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)
244	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:	35607
	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	1465
	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.	1034
245	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:	29227
	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	1465
	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	1034
246	Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as reference member state, to which are added, as appropriate:	26985
	a) Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as reference member state for each other target species/way of administration, for food producing animals	1465
	b) Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as reference member state for each other target species/way of administration, for animals not intended for human consumption	1034
247	Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as concerned member state, to which are added, as appropriate:	19744

No.	Type of authorization	Fee/Rate (lei)
	a) Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as concerned member state for each other target species/way of administration, for food producing animals	1465
	b) Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as concerned member state for each other target species/way of administration, for animals not intended for human consumption	1034
248	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:	46815
	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	1465
	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	1034
249	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:	33710
	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	1465
	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	1034
250	Authorization of veterinary medicinal products based on bibliographic data, by mutual recognition procedure, with Romania acting as reference member state, to which are added, as appropriate:	33021
	a) Authorization of veterinary medicinal products based on bibliographic data by mutual recognition procedure, with Romania acting as reference member state for each other target species/way of administration, for food producing animals	1465
	b) Authorization of veterinary medicinal products based on bibliographic data, 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	1034

No.	Type of authorization	Fee/Rate (lei)
251	Authorization of veterinary medicinal products based on bibliographic data, by mutual recognition procedure, with Romania acting as concerned member state, to which are added, as appropriate:	24917
	a) Authorization of veterinary medicinal products based on bibliographic data by mutual recognition procedure, with Romania acting as concerned member state for each other target species/way of administration, for food producing animals	1465
	b) Authorization of veterinary medicinal products based on bibliographic data, 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	1034
252	Authorization of veterinary medicinal products based on bibliographic data, by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as reference member state, to which are added, as appropriate:	23537
	a) Authorization of veterinary medicinal products based on bibliographic data, by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as reference member state for each other target species/way of administration, for food producing animals	1465
	b) Authorization of veterinary medicinal products based on bibliographic data, by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as reference member state for each other target species/way of administration, for animals not intended for human consumption	1034
253	Authorization of veterinary medicinal products based on bibliographic data, by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as concerned member state, to which are added, as appropriate:	18881
	a) Authorization of veterinary medicinal products based on bibliographic data, by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as concerned member state for each other target species/way of administration, for food producing animals	1465
	b) Authorization of veterinary medicinal products based on bibliographic data, by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as concerned member state for each other target species/way of administration, for animals not intended for human consumption	1034
254	Authorization of veterinary medicinal products based on bibliographic data, by decentralized procedure, with Romania acting as reference member state, to which are added, as appropriate:	42504
	a) Authorization of veterinary medicinal products based on bibliographic data, by decentralized procedure, with Romania acting as reference member state for each other target species/way of administration, for food producing animals	1465
	b) Authorization of veterinary medicinal products based on bibliographic data, 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	1034

No.	Type of authorization	Fee/Rate (lei)
255	Authorization of veterinary medicinal products based on bibliographic data, by decentralized procedure, with Romania acting as concerned member state, to which are added, as appropriate:	29399
	a) Authorization of veterinary medicinal products based on bibliographic data, by decentralized procedure, with Romania acting as concerned member state for each other target species/way of administration, for food producing animals	1465
	b) Authorization of veterinary medicinal products based on bibliographic data, 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	1034
256	Authorization of generic veterinary medicinal products, by mutual recognition procedure, with Romania acting as reference member state	26985
257	Authorization of generic veterinary medicinal products, by mutual recognition procedure, with Romania acting as concerned member state	19744
258	Authorization of generic veterinary medicinal products, by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as reference member state	20951
259	Authorization of generic veterinary medicinal products, by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as concerned member state	17158
260	Authorization of generic veterinary medicinal products, by decentralized procedure, with Romania acting as reference member state	36900
261	Authorization of generic veterinary medicinal products, by decentralized procedure, with Romania acting as concerned member state	26641
262	Authorization of hybrid veterinary medicinal products, by decentralized procedure, with Romania acting as reference member state, to which are added, as appropriate:	37331
	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	1465
	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	1034
263	Authorization of hybrid veterinary medicinal products, by decentralized procedure, with Romania acting as concerned member state, to which are added, as appropriate:	29399
	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	1465
	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	1034
264	Authorization of hybrid veterinary medicinal products, by mutual recognition procedure, with Romania acting as reference member state, to which are added, as appropriate:	33021

