MINISTRY OF HEALTH

ORDER

on approval of tariffs and amount of marketing authorisation maintenance fee required by the National Medicines Agency

On seeing Approval Report no. 5751/2009 of the Pharmaceutical Directorate of the Ministry of Health,

Taking into account provisions of Article 8(e) of Government Ordinance no. 125/1998 on the set up, organisation and functioning of the National Medicines Agency, approved with changes and completions through Law no. 594/2002, with further amendments and supplementations,

based on Government Decision no. 1718/2008 on organisation and functioning of the Ministry of Health, with further amendments and supplementations,

the minister of health hereby issues the following order:

Article 1. - Tariffs are approved for activities carried out by the National Medicines Agency, as provided in Annexes 1-3, which are integral part of this order.

Article 2. – The marketing authorisation maintenance fee is 230 euro/year.

Article 3. - (1) Romanian applicants for services provided by the National Medicines Agency shall pay equivalent dues in Lei as provided under article 1 based on the National Bank of Romania exchange rate on invoicing day.

(2) Foreign applicants for services provided by the National Medicines Agency shall pay dues as provided under article 1 in either equivalent Lei or foreign currency, based on the National Bank of Romania exchange rate on invoicing day.

Article 4. – In case of discontinuation of the marketing authorisation/marketing authorisation (MA) renewal and variations approval procedures, the administrative procedure for management of amounts entered into National Medicines Agency accounts is as follows:

a) In case of notification by applicants on withdrawal of MA/MA renewal application after payment of dues for MA/MA renewal procedure, the National Medicines Agency shall transfer to the state budget the marketing authorisation/marketing authorisation renewal fee paid by applicants according to Article 854 of Law 95/2006 on healthcare reform, with further amendments and supplementations on submission of the marketing authorisation/marketing authorisation renewal application;

b) In case of notification by applicants on withdrawal of MA/MA renewal application after payment of dues for MA/MA renewal procedure, the marketing

authorisation/marketing authorisation renewal tariff paid by applicants according to Annex 3 provisions shall be managed as follows:

(i) Should the applicant submit an application for discontinuation of the marketing authorisation/marketing authorisation renewal procedure prior to validation of the marketing authorisation/marketing authorisation renewal application, on applicant's request, the respective amount may be returned/directed to a different payment due by the applicant in question to the National Medicines Agency;

(ii) Should the applicant submit an application for discontinuation of the marketing authorisation/marketing authorisation renewal procedure after validation of the marketing authorisation/marketing authorisation renewal application but prior to start of the mutual recognition or decentralised procedure, or no later than 90 calendar days as of payment in case of national procedure, respectively, on applicant's request, 90% of the tariff may returned/directed to a different payment due by the applicant in question to the National Medicines Agency;

(iii) Should the applicant submit an application for discontinuation of the marketing authorisation/marketing authorisation renewal procedure after start of the mutual recognition or decentralised procedure, or after 90 calendar days as of payment in case of national procedure, respectively, the paid amount shall be retained by the National Medicines Agency and may not be returned;

c) In case of notification by applicants on withdrawal of the application for variation approval after payment of dues for variation approval procedure and after validation of the application for variation approval but prior to request for additional information by the National Medicines Agency, on applicant's request, 90% of the tariff may returned/directed to a different payment due by the applicant in question to the National Medicines Agency;

d) In case of notification by applicants on withdrawal of the application for variation approval after request for additional information by the National Medicines Agency, the paid amount shall be retained by the National Medicines Agency and may not be returned.

Article 5. – On the present order coming into force, the following shall be repealed: Order of the minister of health no. 1038/2008 concerning approval of tariffs and amount of marketing authorisation maintenance fee due to the National Medicines Agency, published in the Official Gazette of Romania, Part I, no. 461 of 31 May 2005; Order of the minister of health no. 1454/2005 on approval of tariffs for activities carried out by the National Medicines Agency, published in the Official Gazette of Romania, Part I no. 419 of 4 June 2008, with further amendments and supplementations, Order of the minister of health no. 172/2009 on approval of tariffs for certain activities carried out by the Pharmaceutical inspection department within the National Medicines Agency, published in the Official Gazette of Romania, Part I no. 113 of 25 February 2009, as well as any other contrary provisions.

Article 6. - The present order is to be published in the Official Gazette of Romania, Part I.

