The Ministry of Health

ORDER No. 3.467
of 17 November 2022
on approval of the tariffs for the activities carried out by the National Agency for Medicines and Medical Devices of Romania (NAMMDR) in the field of medical devices

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On seeing Approval Report no. AR 20.535/2022 of the Pharmaceutical and Medical Devices Directorate and the notification of the National Agency for Medicines and Medical Devices of Romania no. 59.726E of 30.09.2022, registered at the Ministry of Health with no. P 1.146 of 3.10.2022,

Considering the provisions of:

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC;

- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU;

- Art 4 (4), Art. 9 b) and Art. 17 (1) and (2) of Law no. 134 of 12 July 2019 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions;

- Art. 930 of Law 95/2006 on healthcare reform, republished, with further amendments and supplementations;

- Art. 6 (2), Art. 11 (2), Art. 16 (2), Art. 21 (2) a) and (6) and of Art. 27 of Emergency Government Ordinance no. 46/2021 on establishment of an institutional framework and measures for enforcement of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, in line with Art. 7 (4) of Government Decision no. 144/2010 on the organisation and operation of the Ministry of Health, as further amended and supplemented,

the minister of health hereby issues the following order:

Art. 1 - The tariffs for the activities carried out by the National Agency for Medicines and Medical Devices of Romania (hereinafter the NAMMDR) in the field of medical devices are approved, in line with Annex 1 which is an integral part of this Order.

Art. 2 - (1) The applicants for services provided by the NAMMDR in the field of medical devices have the obligation to pay in lei the tariffs provided in Annex 1.

(2) The tariffs provided in Annex 1 are paid prior to the registration of applications for the provision of the requested services, unless otherwise provided by the regulatory documents that regulate them.

(3) The tariffs provided in Annex 1 are paid by the applicant or by any other person on the applicant's behalf. Payment documents are issued in the applicant's name.

(4) Failure to pay the tariff corresponding to the requested services leads to the rejection of the request.

(5) Incomplete pricing detected after registration of the application leads to the issuance of a supplementary note regarding the difference of tariffs, drawn up as shown in Annex 2 which is an integral part of this Order. The request is thus rejected, unless the tariff is not completed within 30 days following the notification.

(6) The tariffs paid for rejected applications are not refunded.

Art. 3 - The tariffs provided in Annex 1 are indexed annually, until 31 January, according to the average inflation rate of the previous year, in line with the data published by the National Institute of Statistics, starting from January 2024.

Art. 4 - (1) Travel expenses, respectively accommodation and transport, for the provision of the services provided for in points 2.1 - 2.3 and 6.1 - 6.9 of Annex 1 shall be paid by the applicant.

(2) The expenses provided for in (1) are the subject of a tax invoice, which is issued after the trip. In order to sign and submit the final documents to the beneficiary, this invoice must be paid within 15 days following issuance.

Art. 5 - (1) The tariffs mentioned in Annex 1, points 6.1 - 6.9, are paid for the verification or testing of a single medical device.

(2) The tariffs provided for in points 6.2 - 6.3 and 6.10 - 6.12 of Annex 1 apply accordingly for medical devices from the endowment of means of intervention for pre-hospital emergency medical assistance.

Art. 6 - (1) As regards the approval, renewal or addition of an activity to the assessment activity, the tariffs specified in Annex 1 are valid for a single activity or a single work point, as the case may be.

(2) Non-profit registered offices are not charged.

(3) For applicants who carry out several activities: starting with the second activity, 50% of the tariff applied to the first activity is charged.

(4) For applicants with several work points carrying out the same activity, starting with the second work point, 50% of the tariff applied to the first work point, mentioned in the same application, is charged. For more than 10 work points, starting with the 11th work point, 25% of the tariff applied to the first work point mentioned in the same application is charged.

(5) The tariff for reassessment of the activity in case of an unfavourable assessment report is 50% of the basic tariff established for the assessment.

(6) The import activity is only charged once.

(7) After two reassessments carried out as a result of the application for request of non-tariff additions, any new reassessment imposes a new tariff in the amount of 50% of the initial tariff.

