Order no. 1473
of 22 November 2018

on setup of the framework for implementation of provisions of Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed implementation rules for the features appearing on the packaging of medicinal products for human use

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***) Important Notice:**
For implementation of these Rules please refer to Article 3.

On seeing Approval Report no. SP13.998 of 21.11.2018 of the Medicinal Product and Medical Devices Policy Directorate of the Ministry of Health and Letter of the National Agency for Medicines and Medical Devices no. 47.274E of 10.08.2018, registered with the Ministry of Health under no. 40.909 of 13.08.2018,

Taking into account provisions of Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed implementation rules for the features appearing on the packaging of medicinal products for human use,

In consideration of provisions of Article 775(3) of Law no. 95/2006 on healthcare reform, republished as amended,

Pursuant to provisions of Article 4 (2)a) of Government Decision no. 734/2010 on the organisation and operation of the National Agency for Medicines and Medical Devices, as amended,

Based on Article 7 (4) of Government Decision no. 144/2010 on the organisation and operation of the Ministry of Health, as amended,

the Minister of Health hereby issues the following Order:

Article 1 – This Order establishes the framework for implementation of provisions of Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed implementation rules for the features appearing on the packaging of medicinal products for human use.

Article 2 – The detailed implementation rules for the features appearing on the packaging of medicinal products for human use are hereby approved, as provided in the Annex which is an integral part of this Order.

Article 3 – This Order shall be published in the Official Journal of Romania, Part I.

Minister of Health,
Sorina Pintea

Detailed implementation rules for the features appearing on the packaging of medicinal products for human use

Chapter I
Definitions, general provisions

Section 1
Definitions

Article 1 - (1) For the purposes of these Rules, definitions shall apply as laid out in the Commission Delegated Regulation (EU) 2016/161of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed implementation rules for the safety features appearing on the packaging of medicinal products for human use, hereinafter referred to as the ***Delegated Regulation***, as well as in Law no. 95/2006 on healthcare reform republished as amended.

(2) For the purposes of the Delegated Regulation, the national competent authority is the National Agency for Medicines and Medical Devices (***NAMMD***).

(3) For the purposes of these Rules, the following definitions shall apply:

a) ***packaging*** - outer packaging in accordance with provisions of Article 699 (26) of Law no. 95/2006, republished as amended;

b) The ***Romanian Organization for Serializing Medicines (OSMR)*** – private, non-profit legal entity established pursuant to provisions of Government Ordinance no. 26/2000 on foundations and associations, approved as amended through Law no. 246/2005, as amended, in charge of set up and management of the national repository entitles the National Medicinal Product Verification System (***Sistem naţional de verificare a medicamentelor - SNVM)***;

c) ***the National Medicinal Product Verification System (Sistem naţional de verificare a medicamentelor - SNVM)*** – repository system connected to the European Medicines Verification System (EMVS) in line with provisions of Articles 31 and 32of the Delegated Regulation, established and managed by the OSMR;

d) ***end user location (locaţie utilizator final = LUF)*** – any material or functional location established by the final user accessing the SNVM in order to meet obligations laid out in these Rules;

e) ***batch number*** – number of the manufacturing batch as per Article 774m) of Law no. 95/2006, republished as amended;

f) ***European Medicines Verification Organisation (EMVO)*** - private, non-profit legal entity in charge of set up and management of the national repository entitles the European Medicinal Product Verification System (EMVS);

g) ***the European Medicinal Product Verification System*** (EMVS/European Hub) - central information and data router, set up in accordance with provisions of Article 32 (1)(a) of the Delegated Regulation, established and managed by the EMVO;

h) ***technical connection point (punct tehnic de conectare = PTC)*** – IT terminal connected to the scanner, provided with internet access, on which the digital certificate used for authentication is installed and provided with the installed NMVS connecting application for delivery and receipt of automated messages to/from the NMVS;

i) ***UI*** – unique identifier;

j) ***inactive status*** – status of a decommissioned UI;