Minister of public health,
Ion Bazac

Bucharest, 11 June 2009
Nr. 716

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ANNEX 1

TARIFFS
for laboratory control of non-biological and biological medicinal products for human use and related activities

No. crt.	Performance	Tariff -euro-
A.	**Physico-chemical control**	
1.	Spray jet aspect	5
2.	Stretching capacity of ointments	6
3.	Liquid clarity and opalescence	30
4.	Concentration of aqueous extractive solutions through distillation at rotavapor	50
5.	Alcoholic concentration of pharmaceutical preparations	47
6.	Control of macroscopic impurities in solutions for injections and infusions in vials and bottles/powders for injection and liophylisated medicinal products	11
7.	Control of limits of inorganic impurities and foreign organic substances	52
8.	Control of size and shape of particles in suspension under microscope	12
9.	Micro-chemical/Microscopic control of herbal medicinal products	26
10.	Organoleptic control (appearance, colour, taste, smell)	5
11.	De-fattening of herbal medicinal products for undergoing dosage	19
12.	Relative density	12
13.	Determination of water, titration with Karl-Fischer reagent (calibration included)	54
14.	Determination of tea components	36
15.	Chromatographic determination on columns	142
16.	Determination of apparent density in powders	14
17.	Determination of tablet size (thickness, diameter, length, width)	7
18.	Determination of rehomogenisation duration of suspensions	5
19.	Determination of tablet friability	12
20.	Granulometric determination in powders	14
21.	Determination of total impurities in herbal medicinal products [dirt, dust, silica and other contaminants (fungi, insects, animal products etc.)]	19
22.	Determination of acidity-alkalinity limit	14
23.	Determination of number of doses per spray vial	11

No. crt.	Performance	Tariff -euro-
24.	Determination of osmolality	13
25.	Determination of ointment, suppositories homogeneity	6
26.	pH determination	20
27.	Determination of distillate percentage within a certain time frame	23
28.	Determination of kinetic profile of release of the medicinal substance from oral solid pharmaceutical forms with prolonged release	173
29.	Determination of purity of pharmaceutical products for human use through high performance liquid chromatography	323
30.	Determination of suppository resistance	22
31.	Determination of total fat substances	25
32.	Determination of dissolution time of liophylised products	12
33.	Determination of emulsion type	12
34.	Determination of volatile oils from herbal medicinal products	10
35.	Determination of viscosity with ball/rotational/capillary viscosimeter	39
36.	Determination of sedimentation rate	16
37.	Suppository and ovule desegregation	33
38.	Effervescent/Gastro-soluble medicinal product desegregation	12
39.	Entero-soluble product desegregation	39
40.	Sample destruction for determination of inorganic impurity limits	24
41.	Physico-chemical determination in aquaeous environment/of acid substances in non-aquaeous environment/of alkali substances in non-aquaeous environment	55
42.	Gas chromatographic dosage	209
43.	Gas chromatographic coupled with Head - Speace dosage	470
44.	Dosage through atomic absorption spectrophotometry	120
45.	Potentiometric dosage	75
46.	Dosage through high performance liquid chromatography	326
47.	CSS chromatographic dosage through the densitometric method – version I/II/III	97
48.	Nitrogen determination in organic combinations	32

No. crt.	Performance	Tariff -euro-
49.	Oxygen dosage	34
50.	Spectrophotometric identification in UV and visible or fluorimetric – in alcohol solution/in organic solvents/in aqueous solution	117
51.	Dosage of soluble substances in herbal medicinal products	20
52.	Dosage of tannins in herbal medicinal products	79
53.	Capillary electrophoresis	113
54.	Tightness of spray vials/of envelopes with effervescent powder	12
55.	Extraction of active principles from pharmaceutical products /herbal medicinal products for identification or dosage purposes	79
56.	Imbuement factor of herbal medicinal products	13
57.	Filtration through membrane filters with the porosity of 0.30 - 0.50 μm for determinations with high performance devices	15
58.	Working of pulverisation system (spray)	14
59.	Liquid degrees of coloration	19
60.	Identification through thin layer chromatography	38
61.	Identification through dinytrogenation chemical reactions – coupling/oxide-reduction/other types/anion identification/cation identification	22
62.	Identification and purity through gas - chromatography	200
63.	Spectrophotometric identification in I.R.	15
64.	Spectrophotometric identification in UV and visible in alcohol solution/in aqueous solution/in organic solvents	78
65.	Acetyl/Acidity/Bitterness/Ester/Hydroxyl Iodine/peroxide index	35
66.	Refraction index	19
67.	Saponification index	26
68.	Total weight per recipient (solutions, suspensions, emulsions, ointments)	17
69.	Loss through etuve or exsiccator drying	21
70.	Sedimentation assay	7
71.	Boiling point/Dropping point/Melting point for capillaries/Melting point for suppositories	14
72.	Purity through thin layer chromatography	79
73.	Rotatory power	26

