

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:	41017
	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	1688
	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.	1191
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:	33668
	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	1688
	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	1191
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:	31085
	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	1688
	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	1191
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:	22744

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	1688
	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	1191
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:	53928
	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	1688
	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	1191
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:	38832
	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	1688
	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	1191
250	Authorization of veterinary medicinal products with well-established use, by mutual recognition procedure, with Romania acting as reference member state, to which are added, as appropriate:	38039
	a) Authorization of veterinary medicinal products with well-established use by mutual recognition procedure, with Romania acting as reference member state for each other target species/way of administration, for food producing animals	1688
	b) Authorization of veterinary medicinal products with well-established use, 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	1191

No.	Type of authorization	Fee/Rate (lei)
251	Authorization of veterinary medicinal products with well-established use, by mutual recognition procedure, with Romania acting as concerned member state, to which are added, as appropriate:	28703
	a) Authorization of veterinary medicinal products with well-established use data by mutual recognition procedure, with Romania acting as concerned member state for each other target species/way of administration, for food producing animals	1688
	b) Authorization of veterinary medicinal products with well-established use, 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	1191
252	Authorization of veterinary medicinal products with well-established use a, by mutual recognition procedure and proposed by “subsequent recognition” procedure, with Romania acting as reference member state, to which are added, as appropriate:	27113
	a) Authorization of veterinary medicinal products with well-established use, 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	1688
	b) Authorization of veterinary medicinal products with well-established use, 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	1191
253	Authorization of veterinary medicinal products with well-established use, by mutual recognition procedure and proposed by “subsequent recognition” procedure, with Romania acting as concerned member state, to which are added, as appropriate:	21750
	a) Authorization of veterinary medicinal products with well-established use, 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	1688
	b) Authorization of veterinary medicinal products with well-established use, 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	1191
254	Authorization of veterinary medicinal products with well-established use, by decentralized procedure, with Romania acting as reference member state, to which are added, as appropriate:	48962
	a) Authorization of veterinary medicinal products with well-established use, by decentralized procedure, with Romania acting as reference member state for each other target species/way of administration, for food producing animals	1688
	b) Authorization of veterinary medicinal products with well-established use, 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	1191

No.	Type of authorization	Fee/Rate (lei)
255	Authorization of veterinary medicinal products with well-established use, by decentralized procedure, with Romania acting as concerned member state, to which are added, as appropriate:	33866
	a) Authorization of veterinary medicinal products with well-established use, by decentralized procedure, with Romania acting as concerned member state for each other target species/way of administration, for food producing animals	1688
	b) Authorization of veterinary medicinal products with well-established use, 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	1191
256	Authorization of generic veterinary medicinal products, by mutual recognition procedure, with Romania acting as reference member state	31085
257	Authorization of generic veterinary medicinal products, by mutual recognition procedure, with Romania acting as concerned member state	22744
258	Authorization of generic veterinary medicinal products, by mutual recognition procedure and proposed by “subsequent recognition” procedure, with Romania acting as reference member state	24135
259	Authorization of generic veterinary medicinal products, by mutual recognition procedure and proposed by “subsequent recognition” procedure, with Romania acting as concerned member state	19765
260	Authorization of generic veterinary medicinal products, by decentralized procedure, with Romania acting as reference member state	42507
261	Authorization of generic veterinary medicinal products, by decentralized procedure, with Romania acting as concerned member state	30689
262	Authorization of hybrid veterinary medicinal products, by decentralized procedure, with Romania acting as reference member state, to which are added, as appropriate:	43003
	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	1688
	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	1191
263	Authorization of hybrid veterinary medicinal products, by decentralized procedure, with Romania acting as concerned member state, to which are added, as appropriate:	33866
	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	1688
	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	1191
264	Authorization of hybrid veterinary medicinal products, by mutual recognition procedure, with Romania acting as reference member state, to which are added, as appropriate:	38039

