

RATES

authorization for the marketing of medicinal products and other products for veterinary use practiced by Institute for Control of Veterinary Biological and Medicinal products

Nr.	Name of the analysis/examination/operation/product	Rate - RON -
1.	Authorization of VMPs containing a new active substance, by MRP or DCP, with Romania acting as RMS, to which is added, if applicable:	21309
	a) for each target species/way of administration, for food producing animals	991
	b) for each target species/way of administration, for pet animals.	733
2.	Authorization of VMPs resulting from an association of known substances (fixed combination), by MRP or DCP, with Romania acting as RMS, to which is added, if applicable	19721
	a) for each target species/way of administration, for food producing animals	991
	b) for each target species/way of administration, for pet animals	684
3.	Authorization of VMPs with well established use, by MRP or DCP, with Romania acting as RMS	18013
4.	Authorization of generic VMPs, by MRP or DCP, with Romania acting as RMS	15815
5.	Authorization of VMPs containing a new active substance, by MRP or DCP, with Romania acting as CMS, first wave	20823
6.	Authorization of VMPs resulting from an association of known substances (fixed combination), by MRP or DCP, with Romania acting as CMS, first wave	20455
7.	Authorization of VMPs with well established use, by MRP or DCP, with Romania acting as CMS, first wave	18257
8.	Authorization of generic VMPs, by MRP or DCP, with Romania acting as CMS, first wave	17463
9.	Authorization of VMPs containing a new active substance authorized in the EU by MRP and proposed by "repeat use" procedure, with Romania acting as CMS	12151
10.	Authorization of VMPs resulting from an association of known substances (fixed combination), authorized in the UE by MRP and proposed by "repeat use" procedure, with Romania acting as CMS	11113
11.	Authorization of VMPs with well established use authorized in the UE by MRP and proposed by "repeat use" procedure, with Romania acting as CMS	11050
12.	Authorization of generic VMPs authorized in the UE by MRP and proposed by "repeat use" procedure, with Romania acting as CMS	10199
13.	Renewal of marketing authorization of VMPs by MRP or DCP, with Romania acting as CMS	7451
14.	Renewal of marketing authorization of VMPs by MRP or DCP, with Romania acting as RMS	8364
15.	Evaluation of variation type IA (MRP/DCP)	768
16.	Evaluation of variation type IB (MRP/DCP)	1191
17.	Evaluation of variation type II (MRP/DCP)	2839

Nr.	Name of the analysis/examination/operation/product	Rate - RON -
18.	Issuing of marketing authorization for parallel import	2137
19.	Authorization of VMPs containing a new active substance, by national procedure, to which is added, if applicable:	7326
	a) for each target species/way of administration, for food producing animals	611
	b) for each target species/way of administration, for pet animals	426
20.	Authorization of VMPs resulting from an association of known substances (fixed combination), by national procedure, to which is added, if applicable:	7144
	a) for each target species/way of administration, for food producing animals	611
	b) for each target species/way of administration, for pet animals	426
21.	Authorization of VMPs with well established use, by national procedure	6229
22.	Authorization of generic VMPs, by national procedure	6229
23.	Authorization of homeopathic products with therapeutic indications, by national procedure	4091
24.	Notice on VMPs without therapeutic indications, by national procedure	917
25.	Evaluation of variation type IA, by national procedure	611
26.	Evaluation of variation type IB, by national procedure	855
27.	Evaluation of variation type II, by national procedure	2014
28.	Evaluation of applications for the change of design and writing of the primary and secondary packaging of the VMP, of the package insert and SPC, other than those derived from type IA, IB and II, by national procedure	855
29.	Renewal of marketing authorization of VMPs by national procedure	4335
30.	Approval of advertising material for biological/medicinal/feed additives/other products, for each media type	885
31.	Issuing of a duplicate of the marketing authorization, by national procedure	147
32.	Consultancy in the field of medicinal products and other veterinary use products/hour	60
33.	Notice on products that do not require authorization/product	611
34.	Authorization of VMPs containing a known active substance, by MRP or DCP, first wave, with Romania acting as CMS, first wave	16425
35.	Authorization of VMPs containing a known active substance authorized by MRP and proposed by "repeat use" procedure, with Romania acting as CMS	9163
36.	Authorization of VMPs containing a known active substance, by MRP or DCP, with Romania acting as RMS, first wave, to which is added, if applicable:	20761
	a) for each target species/way of administration, for food producing animals	991
	b) for each target species/way of administration, for pet animals	733
37.	Authorization of VMPs containing a known active substance, authorized by national procedure, to which is added, if applicable:	6015

Nr.	Name of the analysis/examination/operation/product	Rate - RON -
	a) for each target species/way of administration, for food producing animals	611
	b) for each target species/way of administration, for pet animals	426
38.	National authorization of the veterinary medicinal products by "informed consent"	4947
38a	National authorization of the veterinary medicinal products by "informed consent" by MRP or DCP, with Romania as CMS, first wave	8312
38b	National authorization of the veterinary medicinal products by "informed consent" by MRP or DCP, with Romania as RMS	11746
39.	Extension of the marketing authorization of the veterinary medicinal products by national procedure	6960
40.	Extension of the marketing authorization of the veterinary medicinal products by MRP or DCP, with Romania acting as RMS	19479
41.	Extension of the marketing authorization of the veterinary medicinal products by MRP or DCP, with Romania acting as CMS	17709
42.	Authorization of hybrid veterinary medicinal products by MRP or DCP, with Romania acting as RMS	18869
43.	Authorization of hybrid veterinary medicinal products by MRP or DCP, with Romania acting as CMS, first wave	16731
44.	Authorization of hybrid veterinary medicinal products by MRP and proposed by "repeat use" procedure, with Romania acting as CMS	11968
45.	Renewal of marketing authorization for veterinary homeopathic products with therapeutic indications, by national procedure	1404
46.	Limited marketing authorization of the veterinary medicinal products	2748
47.	Marketing advice for VMPs	1404
48.	Evaluation of technical documentation for food supplements, cosmetics and other veterinary use products for notification	549
49.	Consolidated notification for the completion of the technical documentations for the products in course of authorization or renewal, by national procedure	611
50.	Annual fee to maintain in force of the marketing authorization	335
51.	Variation to the marketing authorization for parallel import	611