No. crt.	Performance	Tariff -euro-
74.	Reconstitution of disperse system for laboratory verifications (oral suspensions, suspensions for injection)	8
75.	Insoluble residue in chlorhydric acid 100 g/l/through calcination/through evaporation	34
76.	Hardmeter determined resistance of tablets	6
77.	Solubility	20
78.	Non-saponifiable substances	60
79.	Substances soluble in water or acids	17
80.	Dissolution test	85
81.	Content uniformity	35
82.	Unidose forms/Powder for injection mass uniformity	20
83.	Volume uniformity per vial, bottle	10
84.	Drying and pulverisation of herbal medicinal products for measurement	27
B.	**Microbiological control**	
85.	Microbiological activity of antibiotics - turbidimetric method	184
86.	Microbiological activity of antibiotics and vitamins - diffusion method	200
87.	Microbiological activity of vitamins - turbidimetric method	235
88.	Microbial contamination - direct seeding method	233
89.	Microbial contamination - membrane filtration method	287
90.	Antimicrobial preservatives efficacy control	331
91.	Control of antibiotics sterility through "Steritest" method of closed system membrane filtration	300
92.	Control of antibiotics sterility through open system membrane filtration method (Millipore)	331
93.	Control of sterility of aqueous solutions and soluble powders through "Steritest" method of closed system membrane filtration	264
94.	Control of sterility of aqueous solutions and soluble powders through open system membrane filtration method (Millipore)	243
95.	Control of sterility of aqueous solutions and oily solutions up to 4 ml/4 ml and 10 ml/10 ml and 40 ml in volume, of powders, ointments and creams through the direct seeding method	184
96.	Control of sterility of solutions for infusion or medicinal products with antimicrobial activity through the direct seeding method	204
97.	Control of sterility of oils and oily solutions, ointments and creams through "Steritest" method of closed system membrane filtration	283
98.	Control of sterility of oils and oily solutions, ointments and creams through open system membrane filtration method (Millipore)	261
99.	Determination of bactericide and fungicide activity of antiseptics and disinfectants	402
100.	Exposure of enterobacteria and certain other gram-negative bacteria	131

No. crt.	Performance	Tariff -euro-
101.	Exposure of Clostridium/Salmonella/Escherichia Coli/Pseudomonas aeruginosa/Staphylococcus aureus genre micro-organisms	151
	*** Pharmaco –toxicological control**	
102.	Antigenicity control at 21 days	435
103.	Control of endotoxin content through the Kinetic Cromogenic/turbidimetric/gel - clot (L.A.L. test) method	491
104.	Control of blood pigments distorting impurities	113
105.	Control of haemolytic impurities in plastics	124
106.	Control of pyrogenic impurities	496
107.	Control of pyrogenic impurities in 6 rabbits	929
108.	Control of local tolerance through intramuscular injection in rabbit	757
109.	Control of acute toxicity for articles and devices made of plastics	249
110.	Control of toxicity in 5 mice	84
111.	Control of toxicity in 3 rabbits	375
112.	Determination of amylolythic/cellulasic and hemicellulasic/hyaluronidasic/antihyaluronidasic/lipolitic/proteolitic activity	235
113.	Determination of hypotensive impurities	119
114.	Determination of passage assay of suspension	9
115.	Determination of systemic toxicity in subacute experiments with anatomo-pathologic examination	1.876
116.	Dosage of amino acids though high performance liquid chromatography	680
117.	Biological determination of heparin	280
118.	Biological determination of oxytocine in rooster	188
119.	Biological determination of gonadotrope hormone	712
120.	Local tolerance on rabbit conjunctiva	547
121.	Subacute gastrointestinal tolerance	106
D.	**Radiopharmaceutical control**	
122.	Radioactivity measurement	29
123.	Determination of radiochemical purity	91
124.	Determination of radionuclide purity	117
E.	**Immunogeniticity and pathological anatomy control**	
125.	Control of specific activity (in vivo antigenic titre - U.B.) in 7 mice	152
126.	Control of in vivo immunogenicity in 12 guinea pigs	793
127.	Control of in vivo immunogenicity in 22 guinea pigs	1.266
128.	Non-pathogenicity control	347
129.	Control of in vivo innocuity in 5 mice and 2 guinea pigs	227
130.	Control of in vivo innocuity in 5 mice	98
131.	Control of in vivo specific toxicity in 5 guinea pigs	502
F.	**** Biological product control**	
132.	Control of purity (blade) Gram smear	36
133.	Control of purity through seeding (in tube)	83
134.	Control of in vitro specific activity (viral titre determination monovalent vaccine: measles, mumps or rubella)	255
135.	Control of in vitro specific activity - viral titre determination, polio vaccine	518
136.	Control of specific activity through double diffusion	163
137.	Control of concentration (nefelometry)	31

