ORDER no. 888 of 25 July 2014
on approval of fees payable to the National Agency for Medicines and Medical Devices for services related to medicinal products for human use

ISSUED: THE MINISTRY OF HEALTH

PUBLISHED IN: THE OFFICIAL GAZETTE OF ROMANIA, no. 572 of 31 July 2014

On seeing the report for approval No. NB 5.816/2014 of the Medicinal Product and Medical Device Policy Directorate and Notification no. 50.401E of 2 July 2014, registered at the Ministry of Health no. 40.224 of 2 July 2014,

taking into account provisions of:

- Article 857 of Law 95/2006 on healthcare reform, as amended,
- Article 10 d) of Government Decision no. 734/2010 on the organisation and operation of the National Agency for Medicines and Medical Devices, as amended,
- Article 7 (4) of Government Decision no. 144/2010 on the organisation and operation of the Ministry of Health, as amended,

the Minister of Health hereby issues the following Order:

ARTICLE 1

Fees payable to the National Agency for Medicines and Medical Devices for services related to medicinal products for human use are hereby approved, according to the Annex, which is integral part of this Order.

ARTICLE 2

(1) Fees payable according to the Annex by Romanian applicants for services provided by the National Agency for Medicines and Medical Devices are paid in LEI, as per the exchange rate of the National Bank of Romania on the day of invoice issuance.

(2) Fees payable according to the Annex by foreign applicants for services provided by the National Agency for Medicines and Medical Devices are paid in either foreign currency, or its equivalent in LEI, as per the exchange rate of the National Bank of Romania on the day of invoice issuance.

ARTICLE 3

In case of discontinuation of the procedure for marketing authorisation/marketing authorisation renewal/variation approval, the administrative procedure for management of the sums entered into NAMMD accounts is as follows:

a) for notification by applicants on withdrawal of the application for marketing authorisation/marketing authorisation renewal after payment of the fee for marketing authorisation/marketing authorisation renewal procedure, the fee for marketing authorisation/marketing authorisation renewal paid by applicants in

accordance with provisions of Article 854 of Law 95/2006 on healthcare reform, as amended, on submission of applications for marketing authorisation/marketing authorisation renewal shall be transferred by the National Agency for Medicines and Medical Devices to the state budget;

b) for notification by applicants on withdrawal of the application for marketing authorisation/marketing authorisation renewal after payment of the fee for marketing authorisation/marketing authorisation renewal procedure, the fee for marketing authorisation/marketing authorisation renewal paid by applicants, in accordance with provisions of point III of this Annex shall be managed as follows:

(i) for applications for discontinuation of the marketing authorisation/ marketing authorisation renewal procedure submitted prior to validation of the application for marketing authorisation/marketing authorisation renewal, upon request, the respective fee may be returned/redirected to cover a different fee due by the same applicant to the National Agency for Medicines and Medical Devices;

(ii) for applications for discontinuation of the marketing authorisation/ marketing authorisation renewal procedure submitted after validation of the application for marketing authorisation/marketing authorisation renewal, but prior to start of the procedure (for the mutual recognition/decentralised procedure) or, for the national procedure, respectively, no later than 90 calendar days as of actual fee payment, upon applicant's request, 90% of the fee may be returned/redirected to cover a different fee due by the same applicant to the National Agency for Medicines and Medical Devices;

(iii) for applications for discontinuation of the marketing authorisation/ marketing authorisation renewal procedure submitted after start of the procedure (for the mutual recognition/decentralised procedure) or, for the national procedure, respectively, no later than 90 calendar days as of actual fee payment, the fee paid is to be retained by the National Agency for Medicines and Medical Devices and may no longer be returned;

c) for notifications of withdrawal by the applicant of the application for approval of a variation after actual payment of the fee for conduct of the procedure for approval of the variation and after validation of the application for variation approval, but prior to NAMMD request for additional information, upon request, 90% of the fee may be returned/ redirected to cover a different fee due by the same applicant to the National Agency for Medicines and Medical Devices;

d) for notifications of withdrawal by the applicant of the application for approval of a variation after actual payment of the fee for conduct of the procedure for approval of the variation and after NAMMD request for additional information, the fee paid shall be retained by the National Agency for Medicines and Medical Devices and may no longer be returned.

ARTICLE 4

The administrative procedure for the management of fees paid into the NAMMD account for discontinuation of the procedure for assessment, authorisation and amendment of is as follows:

a) for notifications of withdrawal by the applicant of the application for authorisation of a clinical trial with a medicinal product for human use after payment of the fee for conduct of the procedure for authorisation of a clinical trial, the fee for authorisation of the clinical trial paid by applicants in accordance with provisions of point III of the Annex shall be managed as follows:

(i) for applications for discontinuation of the procedure for authorisation of a clinical trial with a medicinal product for human use submitted prior to validation of the application, upon request, the respective fee may be returned/redirected to cover a different fee due by the same applicant to the National Agency for Medicines and Medical Devices;