k) ***end user (utilizator final = UF)*** - legal entity in charge of verification and/or change by means of the SNVM of a given medicinal product status as identified by an IU, i.e. wholesaler, community pharmacy, local distribution unit, closed circuit pharmacy, drugstore, respectively, dispensing over-the-counter medicinal products/medicinal product categories as included in Annex II to the Delegated Regulation, provided with safety features, and established in any entity authorised by the Ministry of Health for provision of healthcare, with/without closed circuit pharmacy, as well as persons entitled to supply medicines to the public in Romania, as provided for in Article 1n) of Order of the Minister of Health no. no. 131/2016, as amended for approval of the Rules on authorisation of human medicinal product wholesalers, Good Distribution Practice certification and registration of brokers of medicinal products for human use Rules for authorisation of wholesale distributors of medicinal products for human use;

l) ***collective verification or decommissioning*** - concurrent verification or change of status of more than one medicinal product packages provided with an UI, by inclusion of their respective unique identifiers into one single message to the SNVM.

Section 2
General provisions

Article 2 – Pursuant to provisions of the Delegated Regulation, the NAMMD shall publish and update its own website List of medicinal products authorised for marketing with mandatory safety features in accordance with Article 774o) of Law no. 95/2006, republished as amended, and the List of medicinal products authorised for marketing with mandatory anti-tampering device.

Article 3 - (1) These Rules do not apply to medicinal products distributed/supplied pursuant to a special needs authorisation in accordance with provisions of Article 703 (1) or (2) of Law no. 95/2006, republished as amended, in case of suspected/confirmed outbreak with pathogens, toxins, or suspected/confirmed spread of health threatening chemical agents/nuclear radiations.

(2) Medicinal products under (1) and those distributed/supplied based on the donation notice granted by the NAMMD, the Ministry of Health, respectively, in line with provisions of Order of the Minister of Health no. 1.032/2011 for approval of Rules on donations of medicinal products, sanitary materials, medical devices, vaccines, sera and related consumables, as amended, already bearing safety features in accordance with provisions of the Delegated Regulation (EU) 2016/161, persons authorised to distribute/entitled to supply the respective medicines to the general public in Romania shall verify and decommission the UI on medicinal product supply to the patient.

Article 4 – Unique identifier application by manufacturers on medicines out of the scope of the Delegated Regulation is prohibited.

Article 5 – To meet obligations laid out in the Delegated Regulation and these Rules:

a) marketing authorisation holders (MAH) in Romania, parallel import authorisation holders (PIAH) and holders of authorisation for supply of special needs medicines (ASSNM) granted in accordance with provisions of Article 703 (2) of Law no. 95/2006, republished as amended, intended to cover medical needs not covered by already authorised medicines shall connect to the EMVS and the SNVM;

b) in line with provisions of Article 23 of the Delegated Regulation and unless otherwise provided for in national legislation, the end user shall meet all conditions required to connect to the SNVM.

Article 6 – Data elements established for mandatory inclusion in the UI of the medicinal product for marketing in Romania are as follows: product code, batch number, serial number and the expiry, as laid out in Annex 1 to these Rules.

Article 7 - (1) Manufacturers shall print the afore-mentioned elements on the packaging as stipulated in Article 5 (3) of the Delegated Regulation.

(2) The NAMMD only accepts placing of the unique identifier by means of sticker in the following circumstances:

a) No legal and/or technically feasible alternative exists (e.g. safeguard of trademark rights; glass/plastic immediate packaging without outer packaging; etc.); or

b) Mandatory on grounds of public health safeguarding and for ensuring continued supply.

(3) In cases where placing the unique identifier by means of stickers is authorised under the circumstances mentioned under (2), the sticker bearing the UI print shall be applied to the packaging by an authorised manufacturer so as the

above, the sticker should be tamper-evident and it should not be possible to remove it without damaging the packaging; the packaging on which the sticker is placed shall be printed compliant with legal labelling requirements includes.

(4) Placing the unique identifier by means of stickers is not allowed when it impairs readability of labelling information or when the sticker on which the unique identifier is printed is intended to be placed on top of an existing sticker.