No. crt.	Performance	Tariff -euro-
138.	Control of identity (blade) Ziehl-Nielsen smear	42
139.	Control of identity and/or specific activity by counterimmunoelectrophoresis	215
140.	Control of identity and/or specific activity by immunoelectrophoresis	219
141.	Control of identity and/or titre through in tube agglutination	36
142.	Control of identity and/or titre through on plate agglutination	29
143.	Control of purity through seeding (on plate)	69
144.	Control of protein purity through electrophoresis by Agarosa- Sebia gel	208
145.	Control of protein concentration through the biuret method	60
146.	Control of protein concentration through the Lowry method	121
147.	Control of aluminium content through the complexonometric method	107
148.	Determination of phenol content	116
149.	Control of free formaldehyde content	60
150.	Control of Thyomersal content	95
151.	Calibration curve for protein concentration (biuret method)	62
152.	Calibration curve for determination of phenol content	114
153.	Calibration curve for determination of Thyomersal content (dosage)	96
154.	Calibration curve for determination of protein concentration in influenza vaccine	179
155.	Calibration curve for determination of free formaldehyde content	64
156.	Determination of Na, K and Cl ionic concentration with AVL List analyzer	32
157.	Determination of hemaglutinin and ovalbumine identity and/or concentration through simple radial imunodiffusion IDRS in purified and inactivated influenza trivalent vaccine	177
158.	Determination of identity through the Ouchterlony radial double immunodiffusion method in vaccines	144
159.	Determination of protein concentration through the Bradford method	132
160.	Determination of vaccine potency through the ELISA method of antibody measurement in serum (on mice)	458
161.	Determination of vaccine potency through the ELISA method of antibody measurement in serum (on guinea pigs)	458
162.	Determination through seeding on solids for BCG products (identity, number of viable units, thermal stability, average survival rate)	337
163.	Identification/titre in ant A and anti B hemaglutinine (the indirect method)	101
164.	Ph. Eur calibration curve for determination of free formaldehyde content.	66
165.	Ph. Eur. free formaldehyde content control	64
G.	**Related activities: growth of test animals on NMA farms**	
166.	Rabbits up to 2000 g	72
167.	Rabbits over 2000 g	172

*****The remaining specific materials are to be brought by the beneficiary (reference substance, international standard and certain calibrators).

**The remaining specific materials are to be brought by the beneficiary (reference substance, immuno-plates, Cormay gel prot 100 kit).

ANNEX 2

TARIFFS
due for various inspections and related activities

No.	Performance	TARIFF -euro- ***	Fixed component *	Variable component **
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 during 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/de investigational medicinal products/raw materials	778	778	-
5.	Inspection to medicinal products for human use/investigational medicinal products importers for check of release by the Qualified Person of medicinal product batches imported from third countries	360	360	-
6.	Inspection in view of grant of the Manufacturing authorisation to medicinal products for human use/investigational medicinal products/raw materials importers carrying out certain manufacturing operations (e.g. division, labelling, packaging, re-packaging, other manufacturing process parts)	863	863	-
7	Inspection in view of grant of the Good Manufacturing Practice Certificate to medicinal products for human use/investigational medicinal products/raw materials manufacturers in third countries for manufacturing of sterile products	2.035	981	1.054
8.	Inspection in view of grant of the Good Manufacturing Practice Certificate to medicinal products for human use/investigational	1.753	882	871