(ii) for applications for discontinuation of the procedure for authorisation of a clinical trial with a medicinal product for human use submitted after validation of the application for authorisation, but no later than 25 calendar days after start of the procedure, upon applicant's request, 90% of the fee may be returned/redirected to cover a different fee due by the same applicant to the National Agency for Medicines and Medical Devices;

(iii) for applications for discontinuation of the procedure for authorisation of a clinical trial with a medicinal product for human use submitted after day 25 as of start of the procedure, the fee paid shall be retained by the National Agency for Medicines and Medical Devices and may no longer be returned;

b) for applications for authorisation of a clinical trial with a medicinal product for human use rejected after the validation procedure, upon applicant's request, 90% of the fee may be returned/ redirected to cover a different fee due by the same applicant to the National Agency for Medicines and Medical Devices;

c) for notifications of withdrawal of the application for approval of a substantial amendment to a clinical trial with a medicinal product for human use after actual payment of the fee for conduct of the procedure for approval of the clinical trial amendment, the fee for assessment of the clinical trial amendment paid in accordance with provisions of point III of the Annex shall be managed as follows:

(i) for applications for discontinuation of procedure for approval of the clinical trial amendment submitted prior to validation of the application, upon request, the respective fee may be returned/redirected to cover a different fee due by the same applicant to the National Agency for Medicines and Medical Devices;

(ii for applications for discontinuation of procedure for approval of the clinical trial amendment submitted after validation of the application, but no later than 15 calendar days after start of the procedure, upon applicant's request, 90% of the fee may be returned/redirected to cover a different fee due by the same applicant to the National Agency for Medicines and Medical Devices;

(iii) for applications for discontinuation of the authorisation procedure submitted after 15 days after start of the procedure, the fee paid shall be retained by the National Agency for Medicines and Medical Devices and may no longer be returned;

d) for applications for approval of a substantial amendment to a clinical trial rejected after the validation procedure, upon applicant's request, 90% of the fee may be returned/redirected to cover a different fee due by the same applicant to the National Agency for Medicines and Medical Devices.

ARTICLE 5

On this Order coming into force, Order of the Minister of Health no. 716/2009 on approval of fees payable to the National Agency for Medicines and Medical Devices and of the fee for maintenance of marketing authorisation, published in the Official Gazette of Romania, Part I, no. 422 of 19 June 2009, as amended, is repealed.

ARTICLE 6

This Order is published in the Official Gazette of Romania, Part I.

On behalf of the Minister of Health,
Francisk Iulian Chiriac,
Secretary of State

Bucharest, 25 July 2014.
No. 888.

ANNEX 1

FEES
payable to the National Agency for Medicines and Medical Devices for services related to medicinal products for human use

I. Laboratory control of non-biological and biological medicinal products for human use and related activities

No.	Activity	Fee Euro
0	1	2
A.	Physico-chemical control	
1.	Liquid clarity and opalescence	30
2.	Concentration of aqueous/organic solvent-containing solutions for extraction through rotavapor distillation	50
3.	Alcoholic concentration of pharmaceutical preparations	47
4.	Control of macroscopic impurities in solutions for injection and infusion in vials and bottles/powders for injection and lyophilised medicinal products	11
5.	Control of limits of inorganic impurities and foreign organic substances	52
6.	Microscope control of size and shape of particles in suspension	12
7.	Micro-chemical/Microscope control of herbal medicinal products	26
8.	Organoleptic control (appearance, colour, taste, smell)	5
9.	De-fattening of herbal medicinal products for dosage purposes	19
10.	Relative density	12
11.	Determination of water, titration with Karl-Fischer reagent (calibration included)	54
12.	Chromatographic column determination	142
13.	Determination of apparent density in powders	14
14.	Determination of tablet size (thickness, diameter, length, width)	7
15.	Determination of tablet friability	12
16.	Granulometric determination in powders	14
17.	Determination of acidity, alkalinity limit	14
18.	Determination of number of doses per spray vials	11
19.	Determination of osmolality	13
20.	Determination of homogeneity in ointments, suppositories	6
21.	pH determination	20
22.	Determination of kinetic profile of active substance release from oral solid pharmaceutical forms with prolonged release	173
23.	Determination of purity of medicinal products for human use through high-performance liquid chromatography	323
24.	Determination of suppository resistance	22
25.	Determination of total fats	25
26.	Determination of dissolution time in lyophilised products	12
27.	Determination of emulsion type	12
28.	Determination of volatile oils from herbal medicinal products	10

