Minister of Health

ORDER No. 3.277
of 22 September 2023

on amendment of Order of the Minister of Health no. 3.969/2022 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

Published in: the Official Gazette No. 887 of 3 October 2023

On seeing joint approval report no. A.R. 17.319/2023 of the Pharmaceutical and Medical Devices Directorate and of the National Agency for Medicines and Medical Devices of Romania no. 102.652E of 7.02.2023, registered at the Ministry of Health with no. 2/2.628 of 8.02.2023,

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 15 paragraph (6) of Emergency Government Ordinance no. 137/2022 on establishment of the institutional framework, as well as the measures necessary for the implementation of the provisions 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;
- Article 932 paragraphs (1) and (2) of Law 95/2006 on healthcare reform, republished, as further amended and supplemented;
- 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 and supplemented;
- 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 and supplemented,

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. I - Order of the Minister of Health no. 3.969/2022 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, published in the Official Gazette of Romania, Part I, no. 35 of 12 January 2023, is amended as follows:

1. The Order's title is amended and shall read as follows:

"ORDER
on approval of the Methodological Rules for assessment, designation and notification of the bodies assessing medical device and in vitro diagnostic medical device compliance, as

2. Article 1 is amended and shall read as follows:

"Art. 1 - The Methodological Rules for assessment, designation and notification of the bodies assessing medical device and in vitro diagnostic 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."

3. Article 2 is amended and shall read as follows:

"Art. 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 and in vitro diagnostic medical devices, responsible for the assessment, designation and notification of the bodies assessing medical device and in vitro diagnostic 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, hereinafter ***Regulation (EU) 2017/745,*** and with the provisions of Art. 38 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, hereinafter the ***Regulation (EU) 2017/746***.

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

4. The Annex's title is amended and shall read as follows:

"METHODOLOGICAL RULES
on the assessment, designation and notification of the bodies assessing the compliance of medical devices and in vitro diagnostic medical devices, as well as the monitoring and reassessment of the notified bodies"

5. In the Annex, Article 1 is amended and shall read as follows:

"Art. 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 and in vitro diagnostic medical devices, hereinafter ***compliance assessment bodies***, as well as the procedure for monitoring and reassessment of 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, and of the provisions of Article 15 (6) of Emergency Government Ordinance no. 137/2022 on establishment of the institutional framework, as well as the measures necessary for the implementation of the provisions 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."

6. In the Annex, Article 2 is amended and shall read as follows:

"Art. 2 - The terms used in this Order have the meaning established by Regulation (EU) 2017/745 of the European Parliament and of the Council and by Regulation (EU) 2017/746."

7. In the Annex, Article 3 is amended and shall read as follows:

"Art. 3 - Any legal person based in Romania can be designated by the National Agency for Medicines and Medical Devices of Romania ***(NAMMDR)*** 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 in vitro diagnostic medical devices and that complies with the requirements and criteria applicable to the notified bodies referred to in Regulation (EU)

2017/745 or Regulation (EU) 2017/746, as applicable, as well as with the requirements set out in these methodological rules."

8. In the Annex, Article 4 is amended and shall read as follows:

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

9. In the Annex, Article 5 is amended and shall read as follows:

"Art. 5 - The application for designation should be accompanied by the following documents:

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

b) the documentation proving the fulfilment of the requirements set out in Annex VII to Regulation (EU) 2017/745 or Regulation (EU) 2017/746, the case may be, drafted in Romanian or, with the agreement of the NAMMDR, in 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 to Regulation (EU) 2017/745 or Regulation (EU) 2017/746, as applicable."

10. In the Annex, Article 6, paragraph (2) is amended and shall read as follows:

"(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 considered sufficient will be justified on the last page of the application form provided for in Article 4."

11. In the Annex, Article 9 is amended and shall read as follows:

"Art. 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/ guidance- mdcg-endorsed-documents-and-other-guidance_en, and sends it immediately to the European Commission, in electronic format.

(2) Within 14 days following the receipt of the preliminary assessment report, the European Commission, together with the Medical Device Coordination Group (MDCG), shall appoint a joint assessment team which shall examine, within 90 days following appointment, the supporting documents attached to the application for designation of the compliance assessment body and may provide feedback or request clarifications from the NAMMDR on the application and the planned on-site assessment.

(3) The NAMMDR shall transmit to the joint assessment team the requested clarifications regarding the application and the planned on-site assessment, in accordance with the provisions of Article 39(4) of Regulation (EU) 2017/745 or Article 35(4) of Regulation (EU) 2017/746, as applicable.

(4) 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."

12. In the Annex, Article 12 is amended and shall read as follows:

"Art. 12 - After completion of the on-site assessment stage, provided for in Article 9 paragraph (4), 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."

13. In the Annex, Article 13 is amended and shall read as follows:

"Art. 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 Regulation (EU) 2017/745 or Regulation (EU) 2017/746, as the case may be."

14. In the Annex, Article 14 is amended and shall read as follows:

"Art. 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 Regulation (EU) 2017/745 or of Art. 38 of Regulation (EU) 2017/746, as the case may be."

15. In the Annex, Article 15 is amended and shall read as follows:

"Art. 15 - The monitoring and reassessment of notified bodies is carried out by the NAMMDR and the national accreditation body, in accordance with the provisions of Article 44 of Regulation (EU) 2017/745 or of Art. 40 of Regulation (EU) 2017/746, as the case may be, and the procedure for supervision of the national accreditation body."

16. In the Annex, Article 16, paragraph (1) is amended and shall read as follows:

"Art. 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 Regulation (EU) 2017/745 or Regulation (EU) 2017/746, as the case may be, or their ability to carry out the compliance assessment activities related to the devices for which they were designated."

17. In the Annex, Article 18, point a) is amended and shall read as follows:

"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 Regulation (EU) 2017/745 or of Art. 42 (5) of Regulation (EU) 2017/746, as the case may be, in case the designation of the body has been suspended, restricted or withdrawn in whole or in part;

18. In the Annex, Article 19 is amended and shall read as follows:

"Art. 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 Regulation (EU) 2017/745 or of Art. 42 of Regulation (EU) 2017/746 and of Art. 7 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.";

Art. II – This Order is published in the Official Gazette of Romania, Part I.

On behalf of the Minister of Health,
Adriana Pistol,
Secretary of state