TARIFFS

for the activities carried out by the National Agency for Medicines and Medical Devices of Romania (NAMMDR) in the field of medicinal products for human use

- marketing authorisation and related activities -

No.	**Performance** according to amendment of Article 893 of Law no. 95/2006, in accordance with ORDER no. 9/2019 for amendment of Law no. 95/2006 on healthcare reform and amendment of certain healthcare regulatory acts, of regulations for national government programs and regarding fiscal-budgetary measures (published in the Official Gazette No. 668 of 9 August 2019)	**Tariff, euro**
1.	**Tariff for marketing authorisation**	5,000

No.	**Performance** according to Minister of Health Order no. 888/2014 on approval of fees payable to the National Agency for Medicines and Medical Devices of Romania for activities conducted related to medicinal products for human use, as amended (last amendment on June 26, 2017)	**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, as further 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 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, as further amended, or Article 8 (3) of Directive 2001/83 EC – different pharmaceutical form submitted at the same time with the initial application through national procedure	4,750
1.b)	Marketing authorisation of medicinal products submitted – full dossier, according to Article 702(4), of Law No. 95/2006 as further amended, 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, as further amended, 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, as further amended, 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, as further amended, 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, as further amended, 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, as further amended, 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, as further amended, 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, as further amended, 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, as further amended, 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, as further amended, or Article 10 (4) of Directive 2001/83 EC – the second and following strengths submitted at the same time with the initial application through national procedure	2,000
5.	Marketing authorisation of well–established use medicinal products, submitted according to Article 705 of Law No. 95/2006, as further amended, 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, as further amended, 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, as further amended, 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, as further amended, 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, as further amended, 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, as further amended, 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, as further amended, 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, as further amended, 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, as further amended, 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, as further amended (Marketing authorisation through simplified procedure) through national procedure	1,920
9.	Marketing authorisation of traditional herbal medicinal products granted according to Article 714 of Law No. 95/2006, as further amended (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, as further amended, 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, as further amended, (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, as further amended (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, as further 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 with the initial application [Article 10 (1) of Directive 2001/83 EC or Article 704(1) and (2) of Law No. 95/2006, as further 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 with the initial application [Article 10 (1) of Directive 2001/83 EC or Article 704(1) and (2) of Law No. 95/2006, as further 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 No. 95/2006, as further 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 with the initial application [Article 10 (3) of Directive 2001/83 EC or Article 704(3) of Law No. 95/2006, as further 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 with the initial application [Article 10 (3) of Directive 2001/83 EC or Article 704(3) of Law No. 95/2006, as further 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 No. 95/2006, as further 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 with the initial application [Article 10 (4) of Directive 2001/83 EC or Article 704(4) of Law No. 95/2006, as further amended]	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, as further 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 Article 705 of Law No. 95/2006, as further 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 with the initial application [Article 10 (a) of Directive 2001/83 EC or Article 705 of Law No. 95/2006, as further 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 with the initial application [Article 10 (a) of Directive 2001/83 EC or Article 705 of Law No. 95/2006, as further amended]	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, as further 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 with the initial application [Article 10 (b) of Directive 2001/83 EC or Article 706 of Law No. 95/2006, as further 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 with the initial application [Article 10 (b) of Directive 2001/83 EC or Article 706 of Law No. 95/2006, as further 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 No. 95/2006, as further 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 with the initial application [Article 10 (c) of Directive 2001/83 EC or Article 707 of Law No. 95/2006, as further 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 with the initial application [Article 10 (c) of Directive 2001/83 EC or Article 707 of Law No. 95/2006, as further amended]	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, as further 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 with the initial application [Article 8 (3) of Directive 2001/83 EC or Article 702(4) of Law No. 95/2006, as further 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 with the initial application [Article 8 (3) of Directive 2001/83 EC or Article 702(4) of Law No. 95/2006, as further 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 No. 95/2006, as further 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 with the initial application [Article 10 (1) of Directive 2001/83 EC or Article 704(1) and (2) of Law No. 95/2006, as further 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 with the initial application [Article 10 (1) of Directive 2001/83 EC or Article 704(1) and (2) of Law No. 95/2006, as further 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 No. 95/2006, as further 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 with the initial application [Article 10 (3) of Directive 2001/83 EC or Article 704(3) of Law No. 95/2006, as further 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 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, as further amended]	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, as further 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 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, as further 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 with the initial application [Article 10 (4) of Directive 2001/83 EC or Article 704(4) of Law No. 95/2006, as further 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 Article 705 of Law No. 95/2006, as further 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 with the initial application [Article 10 (a) of Directive 2001/83 EC or Article 705 of Law No. 95/2006, as further 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 with the initial application [Article 10 (a) of Directive 2001/83 EC or Article 705 of Law No. 95/2006, as further 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 No. 95/2006, as further 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 with the initial application [Article 10 (b) of Directive 2001/83 EC or Article 706 of Law No. 95/2006, as further 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 with the initial application [Article 10 (b) of Directive 2001/83 EC or Article 706 of Law No. 95/2006, as further 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 No. 95/2006, as further 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 with the initial application [Article 10 (c) of Directive 2001/83 EC or Article 707 of Law No. 95/2006, as further 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 with the initial application [Article 10 (c) of Directive 2001/83 EC or Article 707 of Law No. 95/2006, as further amended]	1,130
27.	Marketing authorisation renewal of medicinal products through mutual recognition procedure or decentralised procedure with Romania as Concerned Member State	2,100
27.a)	Renewal of medicinal product marketing authorisation through the mutual recognition and the decentralised procedure with Romania as Reference Member State	4,305
C.	**Approval of clinical trials and 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 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 and Type IA variations describing the group for medicinal products authorised through national procedure	300
36.	Approval of Type IB variations and Type IB variations describing the group for medicinal products authorised through national procedure	500

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

	NOTICE 1. The fee is paid for each variation to each marketing authorisation. 2. In case of grouped variations, different fees for the main variation in the group (defining the group) and the rest of variations included in the group are applicable. 3. The total fee to be paid in case of grouping is calculated for each marketing authorisation, by summation of the fee for the variation that defines (describes) the group and the fee for variation included in the group applied to each variation in the group, other than the variation defining the group. 4. The fee for the variation defining (describing) the group is the fee for the variation to the marketing authorisation	
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
54.	Approval of variations to parallel import authorisations	250
F.	**Assessment of documentation for scientific opinion / change of scientific opinion on ancillary active substance(s) incorporated as an integral part in the medical device**	
55.	Scientific opinion on ancillary active substance(s) incorporated as an integral part in the medical device for substances not previously assessed by the NAMMD	2.660
56.	Scientific opinion on ancillary active substance(s) incorporated as an integral part in the medical device for substances previously assessed by the NAMMD with a different manufacturer	1.330
57.	Scientific opinion on ancillary active substance(s) incorporated as an integral part in the medical device for substances previously assessed by the NAMMD with the same manufacturer	535
58.	Change of scientific opinion on ancillary active substance(s) incorporated as an integral part in the medical device for substances not previously assessed by the NAMMD	665
59.	Change of scientific opinion on ancillary active substance(s) incorporated as an integral part in the medical device for substances previously assessed by the NAMMD with a different manufacturer	335
60.	Change of scientific opinion on ancillary active substance(s) incorporated as an integral part in the medical device for substances previously assessed by the NAMMD with the same manufacturer	250
G.	**Health technologies assessment**	
61.	Assessment of documentation for grant of approval for medicinal product inclusion into the list of free-of-charge and compensated products provided to insured persons irrespective of personal contribution	1.304