Minister of Health no. 5.813 of 29 November 2024
Special Telecommunications Service No. 56 of 12 December 2024

ORDER
on approval of the Methodology for reporting, collecting and processing data, including personal data, regarding stocks, commercial operations, prescription and release of medicinal products for human use, as well as data regarding their distribution outside the Romanian territory, associated operators and persons empowered by the operator, the conditions and limits of access to personal data, the measures and guarantees regarding the security and confidentiality of data and information in the Electronic Reporting System, as well as the manner of fulfilling the required measures in order to inform the concerned subjects on processing operations and the manner of exercising the rights of concerned subjects, in accordance with the provisions of Art. 804[1] paragraph (7) of Law no. 95/2006 on healthcare reform

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On seeing approval report no. 19.523 of 29 November 2024 of the Pharmaceutical and Medical Devices Directorate of the Ministry of Health,

taking into account the provisions of Art. 804[1] (7) of Law 95/2006 on healthcare reform, republished, as further amended and supplemented,

taking into account the following provisions:

- Art. 10 of Law 92/1996 regarding the organization and functioning of the Special Telecommunications Service, as further amended and supplemented;

- 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 and the head of the Special Telecommunications Service hereby issue the following order:

Art. 1 - The Methodology for reporting, collecting and processing data, including personal data, regarding stocks, commercial operations, prescription and release of medicinal products for human use, as well as data regarding their distribution outside the Romanian territory, associated operators and persons empowered by the operator, the conditions and limits of access to personal data, the measures and guarantees regarding the security and confidentiality of data and information in the Electronic Reporting System, as well as the manner of fulfilling the required measures in order to inform the concerned subjects on processing operations and the manner of exercising the rights of concerned subjects is approved, in line with the provisions of Art. 804^1 (7) of Law 95/2006 on healthcare reform, mentioned in the Annex which is integral part of this Order.

Art. 2 - The Ministry of Health, the Special Telecommunications Service, the National Agency for Medicines and Medical Devices of Romania and the National Institute of Public Health shall carry out the provisions of this Order.

Art. 3 - This Order shall be published in the Official Gazette of Romania, Part I, and shall enter into force 10 days after the date of publication.

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

Head of the Special Telecommunications Service,
Ionel-Sorin Bălan

ANNEX

METHODOLOGY

for reporting, collecting and processing data, including personal data, regarding stocks, commercial operations, prescription and release of medicinal products for human use, as well as data regarding their distribution outside the Romanian territory, associated operators and persons empowered by the operator, the conditions and limits of access to personal data, the measures and guarantees regarding the security and confidentiality of data and information in the Electronic Reporting System, as well as the manner of fulfilling the required measures in order to inform the concerned subjects on processing operations and the manner of exercising the rights of concerned subjects, in accordance with the provisions of Art. 8041 paragraph (7) of Law no. 95/2006 on healthcare reform

SECTION I
General provisions

Art. 1 - (1) This Methodology regulates the reporting, collection and processing of data, including personal data, regarding stocks, commercial operations, prescription and release of medicinal products for human use, as well as data regarding their distribution outside the Romanian territory, associated operators and persons empowered by the operator, the conditions and limits of access to personal data, the measures and guarantees regarding the security and confidentiality of data and information in the Electronic Reporting System, as well as the manner of fulfilling the required measures in order to inform the concerned subjects on processing operations and the manner of exercising the rights of concerned subjects, in accordance with the provisions of Art. 804^1 paragraph (7) of Law no. 95/2006 on healthcare reform, republished, as further amended and supplemented, through the Electronic Reporting System, hereinafter referred to as the *SER*.

(2) The main purpose of the SER is to provide the Ministry of Health and the National Agency for Medicines and Medical Devices of Romania, hereinafter referred to as the ***NAMMDR***, with the necessary data in order to obtain an overall situation of the stocks of medicinal products in the National Catalogue of the Prices of Medicinal Products Authorised for Marketing in Romania (also known as the CANAMED), including their traceability, at the level of the entire country, with the aim of contributing to the development of an integrated information and computer system for public health management and facilitating the provision of medicinal products to the population, as well as for monitoring the prescription and release of certain categories of medicinal products, according to the methodologies approved through Order of the Minister of Health.