Art. 7 - (1) In case of withdrawal of an application prior to transmission by the NAMMDR of the request to complete the final document(s), respectively the assessment report, the periodic verification bulletin, the approval for use, the registration certificate, the free sale certificate or other such documents, the NAMMDR withholds 10% of the total paid value of the tariff.

(2) In case of withdrawal of the request after the NAMMDR has sent the request to complete the documents, the NAMMDR retains 50% of the total paid amount of the tariff.

(3) In case of withdrawal of an application after the NAMMDR has drawn up the final document, the work is considered completed, and the NAMMDR retains the full amount paid.

Art. 8 - On the date of entry into force of this Order, Order of the Minister of Health no. 1.356/2013 on approval of fees of the National Agency for Medicines and Medical Devices for medical devices-related activities, published in the Official Gazette of Romania, Part I, no. 710 of November 19, 2013, is repealed.

Art. 9 – This Order shall be published in the Official Gazette of Romania, Part I.

On behalf of the Minister of Health,
Romică-Andrei Baciu,
Secretary of state

Annex 1

TARIFFS
for medical devices-related activities carried out by the National Agency for Medicines and Medical Devices of Romania

No.	Name of the activity carried out by the National Agency for Medicines and Medical Devices of Romania (NAMMDR)	Tariff - lei -
1.	**Regulatory activities**	
1.1	Issuance of a customs notice (per product)	120
1.2	Grant of an out-of-scope notice (per product)	120
1.3	Issuance of a free-sale certificate (1 – 10 items)	1240
1.4	Standard classification of a product (one product per request)	2840
1.5	Contesting a classification	2840
1.6	(Complex) classification of a borderline product	4740
1.7	Issuance of a certificate of registration of medical devices into the national database (maximum 5 products)	1310
1.8	Assessment of the notification file for medical devices manufactured and used in public or private healthcare facilities (per product)	1310
1.9	Assessment of the notification file of a change in medical devices manufactured and used in public or private healthcare facilities	350
1.10	Registration of changes brought to information from the medical devices database (maximum 5 items)	350
1.11	Tariff for searching into the national database	220
1.12	Validation/Verification of registration into the European Database of Medical Devices (Eudamed)	220
2.	**Designation/Monitoring body for assessment of compliance of medical devices**	
2.1	Designation of a body assessing the compliance of medical devices: analysis of request/documentation of the applicant and assessment/designation/notification of body	40800
2.2	Extension of notified body domains	24970
2.3	Notified body supervision (annual monitoring)	24150
3.	**Clinical investigation**	
3.1	Assessment of the documentation in order to issue an authorisation for clinical investigation with active implantable medical devices, class III, IIb, invasive medical devices and similar devices mentioned	20450

	in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (MDR)	
3.2	Assessment of documentation in order to validate applications for clinical investigation with class IIa and IIb medical devices, non-invasive and similar devices mentioned in Annex XVI to the MDR	18030
3.3	Assessment of the documentation in order to validate applications for clinical investigation with class I and IIa medical devices, non-invasive and similar devices mentioned in Annex XVI to the MDR	8770
3.4	Assessment of substantial and technical amendments for approved clinical investigation with medical devices and similar devices from Annex XVI to the MDR and substantial amendments for a clinical study assessing the performance of an in vitro diagnostic medical device (IVD)	5930
3.5	Assessment of administrative amendments for approved clinical investigation with medical devices and similar devices from Annex XVI to the MDR and non-substantial amendments for an IVD performance assessment study	2620
3.6	Assessment of the resubmission in order to issue an authorisation for clinical investigation whose application was withdrawn or rejected, for medical devices, similar devices from Annex XVI to the MDR and for IVD	6780
3.7	Assessment of the documentation and issuance of the authorisation for the assessment of the performance for IVD, self-testing and classes C and D of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (IVDR)	13710
3.8	Assessment of documentation and issuance of authorisation for assessment of performance for IVD of classes A and B of the IVDR	11200
3.9	Assessment of the documentation for the authorization of performance studies for in vitro diagnostic devices using leftover samples [Art. 58 (2) of the IVDR]	6080
3.10	Assessment of documentation for PMCF notification (MDR) and PMPF notification (IVDR)	1880
4.	**Activities for approval of advertising**	

