ORDER no. 566/2020

on approval of the Methodological rules for application of Title XX of Law 95/2006 on healthcare reform, regarding the approval of activities in the field of medical devices

Amendments (...)

Text published in the Official Gazette of Romania

In force since 08 April 2020

On seeing Approval report no. NT 526 of 3.04.2020 of the Pharmaceutical and Medical Devices Directorate and notification no. 53622E of 25.03.2020 of the National Agency for Medicines and Medical Devices of Romania, registered at the Ministry of Health with no. 16014 of 26.03.2020,

taking into account the provisions of Article 926 of Law 95/2006 on healthcare reform, republished, as further amended and supplemented,

taking into account Decree no. 195/2020 regarding the establishment of the state of emergency on the territory of Romania and Decision no. 9 of 10.03.2020 of the Technical-Scientific Support Group on the management of highly contagious diseases on Romanian territory within the National Committee for Special Emergency Situations,

taking into account the provisions of Article 4 (3) point 1 of Law no. 134/2019 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions;

pursuant to Article 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 Methodological rules for application of Title XX of Law 95/2006 on healthcare reform, regarding the approval of activities in the field of medical devices, provided in the Annex which is an integral part of this Order, are approved.

Art. 2. - The Ministry of Health and the National Agency for Medicines and Medical Devices of Romania, hereinafter the NAMMDR, shall carry out the provisions of this Order.

Art. 3. - On this Order coming into force, Order of the Minister of Health no. 1.008/2016 on approval of the Methodological rules for application of Title XX of Law 95/2006 on healthcare reform, regarding the approval of activities in the field of medical devices, published in the Official Gazette of Romania, Part I, no. 736 of 22 September 2016, as further amended and supplemented, is repealed.

Art. 4. - This Order shall be published in the Official Gazette of Romania, Part I.

Minister of health,

Nelu Tătaru

Bucharest, 3 April 2020

No. 566.

ANNEX

METHODOLOGICAL RULES

for application of Title XX of Law 95/2006 on healthcare reform, regarding the approval of activities in the field of medical devices

The methodological rules for application of Title XX of Law 95/2006 on healthcare reform, regarding the approval of activities in the field of medical devices of 03.04.2020

Art. 1. - These methodological rules establish the general criteria for assessing the competence and ability of economic operators to carry out the activities for which they request the approval provided for in Art. 926 (2) of Law 95/2006 on healthcare reform, republished, as further amended and supplemented.

Art. 2. - Marketing and service activities in the field of medical devices subject to approval control are:

a) import of medical devices;

b) distribution of medical devices;

c) installation and/or maintenance of medical devices.

Art. 3. - For the purposes of this Order, the terms and notions employed have the following meanings:

a) economic operator - authorised natural or legal person who, as part of his/her professional activity, imports, distributes or provides installation and maintenance services for medical devices;

b) importer - any natural or legal person established in Romania or in another member state of the European Union who introduces a medical device from a third country on the Romanian market;

c) distributor - any natural or legal person in the supply chain, other than the manufacturer or importer, who makes medical devices available in the course of a commercial activity. The distribution activity also includes activities related to the purchase, holding and wholesale or retail supply of medical devices, including distance sales of medical devices;

d) supply - making available on the market, for a fee or free of charge, a device, other than a device subject to a clinical investigation, for the purpose of distribution, consumption or use on the Romanian market, in the course of a commercial activity;

e) installation - putting into service and performance of checks/tests, according to the manufacturer's manual, in order to ensure the proper functioning of a medical device;

f) maintenance - all maintenance and repair operations of a medical device;

g) manufacturer - a natural or legal person who designs or fully refurbishes a medical device or manages the design, manufacture or complete refurbishing of that device and markets it under its name or brand;

h) authorised representative - any natural or legal person established within the European Union who has received and accepted a written mandate from a manufacturer located outside the EU, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under the legislation specific to medical devices.

