

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:	20745
	a) for each target species/way of administration, for food producing animals	964
	b) for each target species/way of administration, for pet animals.	714
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	19199
	a) for each target species/way of administration, for food producing animals	964
	b) for each target species/way of administration, for pet animals	666
3.	Authorization of VMPs with well established use, by MRP or DCP, with Romania acting as RMS	17536
4.	Authorization of generic VMPs, by MRP or DCP, with Romania acting as RMS	15396
5.	Authorization of VMPs containing a new active substance, by MRP or DCP, with Romania acting as CMS, first wave	20271
6.	Authorization of VMPs resulting from an association of known substances (fixed combination), by MRP or DCP, with Romania acting as CMS, first wave	19913
7.	Authorization of VMPs with well established use, by MRP or DCP, with Romania acting as CMS, first wave	17773
8.	Authorization of generic VMPs, by MRP or DCP, with Romania acting as CMS, first wave	17000
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	11829
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	10818
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	10758
12.	Authorization of generic VMPs authorized in the UE by MRP and proposed by "repeat use" procedure, with Romania acting as CMS	9928
13.	Renewal of marketing authorization of VMPs by MRP or DCP, with Romania acting as CMS	7253
14.	Renewal of marketing authorization of VMPs by MRP or DCP, with Romania acting as RMS	8142
15.	Evaluation of variation type IA (MRP/DCP)	748
16.	Evaluation of variation type IB (MRP/DCP)	1159

Nr.	Name of the analysis/examination/operation/product	Rate - RON -
17.	Evaluation of variation type II (MRP/DCP)	2764
18.	Issuing of marketing authorization for parallel import	2081
19.	Authorization of VMPs containing a new active substance, by national procedure, to which is added, if applicable:	7132
	a) for each target species/way of administration, for food producing animals	594
	b) for each target species/way of administration, for pet animals	415
20.	Authorization of VMPs resulting from an association of known substances (fixed combination), by national procedure, to which is added, if applicable:	6955
	a) for each target species/way of administration, for food producing animals	594
	b) for each target species/way of administration, for pet animals	415
21.	Authorization of VMPs with well established use, by national procedure	6064
22.	Authorization of generic VMPs, by national procedure	6064
23.	Authorization of homeopathic products with therapeutic indications, by national procedure	3983
24.	Notice on VMPs without therapeutic indications, by national procedure	893
25.	Evaluation of variation type IA, by national procedure	594
26.	Evaluation of variation type IB, by national procedure	832
27.	Evaluation of variation type II, by national procedure	1960
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	832
29.	Renewal of marketing authorization of VMPs by national procedure	4220
30.	Approval of advertising material for biological/medicinal/feed additives/other products, for each media type	862
31.	Issuing of a duplicate of the marketing authorization, by national procedure	143
32.	Consultancy in the field of medicinal products and other veterinary use products/hour	59
33.	Notice on products that do not require authorization/product	594
34.	Authorization of VMPs containing a known active substance, by MRP or DCP, first wave, with Romania acting as CMS, first wave	15990
35.	Authorization of VMPs containing a known active substance authorized by MRP and proposed by "repeat use" procedure, with Romania acting as CMS	8920
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:	20211
	a) for each target species/way of administration, for food producing animals	964
	b) for each target species/way of administration, for pet animals	714

Nr.	Name of the analysis/examination/operation/product	Rate - RON -
37.	Authorization of VMPs containing a known active substance, authorized by national procedure, to which is added, if applicable:	5855
	a) for each target species/way of administration, for food producing animals	594
	b) for each target species/way of administration, for pet animals	415
38.	National authorization of the veterinary medicinal products by "informed consent"	4816
39.	Extension of the marketing authorization of the veterinary medicinal products by national procedure	6776
40.	Extension of the marketing authorization of the veterinary medicinal products by MRP or DCP, with Romania acting as RMS	18963
41.	Extension of the marketing authorization of the veterinary medicinal products by MRP or DCP, with Romania acting as CMS	17239
42.	Authorization of hybrid veterinary medicinal products by MRP or DCP, with Romania acting as RMS	18369
43.	Authorization of hybrid veterinary medicinal products by MRP or DCP, with Romania acting as CMS	16288
44.	Authorization of hybrid veterinary medicinal products by MRP and proposed by "repeat use" procedure, with Romania acting as CMS	11651
45.	Renewal of marketing authorization for veterinary homeopathic products with therapeutic indications, by national procedure	1367
46.	Limited marketing authorization of the veterinary medicinal products	2675
47.	Marketing advice for VMPs	1367
48.	Evaluation of technical documentation for food supplements, cosmetics and other veterinary use products for notification	535
49.	Consolidated notification for the completion of the technical documentations for the products in course of authorization or renewal, by national procedure	594
50.	Annual fee to maintain in force of the marketing authorization	326
51.	Variation to the marketing authorization for parallel import	594
52.	National authorization of veterinary medicinal products by "informed consent" through the mutual recognition procedure or decentralized procedure with Romania acting as concerned member state, first wave	8091
53.	National authorization of veterinary medicinal products by "informed consent" through the mutual recognition procedure or decentralized procedure with Romania acting as reference member state	11435