No.	Performance	TARIFF -euro- ***	Fixed component *	Variable component **
	medicinal products/raw materials manufacturers in third countries for manufacturing of non-sterile products			
9.	Inspection prior to grant of Marketing Authorisation	451	451	-
10.	Inspection for check of compliance with Good Clinical Practice Regulations on a specialised site	1.046	514	532
11.	Inspection for follow up of correction of deficits found on inspection for check of compliance with Good Clinical Practice Regulations	514	514	-
12.	Inspection in view of authorising units for independent control (physico-chemical and/or microbiological)/good laboratory practice certification (bioanalytical laboratories within bioequivalence centres/toxicological laboratories)	994	994	-
13.	Inspection for follow up of correction of deficits found on inspection for authorising units for independent control (phyisico-chemical and/or microbiological)/good laboratory practice certification (bioanalytical laboratories within bioequivalence centres/toxicological laboratories)	800	800	-
14.	Inspection of Marketing Authorisation Holders for check of pharmacovigilance activity	1.117	1.117	-
15.	Inspection of Marketing Authorisation Holders for follow up of correction of deficits found on pharmacovigilance inspection	659	659	-
16.	Inspection for check of compliance with Marketing Authorisation Holders obligations	400	400	-
17.	Inspection for check of compliance with Good Clinical Practice Regulations on a clinical site of a bioequivalence centre	506	506	-
18.	Inspection in view of grant of the Wholesale distribution authorisation	750	750	-
19.	Inspection for follow up of wholesale distributor activity	350	350	-
20.	Inspection in view of grant of the Wholesale distribution authorisation to intermediaries carrying out medicinal product sales, procurement and/or export	350	350	-
21.	Issuance of the Good Manufacturing Practice Compliance Certificate	81	81	-
22.	Approval of the Export declaration/Additional export declaration	20	20	-

No.	Performance	TARIFF -euro- ***	Fixed component *	Variable component **
23.	Operation of changes, on request, in a document issued by the National Medicines Agency (e.g. changes to manufacturing/import authorisations and/or of their annexes, of authorisations of units for independent control and/or of their annexes, of ale good laboratory practice certificates) or issuance of document duplicates (loss/deterioration of the document)	136	136	-
24.	Issuance of the Qualified Person Certificate	75	75	-
25.	Examination of documentation submitted in view of exemption from application of legal provisions in force on medicinal product labelling/packaging as specified in Order of the Minister of Public Health No. 872/2006 for approval of Norms for grant of exemption of specific medicinal products label and package leaflet from the obligation that certain particulars shall appear and that the leaflet must be in Romanian, when the product is not intended to be delivered to the patient for self-administration	75	75	-

NOTE:

Tariffs 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 extracommunity space is concerned.

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

** Referring to one manufacturing flow and is multiplied by the number of manufacturing flows inspected in the calculation of the inspection tariff.

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

ANNEX 3

TARIFFS
for assessment of documentation in view of marketing authorisation/marketing authorisation renewal of medicinal products for human use and development of marketing authorisation related activities

No. crt.	Performance	Tariff – euro –
A.	**Assessment of documentation in view of marketing authorisation/marketing authorisation renewal through national procedure**	
1.	Marketing authorisation of medicinal products submitted – full dossier, according to Article 702(4), of Law No. 95/2006 on healthcare reform, with further amendments and supplementations, 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 through national procedure	9.500
1.a)	Marketing authorisation of medicinal products submitted – full dossier according to Article 702(4), of Law No. 95/2006, with further amendments and supplementations, or Article 8 (3) of Directive 2001/83 EC – different	4.750