29.	Determination of viscosity by ball/rotational/capillary viscosimeter	39
30.	Determination of sedimentation rate	16
31.	Suppository and ovule desegregation	33
32.	Desegregation of effervescent/gastro-soluble medicinal products	12
33.	Entero-soluble product desegregation	39
34.	Sample destruction for determination of inorganic impurity limits	24
35.	Physico-chemical determination in aquaeous environment/ acids in non-aquaeous environment/alkali in non-aquaeous environment	55
36.	Gas chromatographic dosage	209
37.	Gas chromatographic coupled with Head-Speace dosage	470
38.	Dosage through atomic absorption spectrophotometry	120
39.	Potentiometric dosage	75
40.	Dosage through high performance liquid chromatography	326
41.	Nitrogen determination in organic combinations	32
42.	Oxygen dosage	34
43.	Spectrophotometric identification in UV, visible or fluorimetric – in alcohol solution/in organic solvents/in aqueous solution	117
44.	Dosage of soluble substances in herbal medicinal products	20
45.	Dosage of tannins in herbal medicinal products	79
46.	Tightness of spray vials/of sachets with effervescent powder	12
47.	Extraction of active principles from pharmaceutical products/ herbal medicinal products for identification or dosage purposes	79
48.	Imbuement factor of herbal medicinal products	13
49.	Filtration through 0.30-0.50 µm porosity membrane filters	15
50.	Performance of the spraying system (spray)	14
51.	Identification through thin layer chromatography	38
52.	Identification through various chemical reactions: dinytrogenation/coupling/oxide-reduction/other types/anion identification/cation identification	22
53.	Identification and purity through gas-chromatography	200
54.	Spectrophotometric identification in I.R.	15
55.	Spectrophotometric identification in UV and visible in alcohol solution/in aqueous solution/in organic solvents	78
56.	Acetyl/Acidity/Bitterness/Ester/Hydroxyl Iodine/peroxide index	35
57.	Refraction index	19
58.	Saponification index	26
59.	Total weight per recipient (solutions, suspensions, emulsions, ointments)	17
60.	Loss through etuve or exsiccator drying	21
61.	Boiling point/Dropping point/Melting point for capillaries/ Melting point for suppositories	14
62.	Purity through thin layer chromatography	79
63.	Rotatory power	26
64.	Insoluble residue in chlorhydric acid 100 g/l/through calcination/through evaporation	34
65.	Hardmeter-determined tablet-resistance	6
66.	Solubility	20
67.	Non-saponifiable substances	60
68.	Water- or acid- soluble substances	17
69.	Dissolution test	85

70.	Content uniformity	35
71.	Unidose forms/Powder for injection mass uniformity	20
72.	Volume uniformity per vial, bottle	10

B.	Microbiological control	
73.	Microbiological activity of antibiotics-turbidimetric method	184
74.	Microbiological activity of antibiotics and vitamin - diffusion method	200
75.	Microbiological activity of vitamins-turbidimetric method	235
76.	Microbial contamination-direct seeding method	233
77.	Microbial contamination-membrane filtration method	287
78.	Efficacy control of antimicrobial preservatives	331
79.	Control of antibiotics sterility through the "Steritest" method of closed system membrane filtration	300
80.	Control of antibiotics sterility through the open system membrane filtration method (Millipore)	331
81.	Control of sterility of aqueous solutions and soluble powders through the "Steritest" method of closed system membrane filtration	264
82.	Control of sterility of aqueous solutions and soluble powders through the open system membrane filtration method(Millipore)	243
83.	Control of sterility of aqueous solutions and oily solutions in volumes up to 4 ml/4 ml and 10 ml/10 ml and40 ml of powders, ointments and creams through the direct seeding method	184
84.	Control of sterility of solutions for infusion or medicinal products with antimicrobial activity through the direct seeding method	204
85.	Control of sterility of oils and oily solutions, ointments and creams through the "Steritest" method of closed system membrane filtration	283
86.	Control of sterility of oils and oily solutions, ointments and creams through the open system membrane filtration method (Millipore)	261
87.	Determination of bactericide and fungicide activity of antiseptics and disinfectants	402
88.	Exposure of enterobacteria and certain other gram- negative bacteria	131
89.	Exposure of Clostridium/Salmonella/Escherichia Coli/ Pseudomonas aeruginosa/Staphylococcus aureus genre micro-organisms	151

C.	Pharmaco-toxicological control*)	
90.	Antigenicity control at 21 days	435
91.	Control of endotoxin content through the Kinetic Chromogenic/turbidimetric/gel-clot (L.A.L. test) method	491
92.	Control of pyrogenic impurities	496
93.	Control of pyrogenic impurities in 6 rabbits	929
94.	Control of local tolerance through intramuscular injection in rabbits	757
95.	Control of toxicity in 3 rabbits	375
96.	Determination of systemic toxicity in subacute experiments with anatomo-pathologic examination	1,876
97.	Local ocular tolerance in rabbits	547

D.	Radiopharmaceutical control	
98.	Radioactivity measurement	29

99.	Determination of radiochemical purity	91
100.	Determination of radionuclide purity	117

E.	Immunogenicity and pathological anatomy control	
101.	Control of specific activity (in vivo antigenic titre- U.B.) in 7 mice	152
102.	Control of in vivo immunogenicity in 12 guinea pigs	793
103.	Control of in vivo immunogenicity in 22 guinea pigs	1,266
104.	Non-pathogenicity control	347
105.	Control of in vivo innocuity in 5 mice and 2 guinea pigs	227
106.	Control of in vivo innocuity in 5 mice	98
107.	Control of in vivo specific toxicity in 5 guinea pigs	502

