

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.	34294
	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, in case of food producing species.	1411
	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, in case of animals not intended for human consumption.	996
245	Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by mutual recognition procedure, with Romania acting as member state concerned.	28149
	a) Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by mutual recognition procedure, with Romania acting as member state concerned for each other target species/way of administration, in case of food producing animals.	1411
	b) Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by mutual recognition procedure, with Romania acting as member state concerned for each other target species/way of administration, in case of animals not intended for human consumption.	996
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.	25990
	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, in case of food producing species	1411

No.	Type of authorization	Fee/Rate (lei)
	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, in case of animals not intended for human consumption	996
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 member state concerned.	19016
	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 member state concerned for each other target species/way of administration, in case of food producing animals.	1411
	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 member state concerned for each other target species/way of administration, in case of animals not intended for human consumption.	996
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.	45088
	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, in case of food producing species	1411
	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, in case of animals not intended for human consumption	996
249	Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by decentralized procedure, with Romania acting as member state concerned.	32467
	a) Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by decentralized procedure, with Romania acting as member state concerned, for each other target species/way of administration, in case of food producing species	1411

No.	Type of authorization	Fee/Rate (lei)
	b) Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), by decentralized procedure, with Romania acting as member state concerned for each other target species/way of administration, in case of animals not intended for human consumption	996
250	Authorization of veterinary medicinal products based on bibliographic data by mutual recognition procedure, with Romania acting as reference member state.	31803
	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, in case of food producing species	1411
	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, in case of species not intended for human consumption	996
251	Authorization of veterinary medicinal products based on bibliographic data by mutual recognition procedure, with Romania acting as member state concerned.	23998
	a) Authorization of veterinary medicinal products based on bibliographic data by mutual recognition procedure, with Romania acting as member state concerned, for each other target species/way of administration, in case of food producing species.	1411
	b) Authorization of veterinary medicinal products based on bibliographic data, by mutual recognition procedure, with Romania acting as member state concerned, for each other target species/way of administration, in case of species not intended for human consumption	996
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.	22669
	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, in case of food producing species.	1411
	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, in case of species not intended for human consumption	996
253	Authorization of veterinary medicinal products based on bibliographic data, by mutual recognition procedure and proposed by subsequent recognition procedure, with Romania acting as member state concerned.	18185

No.	Type of authorization	Fee/Rate (lei)
	a) Authorization of veterinary medicinal products based on bibliographic data, by mutual recognition procedure and proposed by subsequent recognition procedure, with Romania acting as member state concerned, for each other target species/way of administration, in case of food producing species.	1411
	b) Authorization of veterinary medicinal products based on bibliographic data, by mutual recognition procedure and proposed by subsequent recognition procedure, with Romania acting as member state concerned, for each other target species/way of administration, in case of species not intended for human consumption.	996
254	Authorization of veterinary medicinal products based on bibliographic data by decentralized procedure, with Romania acting as reference member state.	40936
	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, in case of food producing animals.	1411
	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, in case of animals not intended for human consumption.	996
255	Authorization of veterinary medicinal products based on bibliographic data by decentralized procedure, with Romania acting as member state concerned.	28315
	a) Authorization of veterinary medicinal products based on bibliographic data, by decentralized procedure with Romania acting as member state concerned, for each other target species/way of administration, in case of food producing animals.	1411
	b) Authorization of veterinary medicinal products based on bibliographic data, by decentralized procedure with Romania acting as member state concerned, for each other target species/way of administration, in case of animals not intended for human consumption.	996
256	Authorization of generic veterinary medicinal products, by mutual recognition procedure, with Romania acting as reference member state.	25990
257	Authorization of generic veterinary medicinal products, by mutual recognition procedure, with Romania acting as member state concerned.	19016
258	Authorization of generic veterinary medicinal products, by mutual recognition procedure and proposed by subsequent recognition procedure, with Romania acting as reference member state	20178
259	Authorization of generic veterinary medicinal products, by mutual recognition procedure and proposed by subsequent recognition procedure, with Romania acting as member state concerned.	16525