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	1688
	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	1191
265	Authorization of hybrid veterinary medicinal products, by mutual recognition procedure, with Romania acting as concerned member state, to which are added, as appropriate:	28703
	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	1688
	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	1191
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:	27113
	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	1688
	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	1191
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	21750
	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	1688
	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	1191
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:	38039
	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	1688

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	1191
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:	28703
	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	1688
	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	1191
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:	27113
	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	1688
	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	1191
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:	21700
	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	1688
	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	1191
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:	48962
	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	1688

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	1191
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:	33866
	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	1688
	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	1191
274	Authorization of veterinary medicinal products by "informed consent", by mutual recognition procedure, with Romania acting as reference member state	38039
275	Authorization of veterinary medicinal products by "informed consent", by mutual recognition procedure, with Romania acting as concerned member state	28703
276	Authorization of veterinary medicinal products by "informed consent", by decentralized procedure, with Romania acting as reference member state	43003
277	Authorization of veterinary medicinal products by "informed consent", by decentralized procedure, with Romania acting as concerned member state	27212
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	27113
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	21750
280	Authorization of veterinary medicinal products by multiple applications - "duplicate", by mutual recognition procedure, with Romania acting as reference member state	31085
281	Authorization of veterinary medicinal products by multiple applications - "duplicate", by mutual recognition procedure, with Romania acting as concerned member state	19765
282	Authorization of veterinary medicinal products by multiple applications - "duplicate", by decentralized procedure, with Romania acting as reference member state	27412
283	Authorization of veterinary medicinal products by multiple applications - "duplicate", by decentralized procedure, with Romania acting as concerned member state	21131
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	27113
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	21750

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	28703
287	Authorization of similar biological veterinary medicinal products, by mutual recognition procedure, with Romania acting as reference member state	38039
288	Authorization of similar biological veterinary medicinal products, by decentralized procedure, with Romania acting as reference member state	48962
289	Authorization of similar biological veterinary medicinal products, by decentralized procedure, with Romania acting as concerned member state	33866
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	27113
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	21750
292	Authorization of veterinary medicinal products with known active substance, by national procedure, to which are added, as appropriate:	18623
	a) Authorization of veterinary medicinal products with known active substance, for each target species/way of administration, for food producing animals	1688
	b) Authorization of veterinary medicinal products with known active substance, for each target species/way of administration, for animals not intended for human consumption	1191
293	Authorization of veterinary medicinal products based on bibliographic data, by national procedure, to which are added, as appropriate:	18623
	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	1688
	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	1191
294	Authorization of generic veterinary medicinal products, by national procedure	13956
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:	22596
	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	1688
	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	1191
296	Authorization of hybrid veterinary medicinal products, by national procedure, to which are added, as appropriate:	18623
	a) Authorization of hybrid veterinary medicinal products, for each target species/way of administration, for food producing animals, by national procedure	1688

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	1191
297	National authorization of veterinary medicinal products by "informed consent"	18623
298	Authorization of homeopathic veterinary medicinal products with therapeutic indications, by national procedure	18623
299	Authorization of veterinary medicinal products by parallel trade, simplified procedure	4025
300	Limited marketing authorization for veterinary medicinal products	7352
301	Marketing notification for veterinary medicinal products	3383
302	Authorization of similar veterinary biological medicinal products, by national procedure	18623
303	Authorization of veterinary medicinal products by multiple applications - "duplicate", by national procedure	17927
304	Registration of homeopathic veterinary medicinal products	3467
305	1. Variations not requiring assessment (VNRA) by national procedure (T1), to which is added, where applicable*****):	306
	a) Technical grouping of VNRA having the same code for more than 1 product (T2)	121
	b) To change the summary of product characteristics, package leaflet and label (SPC/P/E) of the product (T3)	633
	2. Variations not requiring assessment (VNRA) by community procedures, with Romania acting as concerned member state (T1), to which is added, where applicable*****):	158
	a) Technical grouping of VNRA having the same code for more than 1 product (T2)	113
	b) To change the summary of product characteristics, package leaflet and label (SPC/P/E) of the product (T3)	951
	3. Variations not requiring assessment (VNRA) by community procedures, with Romania acting as reference member state (T1), to which is added, where applicable*****):	784
	a) Technical grouping of VNRA having the same code for more than 1 product (T2)	424
	b) To change the summary of product characteristics, package leaflet and label (SPC/P/E) of the product (T3)	1356
306	Variation requiring assessment by national procedures, reduced timetable, administrative changes	782
307	Variation requiring assessment by mutual/decentralized/subsequent recognition procedures, with Romania as concerned member state, reduced timetable, administrative changes	825
308	Variation requiring assessment by mutual/decentralized/subsequent recognition procedures, with Romania as reference member state, reduced timetable, administrative changes	1098
309	Variation requiring assessment by national procedure, reduced timetable, related to quality, safety, efficacy, pharmacovigilance changes	1779