No. crt.	Performance	Tariff – euro –
	pharmaceutical form submitted at the same time with the initial application through national procedure	
1.b)	Marketing authorisation of medicinal products submitted – full dossier, according to Article 702(4), of Law No. 95/2006 with further amendments and supplementations, or Article 8 (3) of Directive 2001/83 EC – the second and following strengths submitted at the same time with initial application through national procedure	2.830
2.	Marketing authorisation of generic medicinal products submitted according to Article 704(1) and (2) of Law No. 95/2006, with further amendments and supplementations, or Article 10 (1) of Directive 2001/83 EC through national procedure	5.700
2.a)	Marketing authorisation of generic medicinal products submitted according to Article 704(1) and (2) of Law No. 95/2006, with further amendments and supplementations, or Article 10 (1) of Directive 2001/83 EC – different pharmaceutical form submitted at the same time with the initial application through national procedure	2.900
2.b)	Marketing authorisation of generic medicinal products submitted according to Article 704(1) and (2) of Law No. 95/2006, with further amendments and supplementations, or Article 10 (1) of Directive 2001/83 EC – the second and following strengths submitted at the same time with the initial application through national procedure	1.710
3.	Marketing authorisation of medicinal products submitted – "hybrid" (mixed) application according to Article 704(3) of Law No. 95/2006, with further amendments and supplementations, or Article 10 (3) of Directive 2001/83 EC through national procedure	6.650
3.a)	Marketing authorisation of medicinal products submitted as "hybrid" (mixed) application according to Article 704(3) of Law No. 95/2006, with further amendments and supplementations, or Article 10 (3) of Directive 2001/83 EC – different pharmaceutical form submitted at the same time with the initial application through national procedure	3.325
3.b)	Marketing authorisation of medicinal products submitted as "hybrid" (mixed) application according to Article 704(3) of Law No. 95/2006, with further amendments and supplementations, or Article 10 (3) of Directive 2001/83 EC, the second and following strengths submitted at the same time with the initial application through national procedure	2.000
4.	Marketing authorisation of biosimilar medicinal products, submitted according to Article 704(4) of Law No. 95/2006, with further amendments and supplementations, or Article 10 (4) of Directive 2001/83 EC through national procedure	6.650
4.a)	Marketing authorisation of biosimilar medicinal products submitted according to Article 704(4) of Law No. 95/2006, with further amendments and supplementations, or Article 10 (4) of Directive 2001/83 EC – different pharmaceutical form submitted at the same time with the initial application through national procedure	3.325
4.b)	Marketing authorisation of biosimilar medicinal products, submitted according to Article 704(4) of Law No. 95/2006, with further amendments and supplementations, or Article 10 (4) of Directive 2001/83 EC – the second and	2.000

No. crt.	Performance	Tariff – euro –
	following strengths submitted at the same time with the initial application through national procedure	
5.	Marketing authorisation of well–established use medicinal products, submitted according to Article 705 of Law No. 95/2006, with further amendments and supplementations, or Article 10 (a) of Directive 2001/83 EC ("bibliographic" application) through national procedure	6.650
5.a)	Marketing authorisation of well–established use medicinal products, submitted according to Article 705 of Law No. 95/2006, with further amendments and supplementations, or Article 10 (a) of Directive 2001/83 EC ("bibliographic" application) – different pharmaceutical form submitted at the same time with the initial application through national procedure	3.325
5.b)	Marketing authorisation of well–established use medicinal products submitted according to Article 705 of Law No. 95/2006, with further amendments and supplementations, or Article 10 (a) of Directive 2001/83 EC ("bibliographic" application) – the second and following strengths submitted at the same time with the initial application through national procedure	2.000
6.	Marketing authorisation of fixed combination medicinal products, submitted according to Article 706 of Law No. 95/2006, with further amendments and supplementations, or Article 10 (b) of Directive 2001/83 EC through national procedure	8.035
6.a)	Marketing authorisation of fixed combination medicinal products, submitted according to Article 706 of Law No. 95/2006, with further amendments and supplementations, or Article 10 (b) of Directive 2001/83 EC – different pharmaceutical form submitted at the same time with the initial application through national procedure	4.005
6.b)	Marketing authorisation of fixed combination medicinal products, submitted according to Article 706 of Law No. 95/2006, with further amendments and supplementations, or Article 10 (b) of Directive 2001/83 EC – the second and following strengths submitted at the same time with the initial application through national procedure	2.450
7.	Marketing authorisation of informed consent medicinal products submitted according to Article 707 of Law No. 95/2006, with further amendments and supplementations, or Article 10 (c) of Directive 2001/83 EC through national procedure	2.850
7.a)	Marketing authorisation of informed consent medicinal products submitted according to Article 707 of Law No. 95/2006, with further amendments and supplementations, or Article 10 (c) of Directive 2001/83 EC – different pharmaceutical form submitted at the same time with the initial application through national procedure	1.425
7.b)	Marketing authorisation of informed consent medicinal products submitted according to Article 707 of Law No. 95/2006, with further amendments and supplementations, or Article 10 (c) of Directive 2001/83 EC – the second and following strengths submitted at the same time with the initial application through national procedure	900
8.	Marketing authorisation of homeopathic medicinal products, submitted according to Article 710 of Law No. 95/2006, with further amendments and supplementations (Marketing authorisation through simplified procedure) through national procedure	1.920

