romania acting as reference member state	21.988
72.	Authorization of veterinary medicinal products by multiple applications - "duplicate", by decentralized procedure, with Romania acting as concerned member state	18.642

No.	Type of authorization	Fee/Rate (lei)
73.	Authorization of veterinary medicinal products by multiple applications - "duplicate", by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as reference member state	21.749
74.	Authorization of veterinary medicinal products by multiple applications - "duplicate", by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as concerned member state	17.447
75.	Authorization of similar biological medicinal products, by mutual recognition procedure, with Romania acting as concerned member state	23.024
76.	Authorization of similar biological medicinal products, by mutual recognition procedure, with Romania acting as reference member state	30.512
77.	Authorization of similar biological medicinal products, by decentralized procedure, with Romania acting as reference member state	39.275
78.	Authorization of similar biological medicinal products, by decentralized procedure, with Romania acting as concerned member state	27.166
79.	Authorization of similar biological medicinal products", by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as reference member state	21.749
80.	Authorization of similar biological medicinal products", by mutual recognition procedure and proposed by "repeat use" procedure, with Romania acting as concerned member state	17.447
81.	Authorization of veterinary medicinal products containing a new active substance, by national procedure, to which are added, as appropriate:	15.734
	a) Authorization of veterinary medicinal products containing a new active substance, for each target species/way of administration, for food producing animals	1.354
	b) Authorization of veterinary medicinal products containing a new active substance, for each target species/way of administration, for animals not intended for human consumption	956
82.	Authorization of veterinary medicinal products containing a known active substance, authorized by national procedure, to which are added, as appropriate:	14.938
	a) Authorization of veterinary medicinal products containing a known active substance, for each target species/way of administration, for food producing animals	1.354
	b) Authorization of veterinary medicinal products containing a known active substance, for each target species/way of administration, for animals not intended for human consumption	956
83.	Authorization of veterinary medicinal products with well-established medical use, by national procedure, to which are added, as appropriate:	14.938
84.	a) Authorization of veterinary medicinal products with well-established medical use, for each target species/way of administration, for food producing animals	1.354
85.	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	956
86.	Authorization of generic veterinary medicinal products, by national procedure	11.194
87.	Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by national procedure, to which are added, as appropriate:	18.124

No.	Type of authorization	Fee/Rate (lei)
	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	1.354
	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	956
88.	Authorization of hybrid veterinary medicinal products, by national procedure, to which are added, as appropriate:	14.938
89.	a) Authorization of hybrid veterinary medicinal products, for each target species/way of administration, for food producing animals, by national procedure	1.354
90.	b) Authorization of veterinary medicinal products, for each target species/way of administration, for animals not intended for human consumption, by national procedure	956
91.	National authorization of veterinary medicinal products by "informed consent"	14.938
92.	Authorization of homeopathic products with therapeutic indications, by national procedure	14.938
93.	Authorization of veterinary medicinal products by parallel import, simplified procedure	3.228
94.	Limited marketing authorization for veterinary medicinal products	6.255
95.	Marketing notification for veterinary medicinal products	2.778
96.	Authorization of similar biological medicinal products, by national procedure	14.938
97.	Authorization of veterinary medicinal products by multiple applications - "duplicate", by national procedure	14.380
98.	Renewal of marketing authorization of veterinary medicinal products by mutual recognition procedure or decentralized procedure, with Romania acting as reference member state	19.359
99.	Renewal of marketing authorization of veterinary medicinal products by mutual recognition procedure or decentralized procedure, with Romania acting as concerned member state	13.464
100.	Renewal of marketing authorization of veterinary medicinal products by national procedure	8.485
101.	Renewal of marketing authorization of homeopathic veterinary medicinal products with therapeutic indications, by national procedure	8.485
102.	Renewal of marketing authorization for parallel import	2.349
103.	Extension of marketing authorization of veterinary medicinal products by mutual recognition procedure or decentralized procedure with Romania acting as concerned member state	21.430
104.	Extension of marketing authorization of veterinary medicinal products by mutual recognition procedure or decentralized procedure with Romania acting as reference member state	31.069
105.	Extension of marketing authorization of veterinary medicinal products by national procedure	12.349
106.	Evaluation of variation type IA, by mutual recognition procedure or decentralized procedure with Romania acting as concerned member state	1.424
107.	Evaluation of variation type IA, by mutual recognition procedure or decentralized procedure with Romania acting as reference member state	1.822

No.	Type of authorization	Fee/Rate (lei)
108.	Evaluation of variation type IB, by mutual recognition procedure or decentralized procedure with Romania acting as concerned member state	1.742
109.	Evaluation of variation type IB, by mutual recognition procedure or decentralized procedure with Romania acting as reference member state	2.220
110.	Evaluation of variation type II, by mutual recognition procedure or decentralized procedure with Romania acting as concerned member state	3.017
111.	Evaluation of variation type II, by mutual recognition procedure or decentralized procedure with Romania acting as reference member state	4.052
112.	Evaluation of variation type IA, by national procedure	1.145
113.	Evaluation of variation type IB, by national procedure	1.384
114.	Evaluation of variation type II, by national procedure	3.734
115.	Variation of marketing authorization for parallel import	1.185
116.	Emission of a duplicate of the marketing authorization, by national procedure	243
117.	Notification for homeopathic veterinary medicinal products, by simplified national procedure	1.344
118.	Evaluation of applications for the change of design and writing of the primary and secondary packaging of the VMP, of the package leaflet and SPC, other than those derived from type IA, IB and II variations, by national procedure	1.049
119.	Approval of advertising material for veterinary medicinal products	1.368
120.	Consultancy in the field of veterinary medicinal products /hour	173
121.	Consolidated notification for the completion of the technical documentations for the products in course of authorization, renewal, or extension procedure, by national procedure*****	1.300
122.	Annual fee to maintain on the market the marketing authorization for veterinary medicinal products	343
123.	Transfer of the marketing authorization	5.378
124.	Evaluation of technical documentation for nutritive supplements, cosmetics and other veterinary use products for notification	811

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

NOTES:

- 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,
- 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,
- 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,
- 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.