

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:	20380
	a) for each target species/way of administration, for food producing animals	947
	b) for each target species/way of administration, for pet animals.	701
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	18861
	a) for each target species/way of administration, for food producing animals	947
	b) for each target species/way of administration, for pet animals	654
3.	Authorization of VMPs with well established use, by MRP or DCP, with Romania acting as RMS	17228
4.	Authorization of generic VMPs, by MRP or DCP, with Romania acting as RMS	15125
5.	Authorization of VMPs containing a new active substance, by MRP or DCP, with Romania acting as CMS, first wave	19915
6.	Authorization of VMPs resulting from an association of known substances (fixed combination), by MRP or DCP, with Romania acting as CMS, first wave	19563
7.	Authorization of VMPs with well established use, by MRP or DCP, with Romania acting as CMS, first wave	17460
8.	Authorization of generic VMPs, by MRP or DCP, with Romania acting as CMS, first wave	16701
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	11621
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	10628
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	10569
12.	Authorization of generic VMPs authorized in the UE by MRP and proposed by "repeat use" procedure, with Romania acting as CMS	9753
13.	Renewal of marketing authorization of VMPs by MRP or DCP, with Romania acting as CMS	7125
14.	Renewal of marketing authorization of VMPs by MRP or DCP, with Romania acting as RMS	7999
15.	Evaluation of variation type IA (MRP/DCP)	735
16.	Evaluation of variation type IB (MRP/DCP)	1139

Nr.	Name of the analysis/examination/operation/product	Rate - RON -
17.	Evaluation of variation type II (MRP/DCP)	2715
18.	Issuing of marketing authorization for parallel import	2044
19.	Authorization of VMPs containing a new active substance, by national procedure, to which is added, if applicable:	7007
	a) for each target species/way of administration, for food producing animals	584
	b) for each target species/way of administration, for pet animals	408
20.	Authorization of VMPs resulting from an association of known substances (fixed combination), by national procedure, to which is added, if applicable:	6833
	a) for each target species/way of administration, for food producing animals	584
	b) for each target species/way of administration, for pet animals	408
21.	Authorization of VMPs with well established use, by national procedure	5957
22.	Authorization of generic VMPs, by national procedure	5957
23.	Authorization of homeopathic products with therapeutic indications, by national procedure	3913
24.	Notice on VMPs without therapeutic indications, by national procedure	877
25.	Evaluation of variation type IA, by national procedure	584
26.	Evaluation of variation type IB, by national procedure	817
27.	Evaluation of variation type II, by national procedure	1926
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	817
29.	Renewal of marketing authorization of VMPs by national procedure	4146
30.	Approval of advertising material for biological/medicinal/feed additives/other products, for each media type	847
31.	Issuing of a duplicate of the marketing authorization, by national procedure	140
32.	Consultancy in the field of medicinal products and other veterinary use products/hour	58
33.	Notice on products that do not require authorization/product	584
34.	Authorization of VMPs containing a known active substance, by MRP or DCP, first wave, with Romania acting as CMS, first wave	15709
35.	Authorization of VMPs containing a known active substance authorized by MRP and proposed by "repeat use" procedure, with Romania acting as CMS	8763
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:	19856
	a) for each target species/way of administration, for food producing animals	947
	b) for each target species/way of administration, for pet animals	701

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:	5752
	a) for each target species/way of administration, for food producing animals	584
	b) for each target species/way of administration, for pet animals	408
38.	National authorization of the veterinary medicinal products by "informed consent"	4731
39.	Extension of the marketing authorization of the veterinary medicinal products by national procedure	6657
40.	Extension of the marketing authorization of the veterinary medicinal products by MRP or DCP, with Romania acting as RMS	18630
41.	Extension of the marketing authorization of the veterinary medicinal products by MRP or DCP, with Romania acting as CMS	16936
42.	Authorization of hybrid veterinary medicinal products by MRP or DCP, with Romania acting as RMS	18046
43.	Authorization of hybrid veterinary medicinal products by MRP or DCP, with Romania acting as CMS	16002
44.	Authorization of hybrid veterinary medicinal products by MRP and proposed by "repeat use" procedure, with Romania acting as CMS	11446
45.	Renewal of marketing authorization for veterinary homeopathic products with therapeutic indications, by national procedure	1343
46.	Limited marketing authorization of the veterinary medicinal products	2628
47.	Marketing advice for VMPs	1343
48.	Evaluation of technical documentation for food supplements, cosmetics and other veterinary use products for notification	526
49.	Consolidated notification for the completion of the technical documentations for the products in course of authorization or renewal, by national procedure	584
50.	Annual fee to maintain in force of the marketing authorization	817
51.	Variation to the marketing authorization for parallel import	584