No.	Type of authorization	Fee/Rate (lei)
	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	1465
	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	1034
265	Authorization of hybrid veterinary medicinal products, by mutual recognition procedure, with Romania acting as concerned member state, to which are added, as appropriate:	24917
	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	1465
	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	1034
266	Authorization of hybrid veterinary medicinal products, by mutual recognition procedure and proposed by "subsequent recognition" procedure with Romania acting as reference member state, to which are added, as appropriate:	23537
	a) Authorization of hybrid veterinary medicinal products, by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as reference member state for each other target species/way of administration, for food producing animals	1465
	b) Authorization of hybrid veterinary medicinal products, by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as reference member state for each other target species/way of administration, for animals not intended for human consumption	1034
267	Authorization of hybrid veterinary medicinal products, by mutual recognition procedure and proposed by "subsequent recognition" procedure with Romania acting as concerned member state, to which are added, as appropriate	18881
	a) Authorization of hybrid veterinary medicinal products, by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as concerned member state for each other target species/way of administration, for food producing animals	1465
	b) Authorization of hybrid veterinary medicinal products, by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as concerned member state for each other target species/way of administration, for animals not intended for human consumption	1034
268	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:	33021
	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	1465

No.	Type of authorization	Fee/Rate (lei)
	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	1034
269	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:	24917
	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	1465
	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	1034
270	Authorization of veterinary medicinal products containing a known active substance, by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as reference member state, to which are added, as appropriate:	23537
	a) Authorization of veterinary medicinal products containing a known active substance, by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as reference member state for each target species/way of administration, for food producing animals	1465
	b) Authorization of veterinary medicinal products containing a known active substance, by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as reference member state for each target species/way of administration, for animals not intended for human consumption	1034
271	Authorization of veterinary medicinal products containing a known active substance, by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as concerned member state, to which are added, as appropriate:	18838
	a) Authorization of veterinary medicinal products containing a known active substance, by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as concerned member state for each target species/way of administration, for food producing animals	1465
	b) Authorization of veterinary medicinal products containing a known active substance, by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as concerned member state for each target species/way of administration, for animals not intended for human consumption	1034
272	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:	42504
	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	1465

No.	Type of authorization	Fee/Rate (lei)
	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	1034
273	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:	29399
	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	1465
	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	1034
274	Authorization of veterinary medicinal products by "informed consent", by mutual recognition procedure, with Romania acting as reference member state	33021
275	Authorization of veterinary medicinal products by "informed consent", by mutual recognition procedure, with Romania acting as concerned member state	24917
276	Authorization of veterinary medicinal products by "informed consent", by decentralized procedure, with Romania acting as reference member state	37331
277	Authorization of veterinary medicinal products by "informed consent", by decentralized procedure, with Romania acting as concerned member state	23623
278	Authorization of veterinary medicinal products by "informed consent" procedure, by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as reference member state	23537
279	Authorization of veterinary medicinal products by "informed consent" procedure, by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as concerned member state	18881
280	Authorization of veterinary medicinal products by multiple applications - "duplicate", by mutual recognition procedure, with Romania acting as reference member state	26985
281	Authorization of veterinary medicinal products by multiple applications - "duplicate", by mutual recognition procedure, with Romania acting as concerned member state	17158
282	Authorization of veterinary medicinal products by multiple applications - "duplicate", by decentralized procedure, with Romania acting as reference member state	23796
283	Authorization of veterinary medicinal products by multiple applications - "duplicate", by decentralized procedure, with Romania acting as concerned member state	20175
284	Authorization of veterinary medicinal products by multiple applications - "duplicate", by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as reference member state	23537
285	Authorization of veterinary medicinal products by multiple applications - "duplicate", by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as concerned member state	18881