4.1	Approval of advertising material for medical devices NOTE: Tariff set for visas with a validity of 6 months from the date of issuance. The applicant can propose a validity period of maximum 1 year.	2720
4.2	Approval of educational material for medical devices NOTE: Tariff established for visas with a validity of 6 months from the date of issuance. The applicant can propose a validity period of maximum 1 year.	1730
5.	**Activities for approval of economic operators who carry out activities related to import/distribution/installation/maintenance**	
5.1	Assessment of issuance/renewal/modification of operating approval by adding the activity of importing medical devices or by adding the activity of distributing medical devices for:	
	a) 1 - 10 manufacturers	1480
	b) 11 - 30 manufacturers	1730
	c) 31 - 50 manufacturers	1980
	d) 51 - 100 manufacturers	2230
	e) more than 100 de manufacturers	2620
5.2	Assessment of release/renewal/modification of operating approval by adding the activity of installation and/or maintenance of medical devices for:	
	a) 1 - 10 groups of medical devices	1660
	b) 11 - 30 groups of medical devices	1900
	c) 31 - 50 groups of medical devices	2150
	d) more than 50 de groups of medical devices	2320
5.3	Assessment of the modification of the operation approval by adding a work point	990
5.4	Assessment of change of name of economic operator/change of address of non-profit social headquarters	330
5.5	Assessment of amendment of the approval by adding manufacturers for which the economic operator has the status of importer/distributor/authorised representative in the European Union, for a number of:	
	a) 1 - 10 manufacturers	490
	b) 11 - 30 manufacturers	1040
	c) more than 30 de manufacturers	1760
5.6	Assessment of deletion of manufacturers for which the economic operator had the status of importer/distributor/authorised representative in the European Union and deletion of work point	40
5.7	Issuance of operation approval/annex to the operation approval	310
5.8	Issuance of an original document upon request of the applicant	40
6.	**Medical devices tests**	

6.1.	Electric safety tests for electromedical devices, including those related to radiation-producing medical devices	250
6.2	Performance tests for electromedical devices, including those related to radiation-generating medical devices	180
6.3	Performance tests for non-electric medical devices	100
6.4	Tests according to the acceptability criteria of the National Commission for Nuclear Activities Control (CNCAN) for: post graph fixed Rx, post scopy-graphy fixed Rx, two stations fixed Rx, graph mobile Rx, scopy-graphy mobile Rx with C-arm (including lithotripter), Rx mammography, Rx angiograph*), panoramic dental Rx, osteodensitometer*), radiation simulator in therapy*)	1000
6.5	Tests according to CNCAN acceptability criteria for: - intraoral dental x-ray device*) - nuclear medicine devices*)	800
6.6	Tests according to CNCAN acceptability criteria for: - computer tomograph*) - nuclear magnetic resonance equipment*) - computer tomograph simulator*) - equipment for direct digital imaging*) - linear accelerator*) - cobaltron*) - HDR brachytherapy equipment*) - brachytherapy equipment with reduced dose rate*) - irradiator*)	1500
6.7	Verification of radiation protection equipment	100
6.8	Performance of radiography for radiation protection equipment	20
6.9	CNCAN authorisation/reauthorisation checks	30% of the value of the basic tariff
6.10	Assessment of the documentation in order to issue a periodic check bulletin	50
6.11	Issuance or modification of the approval for use/periodic check bulletin	20
6.12	Issuance upon request of the applicant of an original copy of the test report	40

*) Only in case of issuance of an approval for use after commissioning.

Annex 2

THE NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES OF ROMANIA

NOTE
for filling-in the fee
Request no. ...../date .....

To: ..... (identification data of the service beneficiary) Analysing your request regarding ....., (the name of the service) please fill in the fee paid for the above-mentioned request and pay the following amount: .... The deadline for resolution of this request will be extended accordingly from the date of transmission of the full payment of the tariff.

President
of the National Agency for Medicines and Medical Devices of Romania,

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