F.	Biological product control**)	
108.	Control of purity (blade) Gram smear	36
109.	Control of purity through seeding (tube testing)	83
110.	Control of in vitro specific activity (viral titre determination in monovalent vaccine: measles/mumps/rubella	255
111.	Control of in vitro specific activity-viral titre determination, polio vaccine	518
112.	Control of specific activity through double diffusion	163
113.	Control of concentration (nefelometry)	31
114.	Control of identity (blade) Ziel-Nielsen smear	42
115.	Control of identity and/or specific activity by counter-immunoelectrophoresis	215
116.	Control of identity and/or specific activity by immuno-electrophoresis	219
117.	Control of identity and/or titre through in tube agglutination	36
118.	Control of identity and/or titre through on-plate agglutination	29
119.	Control of purity through seeding (on plate)	69
120.	Control of protein purity through electrophoresis by Agarosa-Sebia gel	208
121.	Control of protein concentration through the biuret method	60
122.	Control of protein concentration through the Lowry method	121
123.	Control of aluminium content through the complexometric	107
124.	Determination of phenol content	116
125.	Control of free formaldehyde content	60
126.	Control of Thyomersal content	95
127.	Calibration curve for protein concentration (biuret method)	62
128.	Calibration curve for determination of phenol content	114
129.	Calibration curve for determination of Thyomersal content (dosage)	96
130.	Calibration curve for determination of protein concentration in influenza vaccine	179
131.	Calibration curve for determination of free formaldehyde content	64
132.	Determination of Na, K and Cl ionic concentration with AVL List analyzer	32
133.	Determination of haemaglutinin and ovalbumine identity and/or concentration through simple radial immunodiffusion IDRS in purified and inactivated influenza trivalent vaccine	177
134.	Determination of identity through the Ouchterlony radial double immunodiffusion method in vaccines	144
135.	Determination of protein concentration through the Bradford method	132

136.	Determination of vaccine potency through the ELISA method of antibody measurement in serum (on mice)	458
137.	Determination of vaccine potency through the ELISA method of antibody measurement in serum (on guinea pigs)	458
138.	Determination through seeding on solids for BCG products (identity, number of viable units, thermal stability, average survival rate)	337
139.	Identification/titre in anti A and anti B haemaglutinine (indirect method)	101

140.	Ph. Eur calibration curve for determination of free formaldehyde content	66
141.	Ph. Eur. free formaldehyde content control	64

*) The remaining specific materials are to be provided by the beneficiary (reference substance, international standard and certain calibrators).
**) The remaining specific materials are to be provided by the beneficiary (reference substance, immuno-plates, Cormay gel prot 100 kit).

II. Various inspections and related activities

No.	Activity	Fee*) -Euro-	Invar. compon.**)	Var. compon.***)
0	1	2	3	4
1.	Inspection for grant of Manufacturing authorisation to manufacturers of medicinal products for human use/ investigational medicinal products/raw materials in Romania (for sterile medicinal product manufacturing)	1,742	1,496	246
2.	Inspection for grant of Manufacturing authorisation to manufacturers of medicinal products for human use/ investigational medicinal products/raw materials in Romania (for non-sterile medicinal product manufacturing)	1,561	1,358	203
3.	Inspection for follow up of correction of noncompliances found on inspection for grant of the (total or partial) manufacturing authorisation to manufacturers of medicinal products for human use/investigational medicinal products/raw materials in Romania	1,348	1,348	-
4.	Inspection for grant of importing authorisation to importers of medicinal products for human use/ investigational medicinal products/ raw materials	778	778	-
5.	Inspection to medicinal product/ investigational medicinal product importers for check of release by the Qualified Person of medicinal product batches imported from third countries	360	360	-
6.	Inspection for grant of manufacturing authorisation to importers of medicinal products for human use/investigational medicinal products/raw materials conducting certain manufacturing operations (e.g. division, labelling, packaging, re-	863	863	-

	packaging, other parts of the manufacturing process)			
7.	Inspection for grant of the Good Manufacturing Practice Certificate to third country manufacturers of medicinal products for human use/investigational medicinal products/raw materials for sterile product manufacturing	2,035	981	1,054
8.	Inspection for grant of the Good Manufacturing Practice Certificate to third country manufacturers of medicinal products for human use/investigational medicinal products/raw materials for manufacturing of non-sterile products	1,753	882	871
9.	Inspection prior to grant of Marketing Authorisation	451	451	-
10.	Inspection for check of compliance with Good Clinical Practice Rules on a specialised site	1,046	514	532
11.	Inspection for follow up of correction of inspection finds after check of compliance with Good Clinical Practice Rules	514	514	-
12.	Inspection for authorisation of sites for independent physico-chemical and/or microbiological control/good laboratory practice certification (bioanalytical laboratories in bioequivalence centres/toxicology laboratories)	994	994	-
13.	Inspection for follow-up of correction of inspection finds for authorisation sites for independent control (physico-chemical and/ or microbiological)/good laboratory practice certification (bio-analytical laboratories in bioequivalence centres/toxicology laboratories)	800	800	-
14.	MAH Inspection for check of pharmacovigilance activity	1,117	1,117	-
15.	MAH Inspection for follow-up of correction of inspection finds in pharmacovigilance inspection	659	659	-
16.	Inspection for check of compliance with MAH obligations	400	400	-
17.	Inspection for check of compliance with Good Clinical Practice Rules on a clinical site of a bioequivalence centre	506	506	-
18.	Inspection for grant of wholesale distribution authorisation	750	750	-
19.	Inspection for follow-up of wholesale distributor’s performance	350	350	-
20.	Inspection for grant of wholesale distribution authorisation to brokers conducting sales, procurement and/or export of medicinal products	350	350	-
21.	Issuance of the Good Manufacturing Practice Compliance Certificate	81	81	-
22.	Approval of the Export declaration/ Additional export declaration	20	20	-
23.	Performance of changes, on request, in a document issued by the National Agency for Medicines and Medical Devices (e.g.	136	136	-