Art. 2 - Data is reported and collected in the SER in order to ensure the following objectives:

a) viewing on the website of the Ministry of Health, by means of a secure authentication system, both by the Ministry of Health and by the NAMMDR, all information regarding the stock situation for each medicinal product identified as international non-proprietary name (***INN***), trade name and medicinal product identification code (CIM), at the level of country, regions, county, as the latter were established through Law no. 315/2004 on regional development of Romania, as further amended and supplemented, as well as at the level of wholesale distributor and pharmacy;

b) viewing by the public on the website of the Ministry of Health of information regarding the stock situation for each medicinal product identified as INN, trade name, pharmaceutical form and strength, at the level of country, regions and county, as the latter were established through Law no. 315/2004 on regional development of Romania, as further amended and supplemented;

c) The NAMMDR and the Ministry of Health also have secure access to the following information from the SER: the name of the distributor, the quantities delivered of each medicinal product, namely the trade name, CIM, batch, beneficiary name, country of destination of the delivery, date of the commercial operation;

d) tracking intra-community deliveries and exports;

e) providing the information mentioned in Order of the Minister of Health No. 269/2017 regarding the obligation to ensure adequate and continuous stocks of medicinal products, namely the stock for each medicinal product for each wholesale distributor, average monthly turnover at wholesale distributor level, average national

monthly turnover/product and the indicator related to establishing a national alert level;

f) verifying the traceability of medicinal products throughout the distribution chain, from manufacturing to community pharmacy, closed-circuit pharmacy, and preparing reports on the traceability of a batch of medicinal product, respectively the turnover of the medicinal product to the final beneficiary, namely the CIM, trade name, strength, type of packaging, marketing authorisation holder (***MAH***), batch and turnover - quantity, input/output, supplier/beneficiary name, date of commercial operation;

g) providing the information mentioned in Order of the Minister of Health no. 63/2024 on the regulation of the methodology for monitoring the prescription and release at national level of medicinal products in the category of antibiotics and antifungals for systemic use, as further amended.

Art. 3 - (1) Daily reporting is carried out in an encrypted manner, through a web service whose technical specifications are defined by the Special Telecommunications Service, in collaboration with the Ministry of Health and the NAMMDR, and published on the website of the Ministry of Health in the "Stock Monitoring" section.

(2) The information is transmitted daily between 8:00 and 20:00 for the previous day. If multiple reports are received from a work point for the same day, the last report is taken into account.

(3) Authentication to the system and ensuring the authenticity and protection of the identity of reporting entities is achieved through the use of qualified digital certificates. Community pharmacies use digital certificates enrolled in the SIUI. Closed-circuit pharmacies use the certificates of the medical service providers to which they belong. Community pharmacies which are not enrolled in the SIUI, wholesale distribution units of medicinal products, importers and authorised manufacturers enrol qualified digital certificates in the system through an application available on the website of the Ministry of Health.

(4) In case of exceptional and unforeseen technical difficulties, reporting may be done with a maximum delay of 72 hours, reporting cumulatively the operations carried out during the delay period, as well as the stock on the reporting date. Reporting is not required for days when reporting entities do not have a working schedule.

(5) If the reporting is not completed within 72 hours, the system generates an alert and notifies the Ministry of Health and the NAMMDR. In this case, the reporting can

only be done with the agreement of the Ministry of Health and the NAMMDR, as the case may be, cumulatively including the operations carried out during the delay period, as well as the stock on the reporting date, through a method specified by these institutions.

SECTION II

Associated operators and persons empowered by the operator associated operators and persons empowered by the operator for the purpose of collecting and processing data, including personal data

Art. 4 - (1) The Ministry of Health, as a personal data controller and owner of the data included in the SER, processes personal data, in compliance with the provisions of Regulation (EU) 2016/679, as well as Law 190/2018 on implementing measures for 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 (General Data Protection Regulation), as amended.

(2) The personal data collected and processed in the SER are data regarding the identification of the person: name, surname, National Identification Number (CNP) or Digital Identification Code (CID), respectively the identification code of the insured person, passport number or EU/EC card number, age, gender, and data regarding the health condition: diagnosis or pathological condition.

Art. 5 - (1) In exercising their legal duties, the NAMMDR and the National Institute of Public Health have the quality of associated controller for the processing of personal data, collected through the SER, in compliance with the provisions of Regulation (EU) 2016/679, as well as Law no. 190/2018, as amended.

(2) The Special Telecommunications Service, in order to fulfil the legal duties conferred by Law 95/2006 on healthcare reform, republished, as further amended and supplemented, is empowered by the Ministry of Health to carry out operations regarding the processing, collection, registration, organisation, storage, protection, deletion and destruction of personal data processed through the SER.