No.	Type of authorization	Fee/Rate (lei)
310	Variation requiring assessment by mutual/decentralized/subsequent recognition procedures, with Romania as concerned member state, reduced timetable related to quality, safety, efficacy, pharmacovigilance changes	1915
311	Variation requiring assessment by mutual/decentralized/subsequent recognition procedures, with Romania as reference member state, reduced timetable, related to quality, safety, efficacy, pharmacovigilance changes	2462
312	Variation requiring assessment by national procedure, standard timetable, related to quality, safety, efficacy, pharmacovigilance changes	4506
313	Variation requiring assessment by mutual/decentralized/subsequent recognition procedures, with Romania as concerned member state, standard timetable, related to quality, safety, efficacy, pharmacovigilance changes	4643
314	Variation requiring assessment by mutual/decentralized/subsequent recognition procedures, with Romania as reference member state, standard timetable, related to quality, safety, efficacy, pharmacovigilance changes	4914
315	Variation requiring assessment by national procedure, extended timetable, related to safety, efficacy, pharmacovigilance changes	6776
316	Variation requiring assessment by mutual/decentralized/subsequent recognition procedures, with Romania as concerned member state, extended timetable, related to safety, efficacy, pharmacovigilance changes	6913
317	Variation requiring assessment by mutual/decentralized/subsequent recognition procedures, with Romania as reference member state, extended timetable, related to safety, efficacy, pharmacovigilance changes	7186
318	Variation requiring assessment by national procedure, extended timetable, changes related to active substance, concentration, pharmaceutical form, route of administration, target food-producing species	12483
319	Variation requiring assessment by mutual/decentralized/subsequent recognition procedures, with Romania as concerned member state, extended timetable, changes related to active substance, concentration, pharmaceutical form, route of administration, target food-producing species changes	12619
320	Variation requiring assessment by mutual/decentralized/subsequent recognition procedures, with Romania as reference member state, extended timetables, changes elated to active substance, concentration, pharmaceutical form, route of administration, target food-producing species changes	12892
321	Emission of a duplicate of the marketing authorization, by national procedure	303
322	Approval of advertising material for veterinary medicinal products	1707
323	Consultancy in the field of veterinary medicinal products /hour	215
324	Consolidated notification for the completion of the technical documentations for the products in course of authorization, by national procedure*****	1621
325	Annual fee to maintain on the market the marketing authorization for veterinary medicinal products	411
326	Transfer of the marketing authorization	6705
327	Assessment of technical documentation for nutritional supplements, cosmetics and other veterinary products for notification	925
336	Variation that require urgent assessment, by national procedures	1466

No.	Type of authorization	Fee/Rate (lei)
337	Variation requiring urgent assessment by mutual/decentralized/subsequent recognition procedures, with Romania as concerned member state	1740
338	Variation requiring urgent assessment by mutual/decentralized/subsequent recognition procedures, with Romania as reference member state	2377

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

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

Full fee 1 (T1)	Reduced fee a) (T2)	SPC/P/E fee b) (T3)
-----------------	---------------------	---------------------

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)]: $T1 * 3$.

*****) The price at the time of purchase will be added to the tariff established according to the calculation sheet.

NOTES:

- 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 grouped variations, 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 grouping variations requiring or not 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,
- 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.