Article 8 – The EAN Location Code used for unique identification of the end user entity, of their own allocated LUF and PTC on each LUF shall comply with provisions of ISO/IEC 6523:1998 - *Information technology – Structure for the identification of organizations and organization parts*.

Article 9 - (1) The carrier of the unique identifier, i.e., the graphical representation used to enable automatic reading of the element strings, is the two-dimensional barcode Data Matrix ECC 200 according to the ISO/IEC 16022:2006 Information technology — Automatic identification and data capture techniques — Data Matrix bar code symbology specification.

(2) A template of the Data Matrix ECC 200 two-dimensional barcode allowing for human-readable interpretation printed on a medicinal product packaging is provided in Annex 2, which is an integral part of these Rules.

(3) The symbology identifier for the two-dimensional Data Matrix ECC 200 barcode as mentioned in Annex N of ISO/IEC 16022, is "]d2", pursuant to ISO/IEC 15424, where:

- "]" represents the symbology identifier flag character;
- "d" represents the code character for the Data Matrix symbology;
- "2" represents the modifier character as defined for the Data Matrix ECC 200 symbology.

(4) the Data Matrix ECC 200 two-dimensional barcode uses the “FNC1” codeword in the first position of the data encoded, indicating use of application identifiers according to standard ISO/IEC 15418: 2009. The "FNC1" character symbol also acts as a separator delimiting the variable-length data fields. According to the organisation of data elements specified for the UI, the FNC1 character is only used as a separator for delimiting the second variable length data field.

(5) To express the UI, the ISO/IEC character subset known as the "AI encodable character set 82" is used, whose character size is in line with provisions of Article 10 (4).

Article 10 - (1) Elements included in the UI shall be printed on medicinal product packaging in human-readable format.

(2) Pursuant to provisions of ISO/IEC 1073-II, to achieve human-readable format, the OCR-B type characters set shall be used.

(3) Any UI element is represented on a single row and shall be preceded by the following acronyms, respectively: "PC" for product code, "SN" for serial number, "Lot" or “Batch” for lot/batch number and "EXP" or "Expiry Date” for the date of product expiry.

(4) The size of UI characters shall be as laid out in the European Commission document ENTR/F/2/SF/jr (2009) D/869 - "Guidance on the readability of the labelling and package leaflet of medicinal products for human use", Published in Eudralex Volume 2C.

(5) Data elements play be placed differently on the packaging depending on data elements and the package size. Whenever possible, the product code and the serial number shall be placed on the same side of the packaging.

(6) the acronyms ("PC", "SN", "Lot" or "Batch" and "EXP" or "Expiry Date") may be placed in any position allowing for unequivocal identification of the element represented in human-readable format. Their placement adjacent to or on the same row as the respective element is not mandatory.

Article 11 – A new and unique product code is required whenever at least one of its predefined characteristics are changed, i.e.:

a) trade name;

b) international non-proprietary name;

c) pharmaceutical form;

d) strength;

e) package size;

f) type of UI bearing packaging.

Article 12 – As set out in Article 8 the Delegated Regulation, manufacturers may also include information other than the unique identifier in the two-dimensional barcode carrying the unique identifier, if permitted by the NAMMD; in such instances, additional information included shall be in line with the summary of product characteristics, useful for patients and not contain any advertising.

Article 13 - (1) As stipulated in Article 765 of Law no. 95/2006, republished as amended, parallel import authorisation holders granted pursuant to Order of the Minister of Public Health no. 1.962/2008 on approval of the Procedure for grant of parallel import authorisations for medicinal products for human use, as amended, who delete or in part or entirely cover a product's safety features shall replace them with equivalent ones.

(2) For imported products with changed product code, serial number and/or the expiry date, as compared to the original product, the parallel importer shall only apply the new UI after decommissioning the original UI; the new UI shall meet requirements of these Rules.

Article 14 – The various statuses possible for a UI on decommissioning as outlined in Annex 3, which is integral part of this document and are not exhaustive.

Article 15 - (1) The anti-tampering device shall be placed in such manner on the packaging as to not affect the visibility of the batch number and expiry date after breaking.