No.	Type of authorization	Fee/Rate (lei)
260	Authorization of generic veterinary medicinal products, by decentralized procedure, with Romania acting as reference member state.	35539
261	Authorization of generic veterinary medicinal products, by decentralized procedure, with Romania acting as member state concerned.	25658
262	Authorization of hybrid veterinary medicinal products, by decentralized procedure, with Romania acting as reference member state.	35954
	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, in case of food producing animals	1411
	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, in case of animals not intended for human consumption	996
263	Authorization of hybrid veterinary medicinal products, by decentralized procedure, with Romania acting as member state concerned.	28315
	a) Authorization of hybrid veterinary medicinal products by decentralized procedure, with Romania acting as member state concerned, for each other target species/way of administration, in case of food producing animals	1411
	b) Authorization of hybrid veterinary medicinal products by decentralized procedure, with Romania acting as member state concerned, for each other target species/way of administration, in case of animals not intended for human consumption	996
264	Authorization of hybrid veterinary medicinal products, by mutual recognition procedure, with Romania acting as reference member state.	31803
	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, in case of food producing animals	1411
	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, in case of animals not intended for human consumption	996
265	Authorization of hybrid veterinary medicinal products, by mutual recognition procedure, with Romania acting as member state concerned.	23998
	a) Authorization of hybrid veterinary medicinal products by mutual recognition procedure, with Romania acting as member state concerned, for each other target species/way of administration, in case of food producing animals	1411

No.	Type of authorization	Fee/Rate (lei)
	b) Authorization of hybrid veterinary medicinal products by mutual recognition procedure, with Romania acting as member state concerned, for each other target species/way of administration, in case of animals not intended for human consumption	996
266	Authorization of hybrid veterinary medicinal products, by mutual recognition procedure and proposed by subsequent recognition procedure with Romania acting as reference member state.	22669
	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, in case of food producing animals	1411
	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, in case of animals not intended for human consumption	996
267	Authorization of hybrid veterinary medicinal products, by mutual recognition procedure and proposed by subsequent recognition procedure with Romania acting as member state concerned.	18185
	a) Authorization of hybrid veterinary medicinal products, by mutual recognition procedure and proposed by subsequent recognition procedure, with Romania acting as member state concerned, for each other target species/way of administration, in case of food producing animals	1411
	b) Authorization of hybrid veterinary medicinal products, by mutual recognition procedure and proposed by subsequent recognition procedure, with Romania acting as member state concerned, for each other target species/way of administration, in case of animals not intended for human consumption	996
268	Authorization of veterinary medicinal products containing a known active substance, by mutual recognition procedure, with Romania acting as reference member state.	31803
	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, in case of food producing species.	1411
	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, in case of animals not intended for human consumption	996
269	Authorization of veterinary medicinal products containing a known active substance, by mutual recognition procedure, with Romania acting as member state concerned.	23998

No.	Type of authorization	Fee/Rate (lei)
	a) Authorization of veterinary medicinal products containing a known active substance, by mutual recognition procedure, with Romania acting as member state concerned, for each target species/way of administration, in case of food producing species.	1411
	b) Authorization of veterinary medicinal products containing a known active substance, by mutual recognition procedure, with Romania acting as member state concerned, for each target species/way of administration, in case of animals not intended for human consumption	996
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.	22669
	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, in case of food producing species.	1411
	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	996
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 member state concerned.	18143
	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 member state concerned, for each target species/way of administration, in case of food producing species.	1411
	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 member state concerned, for each target species/way of administration, for animals not intended for human consumption.	996
272	Authorization of veterinary medicinal products containing a known active substance, by decentralized procedure, with Romania acting as reference member state.	40936
	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, in case of food producing species.	1411

