ORDER No. 2.882
of 23 December 2021
on the manner of reporting suspected serious incidents related to medical devices

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On seeing the joint report for approval no. AR 2.751 of 23.12.2021 of the Medicinal Product Policy Directorate, of the medical devices and medical technologies directorate and of the National Agency for Medicines and Medical Devices of Romania and notification no. 64.636E of 29.10.2021, registered at the Ministry of Health with no. 1.197 of 1.11.2021,

taking into account the provisions of:

- Art. 9 (4) of Government Emergency 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;
- Art. 932 (1) of Law no. 95/2006 on healthcare reform, republished, as further amended and supplemented;
- Art. 4 (4) points 1 and 18 of Law no. 134/2019 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions, 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:

Chapter I
General provisions

Art. 1 - This order establishes the manner of reporting suspected serious incidents related to medical devices, in accordance with the provisions of Art. 9 (4) of Government Emergency Ordinance no. 46 of 9 June 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.

Art. 2 - 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 centralised registration, at national level, of reports received from healthcare professionals, users and patients.

Art. 3 - The terms used in this Order have the meaning established by 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 referred to as the Regulation.

Chapter II
Reporting suspected serious incidents related to medical devices

Art. 4 - Healthcare professionals, patients and users report to the NAMMDR any suspected serious incident related to the medical devices they handle, within a maximum of 15 days from the date of occurrence of the incident, depending on its consequences.

Art. 5 - Patients or, as the case may be, relatives or legal representatives of patients can inform their physician, the economic operator from whom they have purchased the medical device and the NAMMDR, when they suspect the occurrence of any serious incident, as a result of the use of the respective medical device.

Art. 6 - In order to report suspected serious incidents related to medical devices, healthcare professionals, patients and users shall use the form provided in the Annex which is an integral part of this Order, which they shall afterwards submit to

the NAMMDR, completed with the data requested therein, in electronic format or on paper, using the contact data available on the NAMMDR website, section *"Medical devices" - Vigilance.*

Chapter III
Evaluation of forms for reporting suspected serious incidents related to medical devices

Art. 7 - The NAMMDR submits to the manufacturers of the medical devices in question the forms received from healthcare professionals, users or patients, provided for in Art. 6, as soon as it is informed about them, in compliance with the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC.

Art. 8 - (1) Within a maximum of 10 days after receiving the statement of reasons provided for in Art. 87 (11) paragraph 3 of the Regulation, the NAMMDR informs the manufacturer if it does not agree with the conclusion of the statement of reasons and may request the manufacturer to submit a report in accordance with the provisions of Art. 87 (1) - (5) of the Regulation and to ensure that appropriate monitoring actions are undertaken in accordance with Art. 89 of the Regulation.

(2) If the NAMMDR agrees with the statement of reasons provided for in paragraph (1), it shall inform the persons who have reported the suspected serious incident, presenting the manufacturer's reasons and the result of the final risk assessment.

Chapter IV
Final provisions

Art. 9 - The NAMMDR shall carry out the provisions of this order.

Art. 10 - This order is published in the Official Gazette of Romania, Part I.

On behalf of the Minister of Health,

Romică-Andrei Baciu,
secretary of state

Annex*)
*) The Annex is reproduced in facsimile.

FORM
for reporting suspected serious incidents related to medical devices

AUTORITATEA COMPETENTĂ/COMPETENT AUTHORITY
AGENŢIA NAŢIONALĂ A MEDICAMENTULUI ŞI A DISPOZITIVELOR MEDICALE DIN ROMÂNIA (ANMDMR)/THE NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES OF ROMANIA (NAMMDR)
RAPORTOR/RAPPORTEUR
FORMULAR TRANSMIS DE:/FORM SUBMITTED BY:
Profesionist din domeniul sănătăţii/Healthcare professional ☐
Utilizator/User ☐
Pacient/Patient ☐
Altul - vă rugăm specificaţi/Other - please specify ☐
NUME/NAME:
ADRESA (strada, număr, oraş)/ADDRESS (street, number, city):
TEL.
FAX
E-MAIL
PERSOANA DE CONTACT/CONTACT PERSON:
DATA TRANSMITERII/SUBMISSION DATE:

INFORMAŢII DESPRE PRODUCĂTOR, DISPOZITIVUL MEDICAL ŞI ACCESORIILE ASOCIATE – DUPĂ CAZ/INFORMATION ABOUT THE MANUFACTURER, THE MEDICAL DEVICE AND THE ASSOCIATED ACCESSORIES - AS THE CASE MAY BE
PRODUCĂTOR/MANUFACTURER:
ADRESA (strada, număr, oraş, ţară)/ADDRESS (street, number, city, country):
TIP DISPOZITIV MEDICAL (ex. seringă, stimulator cardiac, pompă de insulină, aparat auditiv, implanturi de diferite tipuri etc.)/Type of medical device (e.g. syringe, pacemaker, insulin pump, hearing aid, various types of implants etc.)
DENUMIRE COMERCIALĂ DISPOZITIV MEDICAL/MEDICAL DEVICE TRADE NAME
MODEL SAU NR. CATALOG (DUPĂ CAZ)/MODEL OR CATALOGUE NUMBER (AS THE CASE MAY BE)
NR. SERIE SAU NR. LOT/SERIAL NUMBER OR LOT NUMBER ***SN -*** ***LOT -***
ACCESORIILE ASOCIATE DISPOZITIVULUI MEDICAL (DUPĂ CAZ) - VĂ RUGĂM PRECIZAŢI/ACCESSORIES ASSOCIATED WITH THE MEDICAL DEVICE (AS THE CASE MAY BE) - PLEASE SPECIFY ***PRODUCĂTOR/MANUFACTURER:*** ***DENUMIRE COMERCIALĂ/TRADE NAME:*** ***MODEL SAU NR. CATALOG (DUPĂ CAZ)/MODEL OR CATALOGUE NUMBER (AS THE CASE MAY BE):*** ***NR. SERIE SAU NR. LOT/SERIAL NUMBER OR BATCH NUMBER***
INFORMAŢII DESPRE PERSOANA(ELE) AFECTATĂ(E) - VĂ RUGĂM SPECIFICAŢI DACĂ ESTE NECESAR PENTRU EVALUARE/INFORMATION ABOUT THE AFFECTED PERSON(S) - PLEASE SPECIFY IF NECESSARY FOR EVALUATION