Art. 4. - The operation approval and its Annexes are issued by the National Agency for Medicines and Medical Devices of Romania (NAMMDR), in accordance with the provisions of title XX of Law 95/2006, republished, as further amended and supplemented.

Art. 5. - (1) The operation approval is issued upon request of the economic operator and registered into the NAMMDR database.

(2) In order to obtain/renew the operation approval, the applicant submits an application to the NAMMDR, in line with the pattern provided in Annex 1 to these Rules.

(3) The request provided for in paragraph (2) shall be accompanied by the documents provided in the specific description of the approved activity, according to the model provided in Annexes 2 or 3 to these Rules, as the case may be.

(4) The NAMMDR may additionally request technical documents provided for in the legislation applicable to the type of imported/distributed device.

(5) In the case of pharmaceutical units, for which the Ministry of Health has issued an operating authorization, in accordance with the law, an operation approval is no longer issued for the import and distribution of medical devices.

Art. 6. – The operation approval for the activities provided for in Article 2 is issued based on the documents provided for in Article 5 (3) and in the assessment report drawn up by the NAMMDR.

Art. 7. - For the approval of the activities provided for in Article 2, the NAMMDR, based on its own procedure and the documents provided for in Article 5 (3), assesses the applicant's competence and ability to perform the respective activities.

Art. 8. - In order to obtain an operation approval, the economic operator must cumulatively meet the following requirements:

a) to have an adequate location, which must be exclusively used for carrying out the activity requested for approval;

b) to be equipped with equipment suitable for carrying out the activity requested for approval;

c) to have sufficient and qualified/trained staff for the activity he/she carries out/the field in which he/she operates.

Art. 9. - (1) The economic operator must have at their disposal, within their organisation, the services of at least one person responsible for ensuring compliance with the regulations specific to the field of medical devices, applicable to the activity carried out by the economic operator, who possesses the necessary expertise in this field.

(2) The necessary expertise in the field of medical devices, provided for in paragraph (1), is carried out on the basis of the following documents, cumulatively:

a) diploma, certificate or other evidence of formal qualification, awarded upon completion of university studies or a cycle of studies recognised in Romania as equivalent, in law, medicine, pharmacy, engineering, chemistry, physics or other scientific discipline applicable in the field of devices medical, as well as at least one year of professional experience in regulatory activities or in quality management systems in the field of medical devices;

b) diploma, certificate or other document awarded upon completion of continuous training courses with the subject of medical devices legislation.

(3) The training courses shall be carried out by authorised natural and legal persons whose object of activity is to provide the training provided for in paragraph (2) b)

and who provide proof of professional experience in regulatory or compliance assessment activities for medical devices as follows:

a) in regulatory activities with a professional experience of at least four years in the field of medical devices or participation in working groups specific to medical devices at the level of the European Commission/EU Council;

b) in medical device compliance assessment activities within a compliance assessment body notified on the specific medical device directives, for at least two years.

(4) The person responsible for ensuring compliance with medical devices regulations and the head of the warehouse, as applicable, must demonstrate continuous training in the field of medical devices legislation.

(5) Continuous training means training at least every two years. In case of significant legislative changes in the field of medical devices, proof of training shall be provided, including in the situation where the time interval between two trainings is shorter than two years.

(6) The person responsible for compliance with regulations specific to the field of medical devices is responsible for verifying, prior to making a medical device available on the market, whether the following requirements are met cumulatively:

a) whether the device has been CE marked as a result of the conformity assessment procedure and whether the CE declaration of conformity of the device is issued;

b) whether the device is accompanied by the information which must be provided by the manufacturer;

c) in the case of imported devices, whether the importer/authorised representative is identified on the product label;

d) if, as long as the device is under the distributor's responsibility, the storage or transport conditions comply with the conditions established by the manufacturer;

e) if the legal requirements applicable to the medical device in question are met.