	changes to manufacturing/import authorisations and/or of annexes thereof, of authorisation of sites for independent control and/or of annexes thereof, of good laboratory practice certificates) or issuance of document duplicates (document loss/deterioration)			
24.	Issuance of the Qualified Person Certificate	75	75	-
25.	Examination of documentation for exemption from application of legal provisions in force on medicinal product labelling/ packaging as per Order of the Minister of Public Health no. 872/2006 for approval of Norms for grant of exemption for specific medicinal products label and package leaflet from the obligation of wording in Romanian of certain particulars and the leaflet, for products not intended for supply to patient for self-administration	75	75	-
26.	Inspection for certification of legibility tests providers	750	750	-

*) the inspection fee as resulted from summation of the two components (for one manufacturing flow).

**) Referring to general inspection aspects; charged only once, irrespective of the number of manufacturing flows.

⁂) Referring to one manufacturing flow and the calculation of the inspection fee, to be multiplied by the number of manufacturing flows inspected.

NOTE:

Fees do not include travelling expenses (transportation, accommodation, diplomatic visa fees etc.).

According to European legislation, such costs are paid by the beneficiary as far as the extra-community space is concerned.

III. Assessment of documentation for marketing authorisation/marketing authorisation renewal for medicinal products for human use and conduct of other activities

No.	Activity	Fee - Euro -
0	1	2
A.	Assessment of documentation for marketing authorisation/ marketing authorisation renewal through national procedure	
1.	Marketing authorisation through national procedure of medicinal products - full dossier, in accordance with Art. 702(4) of Law 95/2006 on healthcare reform, as amended, or Article 8(3) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use	9,500
1.a)	Marketing authorisation through national procedure of medicinal products - full dossier, in accordance with Art. 702(4) of Law No. 95/2006 on healthcare reform, as	4,750

	amended, or Article 8(3) of Directive 2001/83/EC – different pharmaceutical form, submitted at the same time as the initial application	
1.b)	Marketing authorisation through national procedure of medicinal products - full dossier, in accordance with Art. 702(4) of Law No. 95/2006 on healthcare reform, as amended, or Article 8(3) of Directive 2001/83/EC – the second and following strengths, submitted at the same time as the initial application	2,830
2.	Marketing authorisation through national procedure of generic medicinal products, submitted according to Article 704(1) and (2)of Law 95/2006, as amended, or Article 10 (1) of Directive 2001/83/EC	5,700
2.a)	Marketing authorisation through national procedure of generic medicinal products, submitted according to Article 704(1) and (2) of Law 95/2006, as amended, or Article 10(1) of Directive 2001/83/EC–different pharmaceutical form submitted at the same time as the initial application	2,900
2.b)	Marketing authorisation through national procedure of generic medicinal products, submitted according to Article 704(1) and (2) of Law 95/2006 as amended, or Article 10(1) of Directive 2001/83/EC – the second and following strengths submitted at the same time as the initial application	1,710
3.	Marketing authorisation through national procedure of medicinal products - "hybrid" (mixed) application, submitted according to Article 704(3) of Law No. 95/2006, as amended, or Article 10(3) of Directive 2001/83/EC	6,650
3.a)	Marketing authorisation through national procedure of medicinal products - "hybrid" (mixed) application, submitted according to Article 704(3) of Law No. 95/2006, as amended, or Article 10(3) of Directive 2001/83/EC- different pharmaceutical form, submitted at the same time as the initial application	3,325
3.b)	Marketing authorisation through national procedure of medicinal products - "hybrid" (mixed) application, submitted according to Article 704(3) of Law No. 95/2006, as amended, or Article 10(3) of Directive 2001/83/EC- the second and following strengths, submitted at the same time as the initial application	2,000
4.	Marketing authorisation through national procedure of biosimilar medicinal products, submitted according to Article 704 (4) of Law 95/2006, as amended, or Article 10(4) of Directive 2001/83/EC	6,650
4.a)	Marketing authorisation through national procedure of biosimilar medicinal products, submitted according to Article 704(4) of Law 95/2006, as amended, or Article 10(4) of Directive 2001/83/EC - different pharmaceutical form, submitted at the same time as the initial application	3,325
4.b)	Marketing authorisation through national procedure of biosimilar medicinal products, submitted according to Article 704(4) of Law 95/2006, as amended, or Article 10(4) of Directive 2001/83/EC – the second and following strengths submitted at the same time as the initial application	2,000
5.	Marketing authorisation through national procedure of well- established use medicinal products, submitted according to Article 705 of Law 95/2006, as amended, or	6,650