INIŢIALE PENTRU NUME ŞI PRENUME/INITIALS FOR NAME AND FIRST NAME	
GEN (M - MASCULIN/F - FEMININ)/GENDER (M - MALE/F - FEMALE)	
ANUL NAŞTERII/YEAR OF BIRTH	

INFORMAŢII DESPRE INCIDENTUL GRAV SUSPECTAT/INFORMATION ABOUT THE SUSPECTED SERIOUS INCIDENT	
DATA PRODUCERII INCIDENTULUI/ THE DATE THE INCIDENT OCCURRED	
LOCUL PRODUCERII INCIDENTULUI (spital, cabinet medical, azil de bătrâni, acasă, altul - vă rugăm precizaţi)/ THE PLACE THE INCIDENT OCCURRED (hospital, medical cabinet, asylum for elderly, at home, other - please specify)	

Spital/Hospital |¯|
Cabinet medical/Medical cabinet |¯|
Azil de bătrâni/Asylum for elderly |¯|
Acasă/At home |¯|
Altul - vă rugăm specificaţi/Other - please specify |¯|
DESCRIEREA INCIDENTULUI ŞI A URMĂRILOR PENTRU PACIENT (DACĂ ESTE NECESAR, VĂ RUGĂM UTILIZAŢI PAGINI SUPLIMENTARE)/DESCRIPTION OF THE INCIDENT AND OF THE CONSEQUENCES FOR THE PATIENT (IF NECESSARY, PLEASE USE MORE SHEETS)
VĂ RUGĂM SĂ PRECIZAŢI DACĂ AU FOST CONTACTAŢI PRODUCĂTORUL, REPREZENTANTUL AUTORIZAT ÎN UE AL PRODUCĂTORULUI SAU FURNIZORUL./PLEASE SPECIFY IF THE MANUFACTURER, THE EU AUTHORISED REPRESENTATIVE OF THE MANUFACTURER OR THE SUPPLIER HAVE BEEN CONTACTED. DA/YES |¯| NU/NO |¯|
DESCRIEREA MĂSURILOR CORECTIVE ÎNTREPRINSE - SE COMPLETEAZĂ ÎN CAZUL INCIDENTELOR GRAVE CARE IMPLICĂ UTILIZAREA UNUI DISPOZITIV MEDICAL FABRICAT ÎN CADRUL UNEI INSTITUŢII SANITARE PUBLICE ŞI PRIVATE DIN ROMÂNIA / DESCRIPTION OF CORRECTIVE MEASURES TAKEN – TO BE COMPLETED IN CASE OF SERIOUS INCIDENTS INVOLVING THE USE OF A MEDICAL DEVICE MANUFACTURED WITHIN A PUBLIC OR PRIVATE HEALTHCARE INSTITUTION IN ROMANIA

Semnătura electronică (opţional)/***Digital signature (optional)***

Vă rugăm să aveţi în vedere că ANMDMR vă poate contacta în vederea obţinerii de informaţii suplimentare privind prezentul incident, dacă va fi necesar./***Please be aware that the NAMMDR can contact you in order to obtain supplementary information regarding this incident, if this will be deemed necessary.***

Vă rugăm să aveţi în vedere că prin completarea şi transmiterea acestui formular de raportare vă exprimaţi acordul privind stocarea în siguranţă de către ANMDMR a informaţiilor, inclusiv datelor de contact furnizate în formular. În scopul îndeplinirii cerinţelor legale şi de raportare ale ANMDMR, detalii din acest raport pot fi distribuite şi altor entităţi implicate în activităţi

de monitorizare, în conformitate cu cerinţele de protecţie a datelor. În acest fel informaţiile vor fi disponibile tuturor părţilor interesate. Aveţi dreptul de a cere o copie a datelor personale deţinute de ANMDMR şi a corecta sau elimina orice inexactităţi prezente în acestea./***Please be aware that by completing and submitting this reporting form you express the agreement regarding the safe storage by the NAMMDR of the information, including the contact details provided in the form. In order to fulfil the legal and reporting requirements of the NAMMDR, details from this report may be distributed to other entities involved in monitoring activities, in accordance with the data protection requirements. This way, the information will be available to all interested parties. You have the right to request a copy of the personal data held by the NAMMDR and to correct or eliminate any inaccuracies they may contain.***