No. crt.	Performance	Tariff – euro –
9.	Marketing authorisation of traditional herbal medicinal products granted according to Article 714 of Law No. 95/2006, with further amendments and supplementations (Marketing authorisation through simplified procedure) through national procedure	1.920
10.	Marketing authorisation of medicinal products submitted as line extensions of an already authorised medicinal product through national procedure	4.100
11.	Marketing authorisation renewal according to Article 730(2) of Law No. 95/2006, with further amendments and supplementations, or Article 24 (2) of Directive 2001/83 EC through national procedure	2.400
12.	Marketing authorisation renewal of homeopathic medicinal products, submitted according to Article 710 of Law No. 95/2006, with further amendments and supplementations, (marketing authorisation through simplified procedure) through national procedure	970
13.	Marketing authorisation renewal of traditional herbal medicinal products granted according to Article 714 of Law No. 95/2006, with further amendments and supplementations (Marketing authorisation through simplified procedure) through national procedure	970
B.	**Assessment of documentation in view of 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 No. 95/2006, with further amendments and supplementations]	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 with the initial application [Article 10 (1) of Directive 2001/83 EC or Article 704(1) and (2) of Law No. 95/2006, with further amendments and supplementations]	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 with the initial application [Article 10 (1) of Directive 2001/83 EC or Article 704(1) and (2) of Law No. 95/2006, with further amendments and supplementations]	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 No. 95/2006, with further amendments and supplementations]	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 with the initial application [Article 10 (3) of Directive 2001/83 EC or Article 704(3) of Law No. 95/2006, with further amendments and supplementations]	5.520

No. crt.	Performance	Tariff – euro –
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 with the initial application [Article 10 (3) of Directive 2001/83 EC or Article 704(3) of Law No. 95/2006, with further amendments and supplementations]	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 No. 95/2006, with further amendments and supplementations]	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 with the initial application [Article 10 (4) of Directive 2001/83 EC or Article 704(4) of Law No. 95/2006, with further amendments and supplementations]	5.520
16.b)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – "biosimilar medicinal product" – the second and following strengths submitted at the same time with the initial application [Article 10 (4) of Directive 2001/83 EC or Article 704(4) of Law No. 95/2006, with further amendments and supplementations]	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 Article 705 of Law No. 95/2006, with further amendments and supplementations]	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 with the initial application [Article 10 (a) of Directive 2001/83 EC or Article 705 of Law No. 95/2006, with further amendments and supplementations]	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 with the initial application [Article 10 (a) of Directive 2001/83 EC or Article 705 of Law No. 95/2006, with further amendments and supplementations]	2.760
18.	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Reference Member State – fixed combination [Article 10 (b) of Directive 2001/83 EC or Article 706 of Law No. 95/2006, with further amendments and supplementations]	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 with the initial application [Article 10 (b) of Directive 2001/83 EC	5.870

No. crt.	Performance	Tariff – euro –
	or Article 706 of Law No. 95/2006, with further amendments and supplementations]	
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 with the initial application [Article 10 (b) of Directive 2001/83 EC or Article 706 of Law No. 95/2006, with further amendments and supplementations]	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 No. 95/2006, with further amendments and supplementations]	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 with the initial application [Article 10 (c) of Directive 2001/83 EC or Article 707 of Law No. 95/2006, with further amendments and supplementations]	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 with the initial application [Article 10 (c) of Directive 2001/83 EC or Article 707 of Law No. 95/2006, with further amendments and supplementations]	2.070
20.	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – full dossier [Article 8 (3) of Directive 2001/83 EC or Article 702(4) of Law No. 95/2006, with further amendments and supplementations]	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 with the initial application [Article 8 (3) of Directive 2001/83 EC or Article 702(4) of Law No. 95/2006, with further amendments and supplementations]	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 with the initial application [Article 8 (3) of Directive 2001/83 EC or Article 702(4) of Law No. 95/2006, with further amendments and supplementations]	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 No. 95/2006, with further amendments and supplementations]	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 with the initial application [Article 10 (1) of Directive 2001/83	3.120

No. crt.	Performance	Tariff – euro –
	EC or Article 704(1) and (2) of Law No. 95/2006, with further amendments and supplementations]	
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 with the initial application [Article 10 (1) of Directive 2001/83 EC or Article 704(1) and (2) of Law No. 95/2006, with further amendments and supplementations]	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 No. 95/2006, with further amendments and supplementations]	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 with the initial application [Article 10 (3) of Directive 2001/83 EC or Article 704(3) of Law No. 95/2006, with further amendments and supplementations]	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 submitted at the same time with the initial application [Article 10 (3) of Directive 2001/83 EC or Article 704(3) of Law No. 95/2006, with further amendments and supplementations]	1.800
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 No. 95/2006, with further amendments and supplementations]	6.000
23.a)	Marketing authorisation of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State – biosimilar medicinal products– different pharmaceutical form submitted at the same time with the initial application [Article 10 (4) of Directive 2001/83 EC or Article 704(4) of Law No. 95/2006, with further amendments and supplementations]	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 with the initial application [Article 10 (4) of Directive 2001/83 EC or Article 704(4) of Law No. 95/2006, with further amendments and supplementations]	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 Article 705 of Law No. 95/2006, with further amendments and supplementations]	6.000