	Article 10(a), of Directive 2001/83/EC (“bibliographic" application)	
5.a)	Marketing authorisation through national procedure of well- established use medicinal products, submitted according to Article 705 of Law 95/2006, as amended, or Article 10(a) of Directive 2001/83/EC (“bibliographic" application)-different pharmaceutical form, submitted at the same time as the initial application	3,325
5.b)	Marketing authorisation through national procedure of well- established use medicinal products, submitted according to Article 705 of Law 95/2006, as amended, or Article 10(a) of Directive 2001/83/EC (“bibliographic" application) – the second and following strengths, submitted at the same time as the initial application	2,000
6.	Marketing authorisation through national procedure of fixed 8.035 combination medicinal products, submitted according to Art. 706 of Law 95/2006, as amended, or Article 10(b) of Directive 2001/83/EC	8,035
6.a)	Marketing authorisation through national procedure of fixed combination medicinal products, submitted according to Art. 706 of Law 95/2006, as amended, or Article 10(b) of Directive 2001/83/EC – different pharmaceutical form, submitted at the same time as the initial application	4,005
6.b)	Marketing authorisation through national procedure of fixed combination medicinal products, submitted according to Art. 706 of Law 95/2006, as amended, or Article 10(b) of Directive 2001/83/EC - the second and following strengths, submitted at the same time as the initial application	2,450
7.	Marketing authorisation through national procedure of informed consent medicinal products submitted according to Article 707 of Law 95/2006, as amended, or Article 10(c) of Directive 2001/83/EC	2,850
7.a)	Marketing authorisation through national procedure of informed consent medicinal products, submitted according to Article 707 of Law 95/2006, as amended, or Article 10(c) of Directive 2001/83/EC – different pharmaceutical form, submitted at the same time as the initial application	1,425
7.b)	Marketing authorisation through national procedure of informed consent medicinal pro ducts submitted according to Article 707 of Law 95/2006, as amended, or Article 10(c) of Directive 2001/83/EC – the second and following strengths, submitted at the same time as the initial application	900
8.	Marketing authorisation through national procedure of homeopathic medicinal products, submitted according to Art. 710 of Law 95/2006, as amended (marketing authorisation through simplified procedure)	1,920
9.	Marketing authorisation through national procedure of herbal medicinal products, submitted according to Article 714 of Law 95/2006, as amended (marketing authorisation through simplified procedure)	1,920
10.	Marketing authorisation through national procedure of medicinal products, submitted as line extensions of an already authorised medicinal product	4,100
11.	Marketing authorisation renewal through national procedure, according to Article 730(2) of Law 95/2006, as amended, or Article 24(2) of Directive 2001/83/EC	2,400

12.	Marketing authorisation renewal through national procedure of homeopathic medicinal products, submitted according to Article 710 of Law 95/2006, as amended (marketing authorisation through simplified procedure)	970
13.	Marketing authorisation renewal through national procedure of traditional herbal medicinal products according to Art. 714 of Law 95/2006, as amended (marketing authorisation through simplified procedure)	970
B.	Assessment of documentation for marketing authorisation/ marketing authorisation renewal through European procedures	
14.	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – generic medicinal products [Article 10(1) of Directive 2001/83/EC or Article 704 (1) and (2) of Law 95/2006, as amended	8,050
14.a)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – generic medicinal products – different pharmaceutical form, submitted at the same time as the initial application [Article 10(1) of Directive 2001/83/EC or Article 704 (1) and (2) of Law 95/2006, as amended	4,830
14.b)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – generic medicinal products – the second and following strengths, submitted at the same time as the initial application [Article 10(1) of Directive 2001/83/EC or Article 704 (1) and (2) of Law 95/2006, as amended	2,420
15.	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "hybrid" (mixed) application [Article 10(3) of Directive 2001/83/EC or Article 704 (3) of Law 95/2006, as amended	9,200
15.a)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "hybrid" (mixed) application - different pharmaceutical form, submitted at the same time as the initial application [Article 10(3) of Directive 2001/83/EC ARTICLE 704 (3) of Law 95/2006, as amended	5,520
15.b)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "hybrid" (mixed) application - the second and following strengths, submitted at the same time as the initial application [Article 10(3) of Directive 2001/83/EC or Article 704 (3) of Law 95/2006, as amended	2,760
16.	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "biosimilar medicinal product" [Article 10(4) of Directive 2001/83/EC or Article 704(4) of Law 95/2006, as amended]	9,200
16.a)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "biosimilar medicinal product" - different pharmaceutical form, submitted at the same time as the initial application	5,520