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.	996
273	Authorization of veterinary medicinal products containing a known active substance, by decentralized procedure, with Romania acting as member state concerned.	28315
	a) Authorization of veterinary medicinal products containing a known active substance, by decentralized procedure, with Romania acting as member state concerned, for each target species/way of administration, in case of food producing species.	1411
	b) Authorization of veterinary medicinal products containing a known active substance, by decentralized procedure, with Romania acting as member state concerned, for each target species/way of administration, in case of animals not intended for human consumption	996
274	Authorization of veterinary medicinal products by informed consent, by mutual recognition procedure, with Romania acting as reference member state	31803
275	Authorization of veterinary medicinal products by informed consent, by mutual recognition procedure, with Romania acting as member state concerned.	23998
276	Authorization of veterinary medicinal products by informed consent, by decentralized procedure, with Romania acting as reference member state	35954
277	Authorization of veterinary medicinal products by informed consent, by decentralized procedure, with Romania acting as member state concerned.	22752
278	Authorization of veterinary medicinal products by informed consent, by mutual recognition procedure and proposed by subsequent recognition procedure, with Romania acting as reference member state.	22669
279	Authorization of veterinary medicinal products by informed consent, by mutual recognition procedure and proposed by subsequent recognition procedure, with Romania acting as member state concerned.	18185
280	Authorization of veterinary medicinal products by multiple applications - <duplicate>, by mutual recognition procedure, with Romania acting as reference member state	25990
281	Authorization of veterinary medicinal products by multiple applications - <duplicate>, by mutual recognition procedure, with Romania acting as member state concerned.	16525
282	Authorization of veterinary medicinal products by multiple applications - <duplicate>, by decentralized procedure, with Romania acting as reference member state	22918
283	Authorization of veterinary medicinal products by multiple applications - <duplicate>, by decentralized procedure, with Romania acting as member state concerned.	19431

No.	Type of authorization	Fee/Rate (lei)
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	22669
285	Authorization of veterinary medicinal products by multiple applications - <duplicate>, by mutual recognition procedure and proposed by subsequent recognition procedure, with Romania acting as member state concerned.	18185
286	Authorization of similar biological medicinal products, by mutual recognition procedure, with Romania acting as member state concerned.	23998
287	Authorization of similar biological medicinal products, by mutual recognition procedure, with Romania acting as reference member state	31803
288	Authorization of similar biological medicinal products, by decentralized procedure, with Romania acting as reference member state	40936
289	Authorization of similar biological medicinal products, by decentralized procedure, with Romania acting as member state concerned.	28315
290	Authorization of similar biological medicinal products by mutual recognition procedure and proposed by subsequent recognition procedure, with Romania acting as reference member state	22669
291	Authorization of similar biological medicinal products by mutual recognition procedure and proposed by subsequent recognition procedure, with Romania acting as member state concerned.	18185
292	Authorization of veterinary medicinal products containing a known active substance, by national procedure	15570
	a) Authorization of veterinary medicinal products containing a known active substance, by national procedure, for each target species/way of administration, in case of food producing species.	1411
	b) Authorization of veterinary medicinal products containing a known active substance, by national procedure, for each target species/way of administration, in case of animals not intended for human consumption	996
293	Authorization of veterinary medicinal products based on bibliographic data, by national procedure.	15570
	a) Authorization of veterinary medicinal products based on bibliographic data, for each other target species/way of administration, for food producing species, by national procedure	1411
	b) Authorization of veterinary medicinal products based on bibliographic data, for each other target species/way of administration, for species not intended for human consumption, by national procedure	996
294	Authorization of generic veterinary medicinal products, by national procedure.	11668
295	Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination) by national procedure.	18891

No.	Type of authorization	Fee/Rate (lei)
	a) Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination) for each target species/way of administration, in case of food producing species, by national procedure.	1411
	b) Authorization of veterinary medicinal products resulting from a new association of known substances (fixed combination), for each target species/way of administration, in case of animals not intended for human consumption, by national procedure	996
296	Authorization of hybrid veterinary medicinal products, by national procedure.	15570
	a) Authorization of hybrid veterinary medicinal products for each target species/way of administration, in case of food producing species, by national procedure	1411
	b) Authorization of hybrid veterinary medicinal products for each target species/way of administration, in case of animals not intended for human consumption, by national procedure	996
297	Authorization of veterinary medicinal products by informed consent, by national procedure.	15570
298	Authorization of homeopathic veterinary medicinal products with therapeutic indications, by national procedure.	15570
299	Authorization of veterinary medicinal products by parallel trade.	3365
300	Limited marketing authorization for veterinary medicinal products	6770
301	Marketing notification for veterinary medicinal products	2829
302	Authorization of similar biological medicinal products, by national procedure	15570
303	Authorization of veterinary medicinal products by multiple applications - "duplicate", by national procedure	14988
304	Registration of homeopathic veterinary medicinal products	3057
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, reduced timetable, administrative changes, by national procedure	653