No. crt.	Performance	Tariff – euro –
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 with the initial application [Article 10 (a) of Directive 2001/83 EC or Article 705 of Law No. 95/2006, with further amendments and supplementations]	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 with the initial application [Article 10 (a) of Directive 2001/83 EC or Article 705 of Law No. 95/2006, with further amendments and supplementations]	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 No. 95/2006, with further amendments and supplementations]	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 with the initial application [Article 10 (b) of Directive 2001/83 EC or Article 706 of Law No. 95/2006, with further amendments and supplementations]	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 with the initial application [Article 10 (b) of Directive 2001/83 EC or Article 706 of Law No. 95/2006, with further amendments and supplementations]	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 No. 95/2006, with further amendments and supplementations]	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 with the initial application [Article 10 (c) of Directive 2001/83 EC or Article 707 of Law No. 95/2006, with further amendments and supplementations]	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 with the initial application [Article 10 (c) of Directive 2001/83 EC or Article 707 of Law No. 95/2006, with further amendments and supplementations]	1.130
27.	Marketing authorisation renewal of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	2.100
C.	**Approval of clinical trials and advertising material**	

No. crt.	Performance	Tariff – euro –
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 Summary of Product Characteristics (SPC) in force in the respective trial (regarding indications, dose, administration route, treatment method, target group). Phases I – III	1.000
30.	Approval of clinical trials for medicinal products authorised in Romania, used according to SPC in force. Phase IV	410
31.	Approval of bioequivalence studies	600
32.	Approval of changes to protocol/investigational medicinal product (according to Decision of the National Medicines Agency Scientific Council no. 49/2006 – Annex 5)	200
33.	Approval of advertising material for "Over the Counter" medicinal products (OTCs)	550
34.	Approval of educational material for medicinal products for human use	350
D.	**Approval of variations**	
35.	Approval of Type IA variations for medicinal products authorised through national procedure	300
36.	Approval of Type IB variations for medicinal products authorised through national procedure	450
37.	Approval of Type II variations (major variation, according to the definition provided in Order of the minister of public health no. 874/2006 on approval of Norms regarding National Medicines Agency administrative procedure for management of variations) for medicinal products authorised through national procedure	1.000
38.	Approval of Type II variations concerning all administrative changes to SPC, Labelling and/or Leaflet, as for instance new format, change of administrative information, for which the Marketing Authorisation Holder submits no new scientific data for medicinal products authorised through national procedure	250
39.	Approval of Type II variations concerning changes to SPC, Labelling and/or Leaflet for biosimilar or generic medicinal products, in result of changes to reference medicinal product, for which the Marketing Authorisation Holder submits no new scientific data for medicinal products authorised through national procedure	250
40.	Approval of Type II variations concerning implementation of quality changes as set by the Committee for Medicinal Products for Human Use (CHMP) in result of assessment of pending measures/specific obligations, for which the Marketing Authorisation Holder submits no new scientific data for medicinal products authorised through national procedure	250
41.	Approval of Type II variations – quality (changes of chemical, pharmaceutical and biological documentation, for which the Marketing Authorisation Holder submits no new clinical data) for medicinal products authorised through national procedure	500
42.	Approval of Type II variations concerning implementation of changes to SPC, Labelling and/or Leaflet on CHMP requirement in result of urgent safety restrictions, PSUR assessment, assessment of pending measures/specific obligations, for which the Marketing Authorisation Holder submits no new	500

No. crt.	Performance	Tariff – euro –
	scientific or additional data for medicinal products authorised through national procedure	
43.	Approval of Type IA variations for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	460
44.	Approval of Type IB variations for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	760
45.	Approval of Type II variations for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Reference Member State	2.400
46.	Approval of Type IA variations for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	300
47.	Approval of Type IB variations for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	500
48.	Approval of Type II variations for medicinal products authorised through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	1.600
E.	**Other marketing authorisation related 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 SPC, other than resulting from Type IA, IB and Type II variations	250
51.	Grant of WHO – format medicinal product certificate	230
52.	Marketing authorisation maintenance fee	230
53.	Grant of parallel import authorisation	585