	[Article 10(4) of Directive 2001/83/EC or Article 704 (4) of Law 95/2006, as amended]	
16.b)	Marketing authorisation of medicinal products through procedure or decentralised procedure with Romania as Reference Member State - "biosimilar medicinal product" – the second and following strengths, submitted at the same time as the initial application [Article 10(4) of Directive 2001/83/EC or Article 704(4) of Law 95/2006, as amended]	2,760
17.	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "bibliographic" application [Article 10(a) of Directive 2001/83/EC or Art. 705 of Law 95/2006, as amended]	9,200
17.a)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "bibliographic" application - different pharmaceutical form, submitted at the same time as the initial application [Article 10(a) of Directive 2001/83/EC or Article 705 of Law 95/2006, as amended	5,520
17.b)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "bibliographic" application - the second and following strengths, submitted at the same time as the initial application [Article 10(a) of Directive 2001/83/EC or Article 705 of Law 95/2006, as amended]	2,760
18.	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – fixed combination [Art. 10(b) of Directive 2001/83/EC or Article 706 of Law 95/2006, as amended]	9,780
18.a)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – fixed combination - different pharmaceutical form, submitted at the same time as the initial application [Article 10(b) of Directive 2001/83/EC or Article 706 of Law 95/2006, as amended]	5,870
18.b)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – fixed combination - the second and following strengths, submitted at the same time as the initial application [Article 10(b) of Directive 2001/83/EC or Article 706 of Law 95/2006, as amended]	2,930
19.	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "informed consent" [Article 10(c) of Directive 2001/83/EC or Article 707 of Law 95/2006, as amended]	6,900
19.a)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "informed consent" - different pharmaceutical form, submitted at the same time as the initial application [Article 10(c) of Directive 2001/83/EC or Article 707 of Law 95/2006, as amended]	4,140

19.b)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State - "informed consent" – the second and following strengths, submitted at the same time as the initial application [Article 10(c) of Directive 2001/83/EC or Article 707 of Law 95/2006, as amended]	2,070
20.	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – full dossier [Art. 8(3) of Directive 2001/83/EC or Article 702(4) of Law 95/2006, as amended]	7,500
20.a)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - full dossier – different pharmaceutical form, submitted at the same time as the initial application [Article 8(3) of Directive 2001/83/EC or Article 702(4) of Law 95/2006, as amended]	4,500
20.b)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - full dossier - the second and following strengths, submitted at the same time as the initial application [Article 8(3) of Directive 2001/83/EC or Article 702(4) of Law 95/2006, as amended]	2,250
21.	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State– generic medicinal products [Article 10(1) of Directive 2001/83/EC or Article 704(1) and (2) of Law 95/2006, as amended]	5,200
21.a)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State–generic medicinal products – different pharmaceutical form, submitted at the same time as the initial application [Article 10(1) of Directive 2001/83/EC or Article 704(1) and (2) of Law 95/2006, as amended]	3,120
21.b)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State-generic medicinal products - the second and following strengths, submitted at the same time as the initial application [Article 10(1) of Directive 2001/83/EC or Article 704(1) and (2) of Law 95/2006, as amended]	1,560
22.	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "hybrid" (mixed) application [Article 10(3) of Directive 2001/83/EC or Article 704 (3) of Law 95/2006, as amended]	6,000
22.a)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – "hybrid" (mixed) application - different pharmaceutical form, submitted at the same time as the initial application [Article 10(3) of Directive 2001/83/EC or Article 704 (3) of Law 95/2006, as amended]	3,600
22.b)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "hybrid" (mixed) application – the second and following strengths,	1,800

	submitted at the same time as the initial application [Article 10(3) of Directive 2001/83/EC or Article 704 (3) of Law 95/2006, as amended]	
23.	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "biosimilar medicinal product" [Article 10(4) of Directive 2001/83/EC or Article 704(4) of Law 95/2006, as amended]	6,000
23.a)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "biosimilar medicinal product" - different pharmaceutical form, submitted at the same time as the initial application [Article 10(4) of Directive 2001/83/EC or Article 704(4) of Law 95/2006, as amended]	3,600
23.b)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "biosimilar medicinal product" - the second and following strengths, submitted at the same time as the initial application [Article 10(4) of Directive 2001/83/EC or Article 704(4) of Law 95/2006, as amended]	1,800
24.	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "bibliographic" application [Article 10(a) of Directive 2001/83/EC or Art. 705 of Law 95/2006, as amended]	6,000
24.a)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "bibliographic" application - different pharmaceutical form, submitted at the same time as the initial application [Article 10(a) of Directive 2001/83/EC or Article 705 of Law 95/2006, as amended]	3,600
24.b)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "bibliographic" application – the second and following strengths, submitted at the same time as the initial application [Article 10(a) of Directive 2001/83/EC or Article 705 of Law 95/2006, as amended]	1,800
25.	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – fixed combination [Article 10(b) of Directive 2001/83/EC or Article 706 of Law 95/2006, as amended]	6,400
25.a)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – fixed combination - different pharmaceutical form, submitted at the same time as the initial application [Article 10(b) of Directive 2001/83/EC or Article 706 of Law 95/2006, as amended]	3,840
25.b)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – fixed combination - the second and following strengths, submitted at the same time as the initial application [Article 10(b) of Directive 2001/83/EC or Article 706 of Law 95/2006, as amended]	1,920