No.	Type of authorization	Fee/Rate (lei)
286	Authorization of similar biological veterinary medicinal products, by mutual recognition procedure, with Romania acting as concerned member state	24917
287	Authorization of similar biological veterinary medicinal products, by mutual recognition procedure, with Romania acting as reference member state	33021
288	Authorization of similar biological veterinary medicinal products, by decentralized procedure, with Romania acting as reference member state	42504
289	Authorization of similar biological veterinary medicinal products, by decentralized procedure, with Romania acting as concerned member state	29399
290	Authorization of similar biological veterinary medicinal products", by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as reference member state	23537
291	Authorization of similar veterinary biological medicinal products, by mutual recognition procedure and proposed by "subsequent recognition" procedure, with Romania acting as concerned member state	18881
292	Authorization of veterinary medicinal products with well-established medical use, by national procedure, to which are added, as appropriate:	16166
	a) Authorization of veterinary medicinal products with well-established medical use, for each target species/way of administration, for food producing animals	1465
	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	1034
293	Authorization of veterinary medicinal products based on bibliographic data, by national procedure, with Romania acting as reference member state, to which are added, as appropriate:	16166
	a) Authorization of veterinary medicinal products based on bibliographic data by national procedure, for each other target species/way of administration, for food producing animals	1465
	b) Authorization of veterinary medicinal products based on bibliographic data, by national procedure, for each other target species/way of administration, for animals not intended for human consumption	1034
294	Authorization of generic veterinary medicinal products, by national procedure	12115
295	Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by national procedure, to which are added, as appropriate:	19615
	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	
	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	1034
296	Authorization of hybrid veterinary medicinal products, by national procedure, to which are added, as appropriate:	16166
	a) Authorization of hybrid veterinary medicinal products, for each target species/way of administration, for food producing animals, by national procedure	

No.	Type of authorization	Fee/Rate (lei)
	b) Authorization of veterinary medicinal products, for each target species/way of administration, for animals not intended for human consumption, by national procedure	1034
297	National authorization of veterinary medicinal products by "informed consent"	16166
298	Authorization of homeopathic veterinary medicinal products with therapeutic indications, by national procedure	16166
299	Authorization of veterinary medicinal products by parallel comert, procedure	3494
300	Limited marketing authorization for veterinary medicinal products	6770
301	Marketing notification for veterinary medicinal products	2937
302	Authorization of similar veterinary biological medicinal products, by national procedure	16166
303	Authorization of veterinary medicinal products by multiple applications - "duplicate", by national procedure	15562
304	Authorization of homeopathic veterinary medicinal products	3174
305	1. Variations not requiring assessment (VNRA) by national procedure (T1), to which is added, where applicable*****):	282
	a) Technical grouping of VNRA having the same code for more than 1 product (T2)	112
	b) To change the summary of product characteristics, package leaflet and label (SPC/P/E) of the product (T3)	583
	2. Variations not requiring assessment (VNRA) by community procedures, with Romania acting as concerned member state (T1), to which is added, where applicable*****):	146
	a) Technical grouping of VNRA having the same code for more than 1 product (T2)	104
	b) To change the summary of product characteristics, package leaflet and label (SPC/P/E) of the product (T3)	876
	3. Variations not requiring assessment (VNRA) by community procedures, with Romania acting as reference member state (T1), to which is added, where applicable*****):	722
	a) Technical grouping of VNRA having the same code for more than 1 product (T2)	390
	b) To change the summary of product characteristics, package leaflet and label (SPC/P/E) of the product (T3)	1249
306	Variation requiring assessment by national procedures, reduced timetables, administrative changes	678
307	Variation requiring assessment by mutual/decentralized/subsequent recognition procedures, with Romania as concerned member state, reduced timetables, administrative changes	716
308	Variation requiring assessment by mutual/decentralized/subsequent recognition procedures, with Romania as reference member state, reduced timetables, administrative changes	953
309	Variation requiring assessment by national procedures, reduced timetables, related to quality, safety, efficacy, pharmacovigilance changes	1545