(7) For the installation and/or maintenance of medical devices, the economic operator must have staff with a bachelor's degree in university studies with a duration of at least 4 years in the field of exact and engineering sciences (physics, chemistry, biochemistry, etc.), who occupy the position of engineer/physicist/chemist, and/or

with secondary education - for staff holding the position of technician, and has specific duties mentioned in the job description.

(8) Staff with specific duties of installing and/or maintaining medical devices must provide proof of participation in professional training and training courses for each group of medical devices requested for approval.

(9) The courses provided for in paragraph (8) are supported by trained technical staff:

a) of a manufacturer/representative of a manufacturer;

b) from professional associations in the field of medical devices; or

c) of the economic operators approved by the NAMMDR, if their object of activity is the conduct of training courses.

(10) In order to be able to support the courses provided for in paragraph (8), the staff referred to in paragraph (9) b) and c) must provide proof of participation in professional training and training courses supported by the manufacturer/representative of the manufacturer, for each group of medical devices for which he/she supports these courses.

Art. 10. - (1) Within a maximum of 90 days from the registration of the application, the NAMMDR forwards to the applicant the value of the assessment tariff calculated in line with the Order of the Minister of Health approving the tariffs charged by the NAMMDR for activities related to medical devices.

(2) Failure to pay the tax invoice within a maximum of 60 days after being forwarded leads to the filing of the file and a filing decision is issued by the NAMMDR president.

(3) The assessment of the file is done within a maximum of 120 days from confirmation of the payment.

(4) If the documentation is incomplete or a document does not comply with the applicable legal requirements, completion of the file shall be requested.

(5) If the documentation is not completed within a maximum of 30 days from the request for completion of the file, the file is classified and the NAMMDR president issues a filing decision.

(6) A new request requires the resumption of the procedure in line with paragraph (1).

(7) Following two reassessments carried out as a result of completing the file in line with paragraph (4), non-tariffed, any new reassessment requires a new tariff consisting of 50% of the initial tariff.

(8) The assessment is completed with an assessment report.

(9) In the case of an unfavourable assessment report, an appeal can be made to the NAMMDR within a maximum of 5 days from the receipt of the report by the applicant. NAMMDR's decision regarding the resolution of the appeal is communicated to the applicant within 30 days of its receipt; the decision issued in the resolution of the appeal can be appealed to the administrative court.

(10) In case of a favourable assessment report, the operation approval is issued by the NAMMDR within a maximum of 15 days from the date of drawing up the assessment report.

Art. 11. - (1) The NAMMDR can carry out unexpected inspections of economic operators carrying out the activities provided for in Article 2 in order to verify the authenticity of what is declared in the documentation provided for in Article 5 (3) or as often as needed.

(2) If, following unexpected controls, major noncompliances are detected (such as unqualified/untrained staff, improper storage site, carrying out unauthorised activities, distribution of non-compliant medical devices, etc.), the operation approval is suspended until the elimination of noncompliances, for a maximum period of 3 months.

(3) If, within the deadline provided for in paragraph (2), the detected noncompliances are not remedied, the NAMMDR cancels the issued opinion and a decision to cancel the operation approval is issued by the NAMMDR president.

(4) During the period of suspension of the approval, it is submitted in original format to the NAMMDR, within a maximum of 5 days from the date of communication of the suspension, and the suspension period is mentioned in an Annex to the approval.

(5) Carrying out the activity during the suspension period is prohibited. Otherwise, the approval is cancelled and a decision for cancellation of the operation approval is issued by the NAMMDR president.

(6) Cancelled approvals must be submitted in original to the NAMMDR within 5 days from the date of communication of the cancellation decision.

Art. 12. - (1) The operation approval for economic operators carrying out activities in the field of medical devices is issued in the format presented in Annex 4 to these Rules, in two original copies: one shall be given to the applicant, and the other shall remain in the records of the NAMMDR.