26.	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "informed consent" [Article 10(c) of Directive 2001/83/EC or Article 707 of Law 95/2006, as amended]	3,750
26.a)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "informed consent" - different pharmaceutical form, submitted at the same time as the initial application [Article 10(c) of Directive 2001/83/EC or Article 707 of Law 95/2006, as amended]	2,250
26.b)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State - "informed consent" – the second and following strengths, submitted at the same time as the initial application [Article 10(c) of Directive 2001/83/EC or Article 707 of Law 95/2006, as amended]	1,130
27.	Marketing authorisation renewal for medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	2,100
27.a)	Marketing authorisation renewal for medicinal products through mutual recognition procedure and decentralised procedure with Romania as Reference Member State	4,305
C.	Authorisation of clinical trials, substantial amendments and approval of advertising material	
28.	Approval of clinical trials for investigational medicinal products not authorised worldwide (new substances). Phases I-III	1,250
29.	Approval of clinical trials for investigational medicinal products not authorised for marketing in Romania, authorised in other countries or authorised for marketing (known substances), but not used according to the Summary of Product Characteristics (SmPC) in force (regarding indications, dose, route of administration, treatment method, target group) Phases I – IV	1,000
30.	Approval of clinical trials for medicinal products authorised in Romania, used according to SmPC in force. Phase IV	4,100
31.	Approval of bioequivalence studies	600
32.	Approval of substantial amendments (according to Order of the Minister of Public Health no. 904/2006 on approval of Rules relating to implementation of Good Clinical Practice trials on medicinal products for human use)	200
33.	Approval of advertising material for "over the counter" medicinal products (OTCs)	550
34	Approval of the educational material for medicinal products for human use	350
NOTE: Fees established under Sections 33 and 34 refer to approvals valid for 6 months after grant		
D.	Approval of variations	
35.	Approval of Type IA variations and Type IA variations defining the group for medicinal products authorised through national procedure	300
36.	Approval of Type IB and Type IB group defining variations for medicinal products authorised through national procedure	500

37.	Approval of Type II and Type II group defining variations for medicinal products authorised through national procedure	1,600
38.	Approval of Type IA variations included in the group for medicinal products authorised through national procedure	200
39.	Approval of Type IB variations included in the group for medicinal products authorised through national procedure	340
40.	Approval of Type II variations included in the group for medicinal products authorised through national procedure	1,070
41.	Approval of Type IA variations for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	460
42.	Approval of Type IB variations for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	760
43.	Approval of Type II variations for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	2,400
44.	Approval of Type IA variations for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	300
45.	Approval of Type IB variations for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	500
46.	Approval of Type II variations for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	1,060
47.	Approval of Type IA variation included in the group, other than the group defining variation, for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	375
47.a)	Approval of Type IB variation included in the group, other than the group defining variation, for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	750
47.b)	Approval of Type I variation included in the group, other than the group defining variation, for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	2,400
48.	Approval of Type IA variation included in the group, other than the group defining variation, for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	165
48.a)	Approval of Type IB variation included in the group, other than the group defining variation, for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	225
48.b)	Approval of Type II variation included in the group, other than the group defining variation, for medicinal	825

	products authorised through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	
NOTE: 1. For group variations, the fee is calculated for each marketing authorisation, by summing up the fee for the group defining variation and the fee for the variation included in the group for each group variation, other than the group defining variation 2. The fee for the group is the fee for the variation to marketing authorisation		
E.	Other activities	
49.	Approval of marketing authorisation transfer	400
50.	Approval of changes in primary and secondary packaging design and labelling, regarding changes to Leaflet and SmPC, other than resulting from Type IA, IB and II variations	250
51.	Grant of WHO format medicinal product certificate	230
52.	Setup and update of the Index of medicinal products for human use	230
NOTE: In case of failure to pay for the aforementioned service, the human medicinal product is not included /is excluded from the Index of medicinal products for human use.		
53.	Grant of parallel import authorisation	585
54.	Approval of parallel import authorisations	250
F.	Assessment of documentation for scientific approval, i.e. change of scientific approval of ancillary medicinal substances incorporated into a medical device	
55.	Scientific approval of ancillary medicinal substances incorporated into a medical device, not previously assessed by the National Agency for Medicines and Medical Devices	2,660
56.	Scientific approval of ancillary medicinal substances incorporated into a medical device for substances previously assessed by the NAMMD with a different manufacturer	1,330
57.	Scientific approval of ancillary medicinal substances incorporated into a medical device for substances previously assessed by the NAMMD with the same manufacturer	535
58.	Amendment of the scientific approval of ancillary medicinal substances incorporated into a medical device for substances not previously assessed by the NAMMD	665
59.	Amendment of the scientific approval of ancillary medicinal substances incorporated into a medical device for substances previously assessed by the NAMMD with a different manufacturer	335
60.	Amendment of the scientific approval of ancillary medicinal substances incorporated into a medical device for substances previously assessed by the NAMMD with the same manufacturer	250
G.	Assessment of documentation for approval for inclusion of a medicinal product in the List of reimbursed and free medicinal products for insurants irrespective of contribution	
61.	Assessment of documentation for approval for inclusion of a medicinal product in the List of reimbursed and free medicinal products for insurants irrespective of contribution	1,304