No.	Type of authorization	Fee/Rate (lei)
307	Variation requiring assessment, reduced timetable, administrative changes, by MRP/DCP/Subsequent recognition procedure, with Romania acting as member state concerned.	690
308	Variation requiring assessment, reduced timetable, administrative changes, by MRP/DCP/Subsequent recognition procedure, with Romania acting as reference member state.	918
309	Variation requiring assessment, reduced timetable, changes concerning quality, safety, efficacy and pharmacovigilance, by national procedure.	1488
310	Variation requiring assessment, reduced timetable, changes concerning quality, safety, efficacy and pharmacovigilance, by MRP/DCP/Subsequent recognition procedure, with Romania acting as member state concerned.	1602
311	Variation requiring assessment, reduced timetable, changes concerning quality, safety, efficacy and pharmacovigilance, by MRP/DCP/Subsequent recognition procedure, with Romania acting as reference member state.	2058
312	Variation requiring assessment, standard timetable, changes concerning quality, safety, efficacy and pharmacovigilance, by national procedure.	3767
313	Variation requiring assessment, standard timetable, changes concerning quality, safety, efficacy and pharmacovigilance, by MRP/DCP/Subsequent recognition procedure, with Romania acting as member state concerned.	3881
314	Variation requiring assessment, standard timetable, changes concerning quality, safety, efficacy and pharmacovigilance, by MRP/DCP/Subsequent recognition procedure, with Romania acting as reference member state.	4109
315	Variation requiring assessment, extended timetable, changes concerning quality, safety, efficacy and pharmacovigilance, by national procedure.	5666
316	Variation requiring assessment, extended timetable, changes concerning quality, safety, efficacy and pharmacovigilance, by MRP/DCP/Subsequent recognition procedure, with Romania acting as member state concerned.	5780
317	Variation requiring assessment, extended timetable, changes concerning quality, safety, efficacy and pharmacovigilance, by MRP/DCP/Subsequent recognition procedure, with Romania acting as reference member state.	6008
318	Variation requiring assessment, extended timetable, changes concerning active substance, concentration, pharmaceutical form, way of administration, food producing target species, by national procedure.	10437
319	Variation requiring assessment, extended timetable, changes concerning active substance, concentration, pharmaceutical form, way of administration, food producing target species, by MRP/DCP/Subsequent recognition procedure, with Romania acting as member state concerned.	10551

No.	Type of authorization	Fee/Rate (lei)
320	Variation requiring assessment, extended timetable, changes concerning active substance, concentration, pharmaceutical form, way of administration, food producing target species, by MRP/DCP/Subsequent recognition procedure, with Romania acting as reference member state.	10778
321	Emission of a duplicate of the marketing authorization, by national procedure	253
322	Approval of advertising material for veterinary medicinal products	1426
323	Specialized consultancy in the field of veterinary medicinal products /hour	180
324	Consolidated notification for the completion of the technical documentations for the products in course of authorization, by national procedure*****	1355
325	Annual tariff for maintaining on the market of the marketing authorization for veterinary medicinal products	344
326	Transfer of the marketing authorization	5605

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

4. At Annex 1, letter C, after the footnote***) a new footnote is added, the footnote *****), with the following content:**

„*****) calculation formulas for technical grouping of VNRA:

Full fee 1 (T1)	Reduced fee a) (T2)	SPC/P/E fee b) (T3)
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Example 1 [2 Products (P1, P2) - 4 VNRA codes (C1, C2, C3, C4)]: $T1 * 4 + T2 * 4$

Example 2 [1 Product (P1) - 4 VNRA codes (C1, C2, C3, C4)]: $T1 * 4$

Example 3 [10 Products (P1, P2....P10) - 1 VNRA code (C1)]: $T1 + T2 * 9$

Example 4 [10 Products (P1, P2....P10) - 2 VNRA codes (C1, C2)]: $T1 * 2 + 18 * T2$

Example 5 [2 Products (P1, P2) - 4 VNRA codes (C1, C2 and C3, C4 implies change of SPC/P/E)]: $T1 * 4 + T2 * 4 + T3 * 2$

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

5. At Annex 1, letter C, section “Notes” changes and will have the following content:

“NOTE:

- 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,
- 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,
- in case of variations requiring assessment or grouping variations requiring assessment, requested by worksharing 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.”