The Ministry of Health

ORDER No. 3969
of 28 December 2022
on approval of the Methodological Rules for assessment, designation and notification of the bodies assessing medical device compliance, as well as for monitoring and reassessment of notified bodies

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On seeing approval report no. A.R. 23.856 of 28.12.2022 of the Pharmaceutical and Medical Devices Directorate and the notification of the National Agency for Medicines and Medical Devices of Romania no. 60.423E of 12.12.2022, registered at the Ministry of Health with no. P1.472 from 13.12.2022,

taking into account the provisions of:

- Article 26 paragraph (6) of Emergency Government Ordinance no. 46/2021 on the establishment of the institutional framework and the measures necessary to ensure the direct application of 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;

- Article 932 paragraphs (1) and (2) of Law 95/2006 on healthcare reform, republished, as further amended;

- Article 4 (4) points 1, 7 and 8 of Law 134/2019 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions, as further amended;

- Article 4 (4) b), Article 5 (1) and Article 8 of Government Ordinance no. 20/2010 regarding the establishment of measures for a uniform application of the European Union legislation harmonising the conditions for product marketing, approved as amended through Law 50/2015, as further amended,

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:

Article 1 - The Methodological Rules for assessment, designation and notification of the bodies assessing medical device compliance, as well as for monitoring and reassessment of notified bodies are approved and can be found in the Annex which is an integral part of this Order.

Article 2 - (1) The National Agency for Medicines and Medical Devices of Romania, hereinafter referred to as the NAMMDR, is the competent authority in the field of medical devices, responsible for the assessment, designation and notification of the bodies assessing medical device compliance, as well as for the monitoring of notified bodies.

(2) The designation and notification procedure are carried out by the NAMMDR in accordance with the provisions of Article 42 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.

(3) The list of the bodies assessing medical device compliance, designated by the NAMMDR in line with this Order, is subject to the approval of the Minister of Health.

Article 3 - The specialized departments of the Ministry of Health and the NAMMDR will carry out the provisions of this Order.

Article 4 - On the date of entry into force of this Order, Order of the Minister of Public Health no. 1699/2006 on approval of the Methodological Norms regarding the designation of bodies performing the compliance assessment of medical devices, published in the Official Gazette of Romania, Part I, no. 8 of January 5, 2007, shall be repealed.

Article 5 – This Order shall be published in the Official Gazette of Romania, Part I.

Minister of Health,
Alexandru Rafila

ANNEX

Methodological rules
on the assessment, designation and notification of the bodies assessing the compliance of medical devices, as well as the monitoring and reassessment of the notified bodies

CHAPTER I
General provisions

Article 1 - The purpose of these methodological rules is to regulate the procedure of assessment, designation and notification of the bodies assessing the compliance of medical devices, as well as the monitoring and reassessment of the notified bodies, for the application of the provisions of Article 26 (6) 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.

Article 2 - The terms used in this Order have the meaning established by Regulation (EU) 2017/745 of the European Parliament and of the Council, hereinafter referred to as the Regulation.

Article 3 - Any legal person based in Romania can be designated as a compliance assessment body, provided that it proves that it can perform specific tasks in relation to the assessment of compliance of medical devices and that complies with the requirements set out in Article 4 of Government Ordinance no. 20/2010 regarding the establishment of measures for the uniform application of the European Union legislation harmonizing the conditions for the sale of goods, approved as amended by Law no. 50/2015, with subsequent amendments, the requirements and criteria applicable to notified bodies, provided in the Regulation, as well as the requirements provided by these methodological rules.

CHAPTER II
Assessment of the application for designation by compliance assessment bodies

Article 4 - Compliance assessment bodies submit to the National Agency for Medicines and Medical Devices of Romania (NAMMDR) the application for designation, whose model is provided on the website of the European Commission, https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcgendorsed-documents-and-other-guidance_en;

Article 5 – The application for designation should be accompanied by the following documents:

a) the list of designation and notification domains, whose model is provided on the website of the European Commission, https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en;

b) the documentation proving the fulfilment of the requirements set out in Annex VII to the Regulation, in Romanian and English;

c) the valid accreditation certificate and the corresponding assessment report, issued by the national accreditation body, in line with the provisions of Regulation (EC) no. 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No. 339/93, in order to demonstrate compliance with the general and organisational requirements, as well as with those related to quality management, provided in Annex VII sections 1 and 2 to the Regulation.

Article 6 - (1) Within 30 days of receiving the application for designation provided for in Article 4, the NAMMDR checks whether the application is complete, stating in the application form whether all documents have been submitted according to the requirements set out in Article 5.

(2) If one or several documents from those provided for in Article 5 were not submitted by the applicant, but the application for designation is considered complete by the NAMMDR, the fact that the submitted documents are not considered sufficient will be justified on the last page of the application form provided for in Article 4.

(3) If the information in the application for designation is not complete, the NAMMDR requests the compliance assessment body to send the missing information within a maximum of 10 days from the date of receipt of the request for completion.

(4) In the event of noncompliance with the term provided for in paragraph (3) or retransmission of incomplete information within the term provided for in paragraph (3), the application for designation is rejected.

(5) The NAMMDR informs the European Commission, immediately, about the rejection of the application for designation, under the conditions provided for in paragraph (4).

(6) A new application for designation requires the resumption of the procedure provided for in Article 5 for the compliance assessment body.

Article 7 - If the application for designation is complete and all documents have been submitted according to the requirements set out in Article 5, the NAMMDR sends them, immediately, to the European Commission, in electronic format.