(2) The anti-tampering device may be a transparent sticker placed on top of the two-dimensional barcode on condition it does not impact the latter's readability

and information contained within the two-dimensional barcode is not necessary to patients.

(3) In case of packaging provided with an anti-tampering device is lawfully opened by a repackaging manufacturer, this shall be replaced with an equivalent protection device.

(4) In circumstances as mentioned in par. (3), for purposes of surveillance established as required in Article 765 (1)d) of Law no. 95/2006, republished as amended, manufacturers shall provide the NAMMD with information allowing the ascertaining of equivalence between the former and the current anti-tampering devices, such as description, mock-ups, photographs etc. of both devices.

(5) An anti-tampering device placed on top of a broken one, in circumstances as specified under par. (3) is only effective when:

a) The new anti-tampering device completely seals the packaging and covers any visible sign of the original anti-tampering device

b) The replacement of an anti-tampering device is conducted in accordance with provisions of Article 765 (1)c) and d) of Law no. 95/2006, republished as amended;

c) As laid out in Article 765 (1)a) of Law no. 95/2006, republished as amended, the manufacturer placing the equivalent anti-tampering device has verified the authenticity of the unique identifier and the anti-tampering device's integrity on the original pack before breaking the anti-tampering device or opening the original pack

Article 16 - (1) When the UI decommissioning has been conducted by a wholesaler based on provisions of Article 26 of the Delegated Regulation and the person entitled to supply the medicinal product to the public in Romania finds that the anti-tampering device placed on the product packaging to be distributed/supplied is altered, the respective wholesaler shall not release the product for sale or distribution to the public.

(2) In circumstances as those provided under par. (1), when the UI has been decommissioned for no longer than 10 days, the end user shall notify the decommissioning wholesaler on all relevant information able to allow the respective wholesaler to revert the decommissioned UI status to an active status by allocating it the "LOCKED" status. Reversal of UI status shall be in accordance with provisions of Article 13 of the Delegated Regulation.

(3) For circumstances provided under par. (1), the end user shall inform the NAMMD in as stipulated in Article 20.

Article 17 - (1) As laid down in Article 20 of the Delegated Regulation, wholesalers shall verify the authenticity of the unique identifier on product receipt, prior to their introduction into the saleable stock.

(2) For damaged and therefore unreadable two-dimensional barcodes, wholesalers shall check the UI authenticity using the UI human-readable format.

Article 18 – In cases where, as per provisions in force, end users are not allowed to connect internal applications to the internet, in order to meet

obligations set out in the Delegated Regulation and these Implementation Rules, they shall use the graphic user interface established in Article 35(i) of the Delegated Regulation.

Article 19 – Product transfers between closed-circuit pharmacies conducted in line with legislation in force are only allowed for products with active status in the SNVM on dispatch.

Article 20 - (1) Where manufacturers, wholesalers and persons authorised to supply medicinal products to the public in Romania have reason to believe that the packaging of the medicinal product has been tampered with, or the verification of the safety features of the medicinal product indicates that the product may not be authentic, those persons authorised or entitled to supply medicinal products to the public shall not supply the product and shall immediately inform the NAMMD, also supplying all such relevant information as their own contact data, the reasons of their suspicion, documents related to the product purchase etc.

(2) In such situations as specified under par. (1), manufacturers and wholesalers shall handle the product in question as provided for in the procedure laid out in Article 33 of the Guideline on Good Distribution Practice for medicinal products for human use, approved through Order of the minister of Health no. 761/2015; manufacturers and wholesalers shall decommission the UI of the respective product and allocate it the "LOCKED" status.

(3) Pursuant to stipulations of Article 36b) of the Delegated Regulation, after ruling out technical problems in the SNVM, with data entered into the system or verifying end-user related problems, the OSMR shall immediately inform the NAMMD when an alert is triggered in the system.

Article 21 - (1) In line with its own security procedures and as set out in the Delegated Regulation, the OSMR allows SNVM only access to end users after ascertaining their identity, role and authority.