No.	Type of authorization	Fee/Rate (lei)
310	Variation requiring assessment by mutual/decentralized/subsequent recognition procedures, with Romania as concerned member state, reduced	1663
	timetables related to quality, safety, efficacy, pharmacovigilance changes	
311	Variation requiring assessment by mutual/decentralized/subsequent	2137
	recognition procedures, with Romania as reference member state, reduced	
	timetables related to quality, safety, efficacy, pharmacovigilance changes	
312	Variation requiring assessment by national procedures, standard timetables,	3911
	related to quality, safety, efficacy, pharmacovigilance changes	
313	Variation requiring assessment by mutual/decentralized/subsequent	4030
	recognition procedures, with Romania as concerned member state, standard	
	timetables, related to quality, safety, efficacy, pharmacovigilance changes	
314	Variation requiring assessment by mutual/decentralized/subsequent	4266
	recognition procedures, with Romania as reference member state, standard	
	timetables, related to quality, safety, efficacy, pharmacovigilance changes	
315	Variation requiring assessment by national procedures, extended timetables,	5883
	related to safety, efficacy, pharmacovigilance changes	
316	Variation requiring assessment by mutual/decentralized/subsequent	6001
	recognition procedures, with Romania as concerned member state, extended	
	timetables, related to safety, efficacy, pharmacovigilance changes	
317	Variation requiring assessment by mutual/decentralized/subsequent	6238
	recognition procedures, with Romania as reference member state, extended	
	timetables, related to safety, efficacy, pharmacovigilance changes	
318	Variation requiring assessment by national procedures, extended timetables,	10837
	related to active substance, concentration, pharmaceutical form, route of	
	administration, target food-producing species changes	
319	Variation requiring assessment by mutual/decentralized/subsequent	10955
	recognition procedures, with Romania as concerned member state, extended	
	timetables, related to active substance, concentration, pharmaceutical form,	
	route of administration, target food-producing species changes	
320	Variation requiring assessment by mutual/decentralized/subsequent	11191
	recognition procedures, with Romania as reference member state, extended	
	timetables, related to active substance, concentration, pharmaceutical form,	
	route of administration, target food-producing species changes	
321	Emission of a duplicate of the marketing authorization, by national	263
	procedure	
322	Approval of advertising material for veterinary medicinal products	1481
323	Consultancy in the field of veterinary medicinal products /hour	187
324	Consolidated notification for the completion of the technical	
	documentations for the products in course of authorization, by national	
	procedure****	
325	Annual fee to maintain on the market the marketing authorization for	357
	veterinary medicinal products	
326	Transfer of the marketing authorization	5820
327	Assessment of technical documentation for nutritional supplements,	877
	cosmetics and other veterinary products for notification	
336	Variation requiring emergencies assessment by national procedures	1273

No.	Type of authorization	Fee/Rate (lei)
337	Variation requiring emergencies e assessment by mutual/decentralized/subsequent recognition procedures, with Romania as concerned member state	1511
338	Variation requiring emergencies assessment by mutual/decentralized/subsequent recognition procedures, with Romania as reference member state	2064

SPC/P/E fee b) (T3)

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

Reduced fee a) (T2)

Example 6 [1 Product (P1) - 1 VNRA code selected/transmitted 3 times (C1 * 3)]: T1 *3.

******) Calculation formulas for technical grouping of VNRA:

Example 1 [2 Products (P1, P2) - 4 VNRA codes (C1, C2, C3, C4)]: T1 *4 + T2 * 4
1 2 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7
Example 2 [1 Product (P1) - 4 VNRA codes (C1, C2, C3, C4)]: T1 *4
E1-2 [10 D 1 (D1 D2 D10) 1 VND A 1- (C1)]. T1 + T2 * 0
Example 3 [10 Products (P1, P2P10) - 1 VNRA code (C1)]: T1 + T2 * 9
Example 4 [10 Products (P1, P2P10) - 2 VNRA codes (C1, C2)]: T1 * 2 +18 * T2
Example 4 [10 110ducts (11, 12110) - 2 VNNA codes (C1, C2)]. 11 · 2 +18 · 12
Example 5 [2 Products (P1, P2) - 4 VNRA codes (C1, C2 and C3, C4 implies change of
SPC/P/E)]: T1 * 4 + T2*4 + T3 * 2

NOTES:

Full fee 1 (T1)

- a) Emission of a duplicate of the marketing authorizations is made only upon request, based on the documents attesting the loss of the document, by publishing in the Official Journal of Romania, Part III,
- b) In case of variations requiring grouping assessment, the fee is calculated for each authorization by summing the appropriate fee for the variation that defines the group and 75 % of the fee for the variation included in the group, applied for each variation of the group, other than the variation that defines the group,
- c) In case of variations requiring assessment or grouping variations requiring assessment, requested by «work-sharing» procedure, the same fee established for variations or grouping variations requiring an assessment applies, depending on the type of procedure,
- d) The fee will be paid for each application of a variation not requiring assessment (VNRA), except for the multiple applications due to the technical errors of the system,
- e) The annual fee for maintaining on the market of the marketing authorization of the veterinary medicinal products will be paid within the first 6 months of the current year for all marketing authorizations valid at 31 December of the previous year."