Article 8 - (1) Following transmission of all the documents submitted by the compliance assessment body to the European Commission, the NAMMDR examines the supporting documents submitted in line with Article 5, according to the procedure approved by the NAMMDR president.

(2) If, following examination, the NAMMDR finds that the supporting documents are not sufficient for carrying out the on-site assessment stage, the NAMMDR requests the compliance assessment body to send the necessary additional information, within a maximum of 10 days from the date of receipt of the request for completion.

(3) In the event of noncompliance with the term provided for in paragraph (2) or of the retransmission of incomplete documents within the term provided for in paragraph (2), the application for designation is rejected.

(4) The NAMMDR informs the European Commission, immediately, regarding the rejection of the application for designation, under the conditions provided for in paragraph (3).

(5) A new application for designation requires the resumption of the procedure provided for in Article 5 for the compliance assessment body.

Article 9 - (1) Following examination of the application for designation and the supporting documents, within a maximum of two months, the NAMMDR draws up a preliminary assessment report (Preliminary assessment review template - PAR), the model of which is published on the website of the European Commission, https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidancemdcg-endorsed-documents-and-other-guidance_en, and sends it immediately to the European Commission, in electronic format.

(2) The assessment team appointed by the European Commission and the Medical Device Coordination Group (MDCG) may request clarifications from the NAMMDR regarding the application for designation and the on-site assessment planned according to the provisions of Article 39 (4) of the Regulation.

(3) The NAMMDR and the joint assessment team plan and carry out an on-site assessment of the applying compliance assessment body and, as the case may be, of any subsidiary or subcontractor, located inside or outside the European Union, which is to be involved in the compliance assessment process. The on-site assessment of the compliance assessment body is conducted by the NAMMDR.

Article 10 - Within a maximum of 30 days after receiving the list of noncompliances resulting from the on-site assessment and the assessment summary developed by the joint assessment team, the compliance assessment body is obliged to submit a corrective and preventive action plan to the NAMMDR.

Article 11 - (1) If, upon examination of the corrective and preventive action plan, the NAMMDR considers one or several proposed actions to be inappropriate, it requests the compliance assessment body to submit, within a maximum of 15 days, an accordingly revised corrective and preventive action plan.

(2) In the event of noncompliance with the term provided for in paragraph (1) or of the transmission of incomplete or inappropriate documents within the term provided for in paragraph (1), the application for designation is rejected.

(3) The NAMMDR informs the European Commission, immediately, regarding the rejection of the application for designation, under the conditions provided for in paragraph (2).

Article 12 - After completion of the on-site assessment stage, provided for in Article 9 paragraph (3), the NAMMDR prepares the final assessment report, which it sends, as the case may be, together with the designation proposal, to the European

Commission, the Medical Device Coordination Group (MDCG) and the joint assessment team.

CHAPTER III
Designation and notification of compliance assessment bodies

Article 13 - The NAMMDR can only appoint compliance assessment bodies for which the assessment provided for in Chapter II has been completed and which meet the requirements set out in Annex VII to the Regulation.

Article 14 - The NAMMDR notifies the Commission and the other member states of the compliance assessment bodies designated in compliance with the provisions of Article 42 of the Regulation.

CHAPTER IV
Monitoring and reassessment of notified bodies

Article 15 - The monitoring and reassessment of notified bodies is carried out by the NAMMDR and the RENAR (the national accreditation body), in accordance with the provisions of Article 44 of the Regulation and the procedure for supervision of the national accreditation body.

Article 16 - (1) Notified bodies must notify the NAMMDR and the national accreditation body, within a maximum of 15 days, of any relevant change which could affect compliance with the requirements set out in Annex VII to the Regulation or their ability to carry out the compliance assessment activities related to the devices for which they were designated.

(2) The notified bodies will inform the NAMMDR about the date for implementation of the change, the copy of the updated document, if the changes concern the documents provided for in Chapter II, and the report of the national accreditation body regarding the impact of these changes on accreditation.

Article 17 - The notified body will send to the NAMMDR copies of the certificates of compliance issued, suspended or withdrawn, in relation to the object of the designation, as well as information on the certificates of compliance not granted.

Article 18 - On an yearly basis, before the 1st of March, the notified body will send to the NAMMDR a written report on the activities undertaken during the previous calendar year, which will contain information on:

a) the certificates issued, suspended, refused or withdrawn, which are related to the fields for which the body was notified, as well as the information which the body is obliged to transmit to the manufacturers, in accordance with the provisions of Article 46 (5) of the Regulation, in case the designation of the body has been suspended, restricted or withdrawn in whole or in part;

b) appeals registered against the body's decisions, including information on how to solve them;

c) the difficulties encountered when carrying out the tasks; own measures undertaken and/or proposed in order to improve the activity;

d) subcontracted activities, subcontractors, measures taken and/or proposed in order to improve these activities.

CHAPTER V
Changes to designations and notifications

Article 19 - Any changes brought to the designation of a notified body, such as the suspension, restriction or partial or full withdrawal of the designation, is carried out in compliance with the provisions of Article 46 of the Regulation and of Article 7 of Government Ordinance no. 20/2010, approved as amended through Law 50/2015, as further amended.

Article 20 - The NAMMDR decision regarding the withdrawal of the designation can be contested by the notified body within 30 days of receiving it; the decision issued in the resolution of the appeal can be appealed to the administrative court.