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:	20063
	a) for each target species/way of administration, for food producing animals	932
	b) for each target species/way of administration, for pet animals.	690
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	18568
	a) for each target species/way of administration, for food producing animals	932
	b) for each target species/way of administration, for pet animals	644
3.	Authorization of VMPs with well established use, by MRP or DCP, with Romania acting as RMS	16960
4.	Authorization of generic VMPs, by MRP or DCP, with Romania acting as RMS	14890
5.	Authorization of VMPs containing a new active substance, by MRP or DCP, with Romania acting as CMS, first wave	19605
6.	Authorization of VMPs resulting from an association of known substances (fixed combination), by MRP or DCP, with Romania acting as CMS, first wave	19259
7.	Authorization of VMPs with well established use, by MRP or DCP, with Romania acting as CMS, first wave	17188
8.	Authorization of generic VMPs, by MRP or DCP, with Romania acting as CMS, first wave	16441
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	11440
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	10463
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	10405
12.	Authorization of generic VMPs authorized in the UE by MRP and proposed by “repeat use” procedure, with Romania acting as CMS	9601
13.	Renewal of marketing authorization of VMPs by MRP or DCP, with Romania acting as CMS	7014
14.	Renewal of marketing authorization of VMPs by MRP or DCP, with Romania acting as RMS	7875
15.	Evaluation of variation type IA (MRP/DCP)	724
16.	Evaluation of variation type IB (MRP/DCP)	1121

Nr.	Name of the analysis/examination/operation/product	Rate - RON -
17.	Evaluation of variation type II (MRP/DCP)	2673
18.	Issuing of marketing authorization for parallel import	2012
19.	Authorization of VMPs containing a new active substance, by national procedure, to which is added, if applicable:	6898
	a) for each target species/way of administration, for food producing animals	575
	b) for each target species/way of administration, for pet animals	402
20.	Authorization of VMPs resulting from an association of known substances (fixed combination), by national procedure, to which is added, if applicable:	6727
	a) for each target species/way of administration, for food producing animals	575
	b) for each target species/way of administration, for pet animals	402
21.	Authorization of VMPs with well established use, by national procedure	5864
22.	Authorization of generic VMPs, by national procedure	5864
23.	Authorization of homeopathic products with therapeutic indications, by national procedure	3852
24.	Notice on VMPs without therapeutic indications, by national procedure	863
25.	Evaluation of variation type IA, by national procedure	575
26.	Evaluation of variation type IB, by national procedure	804
27.	Evaluation of variation type II, by national procedure	1896
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	804
29.	Renewal of marketing authorization of VMPs by national procedure	4082
30.	Approval of advertising material for biological/medicinal/feed additives/other products, for each media type	834
31.	Issuing of a duplicate of the marketing authorization, by national procedure	138
32.	Consultancy in the field of medicinal products and other veterinary use products/hour	57
33.	Notice on products that do not require authorization/product	575
34.	Authorization of VMPs containing a known active substance, by MRP or DCP, first wave, with Romania acting as CMS, first wave	15465
35.	Authorization of VMPs containing a known active substance authorized by MRP and proposed by “repeat use” procedure, with Romania acting as CMS	8627
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:	19547
	a) for each target species/way of administration, for food producing animals	932
	b) for each target species/way of administration, for pet animals	690

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:	5663
	a) for each target species/way of administration, for food producing animals	575
	b) for each target species/way of administration, for pet animals	402
38.	National authorization of the veterinary medicinal products by “informed consent”	4657
39.	Extension of the marketing authorization of the veterinary medicinal products by national procedure	6553
40.	Extension of the marketing authorization of the veterinary medicinal products by MRP or DCP, with Romania acting as RMS	18340
41.	Extension of the marketing authorization of the veterinary medicinal products by MRP or DCP, with Romania acting as CMS	16673
42.	Authorization of hybrid veterinary medicinal products by MRP or DCP, with Romania acting as RMS	17765
43.	Authorization of hybrid veterinary medicinal products by MRP or DCP, with Romania acting as CMS	15753
44.	Authorization of hybrid veterinary medicinal products by MRP and proposed by “repeat use” procedure, with Romania acting as CMS	11268
45.	Renewal of marketing authorization for veterinary homeopathic products with therapeutic indications, by national procedure	1322
46.	Limited marketing authorization of the veterinary medicinal products	2587
47.	Marketing advice for VMPs	1322
48.	Evaluation of technical documentation for food supplements, cosmetics and other veterinary use products for notification	518
49.	Consolidated notification for the completion of the technical documentations for the products in course of authorization or renewal, by national procedure	575
50.	Evaluating biocidal products technical documentation in order to obtain Authorization for the experiment or test	804
51.	Technical documentation on the effect assessment of biocide for temporary use of the biocidal product for each function in order to obtain the authorization of emergency (120 days)	804
52.	Evaluation of the technical documentation relating to the common data base for placing biocidal products on the market through the national procedure	977
53.	Technical documentation on the effect assessment of biocide for biocidal products to review or amendment of the ommune ation for placing on the market/approval/marketing	804
54.	Evaluation on the effect of biocide technical documentation for each function for biocidal products to put on the market through the mutual recognition procedure	288
55.	Technical documentation relating to data evaluation relationships for the temporary use of the biocidal product to release emergency Authorization (120 days)	977

Nr.	Name of the analysis/examination/operation/product	Rate - RON -
56.	Technical documentation relating to data evaluation relationships based biocidal products in order to put on the market through the mutual recognition procedure	747
57.	Notification of completion of the technical documentation of the biocidal product	402
58.	Evaluation on the effect of biocide technical documentation for each function for placing biocidal products on the market through the national procedure	804
59.	Technical documentation relating to the assessment of the common data for biocidal products to review or modification of authorization/approval placement on the market/marketing	747
60.	Annual fee to maintain in force of the marketing authorization	804
61.	Evaluation of production and control protocols for immunological veterinary medicinal products for the official release of the series	977
62.	Variation to the marketing authorization for parallel import	575