(2) The following facts are specified in the operation approval:

a) the activities performed (import, distribution and/or installation and maintenance of medical devices);

b) the manufacturers for which the unit is an importer and/or distributor;

c) the manufacturers for which the unit is an authorised representative;

d) the categories and groups of medical devices for which medical device installation and maintenance work is performed.

(3) The data provided for in paragraph (2) is recorded in the operation approval following the evaluation of the applicant's statements, the documents presented and the assessment report.

Art. 13. - (1) Operation approvals issued in accordance with these methodological rules are valid for a 3-year period from the date of issuance, provided that the conditions which represented the basis for approval remain unchanged.

(2) Economic operators who hold an operation approval have the obligation to notify the NAMMDR of any change, including the interruption of collaboration with a manufacturer from the list specified in the approval, which occurs after obtaining the operation approval, within a maximum of 30 days from the date of this change.

(3) The changes provided for in paragraph (2) are recorded in an Annex to the initial operation approval, based on the application form provided in Annex 5 to these Rules.

Art. 14. - The change of the registered office or of the name of the economic operator, the establishment/deletion of operational offices, the termination of the activity are recorded in the Annex to the operation approval based on the documents issued by the trade register office or another official document or regulatory document attesting to these changes.

Art. 15. - The extension of the scope of activities related to import, distribution or installation and maintenance activities or the establishment of new operational

offices where these activities are carried out is recorded in the Annex provided for in Article 13 (3) based on the assessment report drawn up by the NAMMDR.

Art. 16. - (1) The application for the renewal of the operation approval must be submitted to the NAMMDR at least 6 months before its validity expires. Otherwise, the approval procedure provided for in Article 5 shall be resumed.

(2) The request provided for in paragraph (1) shall be accompanied by the documents provided in the specific description of the approved activity, according to the model provided in Annexes 2 or 3 to these Rules, as the case may be.

(3) The renewed operation approval is valid for 3 years, if the conditions that were the basis of the renewal remain unchanged.

Art. 17. -(1) The temporary interruption for a period of at least one year or the cessation of activities in the field of medical devices must be communicated to the NAMMDR within 30 days from the temporary interruption or from the termination of the activity, in which case the NAMMDR president will issue a decision for temporary interruption or cessation of the activity, as the case may be.

(2) In the case of an application for cessation of the activity, the holder must submit the original approval to the NAMMDR in maximum 30 days from cessation of activity.

Art. 18. - Operation approvals issued before the date of entry into force of these methodological Rules, based on Order of the Minister of Health no. 1.008/2016 on approval of the Methodological Rules for the application of title XX of Law 95/2006 on healthcare reform, regarding the approval of activities in the field of medical devices, as further amended and supplemented, remain valid for a period of 2 years and 6 months from the date of issue or 3 years from the date of issue, if an application for renewal has been submitted.

Art. 19. -(1) In the event of the establishment of a state of emergency on the territory of Romania by decree of the President of Romania, the NAMMDR will issue a temporary operation approval in order to ensure the availability of the absolutely necessary medical devices in that particular situation.

(2) Temporary operation approvals are identified by the initial T preceding the number of the operation approval.

(3) By exception to the provisions of Article 5(3), the application shall be accompanied by the specific description of the approved activity, in line with the model provided in Annex 6 to these Rules.

(4) By exception to the provisions of Article 10, the procedure for issuance of a temporary operation approval shall be carried out as an emergency. The temporary operation approval shall be issued within a maximum of 7 days from submission of all the required documents and confirmation of payment of the tax invoice.

(5) By exception to the provisions of Article 13, the validity period of the temporary approval is of 6 months. By the end of the 6-month period, the applicant shall submit the other documents that were exempted in accordance with paragraph (3), in order to issue the final operation approval, in line with all the requirements of this Order.

Art. 20. - Annexes 1-6 are an integral part of these methodological Rules.