SECTION III

Conditions and limits of access to personal data and measures regarding data security and confidentiality

Art. 6 - (1) The Ministry of Health, as the owner of the SER data, provides secure access to the data collected through the SER both to specifically designated employees within its own apparatus and to the institutions provided for in Art. 5 (1).

(2) The transmission of access credentials is carried out through the Special Telecommunications Service, following a request sent to the Ministry of Health and approval by its legal representative.

Art. 7 - In order to fulfil the functional duties provided for in Art. 804^1 of Law 95/2006 on healthcare reform, republished, as further amended and supplemented, and other specific duties provided for by the legislation in force, the Ministry of Health and the institutions provided for in Art. 5 designate, according to internal regulations, representatives for the processing of personal data collected through the SER.

Art. 8 - (1) In order to maintain the security of processed personal data, the Ministry of Health and the institutions mentioned in Article 5 shall implement appropriate technical and organisational measures to ensure an appropriate level of security, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage.

(2) The measures referred to in paragraph (1) include, but are not limited to:

a) implementing policies regarding login and password usage for networks and user accounts;

b) the existence of virus protection systems to protect workstations and servers;

c) the existence of procedures regarding protection against accidental destruction or loss of data.

Art. 9 - (1) Persons responsible for processing personal data are obliged to maintain the confidentiality of patient data in accordance with special regulations on the protection of personal data.

(2) The obligation provided for in paragraph (1) also applies to authorised software providers of technical support to units with data reporting obligations.

(3) The persons referred to in paragraphs (1) and (2) are obliged to maintain the confidentiality of the personal data to which they have access even after the termination of the obligation or employment relationship under which they had the right to access this data and information.

(4) The persons referred to in paragraphs (1) and (2) shall sign a confidentiality declaration prior to granting the right to process the data.

(5) The training of persons involved in the processing of personal data in accordance with the provisions of Regulation (EU) 2016/679, as well as of Law no. 190/2018, as amended, the minimum security requirements for the processing of personal data, as well as the risks involved in the processing of personal data is carried out by the personal data protection officer from the Ministry of Health, respectively within each institution provided for in Art. 5 (1).

SECTION IV

Informing concerned persons about processing operations and how to exercise concerned persons' rights

Art. 10 - (1) According to the provisions of Regulation (EU) 2016/679, the concerned person has the following rights:

a) the right of access;

b) the right to rectification;

c) the right to erasure of data ("right to be forgotten");

d) the right to restriction of processing;

e) the right to data portability;

f) the right to object;

g) the right not to be subject to a decision based solely on automated processing, including profiling.

(2) In accordance with the provisions of Art. 17 paragraph (3) letter (c) of Regulation (EU) 2016/679, the right provided for in paragraph (1) letter (c) does not apply.

(3) In order to exercise these rights, concerned persons may submit a written, dated and signed request to the headquarters of the Ministry of Health or to the e-mail address available on the institution's website.

(4) In case of reasonable doubts regarding the identity of the natural person submitting the request for the exercise of one of the aforementioned rights, the Ministry of Health may request the provision of additional information required in order to confirm the identity of the concerned person.

(5) Requests addressed to the Ministry of Health are analysed by the data protection officer, designated at the institution level, in collaboration with the structure involved in personal data processing operations.

(6) The Special Telecommunications Service, as the person authorised to carry out operations regarding the processing, collection, registration, organisation, storage, protection, deletion and destruction of personal data processed through the SER, communicates, at the request of the Ministry of Health, the information necessary to solve the request.

(7) The response to the request of the concerned person shall be made within 30 days of receipt of the request. This period may be extended by two months when necessary, taking into account the complexity and number of requests.

(8) The concerned person shall be informed of any such extension within 30 days of receipt of the request, stating the reasons therefor.

(9) Where the concerned person submits a request in electronic format, the information shall be provided in electronic format, where possible, unless the concerned person requests a different one.

Art. 11 - (1) In the event that the above-mentioned rights of persons whose personal data are subject to processing carried out within the Ministry of Health with reference to the SER are not respected, the latter may submit a complaint to the National Supervisory Authority for Personal Data Processing.

(2) The complaint to the National Supervisory Authority for Personal Data Processing can be made directly or through a representative and cannot be submitted earlier than 30 days after submission of a complaint with the same content to the Ministry of Health.