(2) As per Article 37 of the Delegated Regulation, for the purposes of Articles 39 and 44 of the Delegated Regulation, the OSMR provides access to the Ministry of Health and the NAMMD to the repository established and data within.

(3) The OSMR notifies the NAMMD and the Ministry of Health on end users whose members certificates are no longer valid, also specifying the reason thereof.

(4) The NAMMD notifies the OSMR on suspension/revocation of manufacturing/ wholesale authorisations. The NAMMD also informs the OSMR when lifting the suspension/revocation of manufacturing/ wholesale authorisations.

(5) The Ministry of Health notifies the OSMR on suspension/revocation of authorisation for persons authorised to supply medicinal products to the public. The Ministry of Health also informs the OSMR when lifting the suspension/revocation of such authorisations.

Cap. II
Transitional provisions

Article 22 - In accordance with provisions of Articles 18, 24 and 30 of the Delegated Regulation and of Articles 20 and 21 of these Implementation Rules, the obligation to notify competent authorities shall enter into force as of 9 February 2019.

Article 23 – Medicinal products bearing no safety features certified and released for supply before 9 February 2019 by a qualified person in line with provisions of Article 769 of Law no. 95/2006, republished as amended, may be placed on the market, distributed and supplied to the public before their expiry date.

Article 24 – Before of the date of Delegated Regulation entry into force, manufacturers are allowed to apply safety features on medicinal product packaging and their UI shall be entered into the SNVM after it has become operational.

Article 25 – Before 9 February 2019, this date included, end user locations activated in the SNVM production environment shall verify of decommission UIs, as the case may be, for any product handled routinely and provided with a UI by the manufacturer.

Article 26 - All holders of marketing authorisations valid on these Implementation Rules entry into force shall finalise the NAMMD notification process on changes required for marketing authorisations for each product within the scope of Delegated Regulation provisions before 7 December 2018.

Article 27 - To meet requirements of the Delegated Regulation and of these Implementation Rules, by 7 December 2018, all holders of marketing authorisations valid on these Implementation Rules entry into force shall hold a unique GTIN code for each medicinal product within the scope of Delegated Regulation provisions, as defined in Annex 1 to these Implementation Rules, associated to any product code.

Annex No. 1
to Implementation Rules

Elements included in the Unique Identifier (UI) for the market in Romania

a) ***Product Code (PC)***: a globally unique 14 digits string, where the first digit is always 0 (zero), and the following 13 represent the product associated GTIN-13 code (Global Trade Item Number according to ISO/IEC 15459:2014);

b) ***Serial Number (SN)***: variable alphanumeric field containing up to 20 digits;

c) ***Lot/Batch Number***: characteristic combination of numbers and/or letters that specifically identify a manufacturing batch. Batch signifies a defined quantity of starting material, packaging material or product processed in one process or

series of processes so that it could be expected to be homogeneous. This number consists of a variable alphanumeric field containing up to 20 digits.

d) ***Date of Product Expiry (EXP or Expiry Date)***: the point in time when a medicinal product may be used; the number consists of a fixed field of 6 numeric digits in the predefined format of YYMMDD (Year=YY, Month=MM and Day=DD). DD signifies the last day of the month the product expires and may also be reported as "00".

Annex No. 2
to Implementation Rules

The Data Matrix ECC 200 two-dimensional barcode and information in human-readable format printed on medicinal product packaging

The product information in this example signify:
Product Code (PC): 05940010999992
Manufacturing Batch/Lot (Lot/Batch): AMDC14263
Expiry Date (EXP or Date of expiry): 9 February 2019
Serial Number (SN): BRF7XHN6GV6KI
The resulting coded data string is as follows:
FNC1010594001099999210AMDC14263FNC11719020921BRF7XHN6GV6KI

Annex No. 3
to Implementation Rules

Possible UI statuses on decommissioning (non-exhaustive listing)

- " DISPENSED" – for packages dispensed to the public;
- "EXPORTED FROM THE EU" - for packages exported to a third country and has actually left the EU area;

- "SUPPLIED OUTSIDE THE NATIONAL MARKET" - for packages subject to parallel trade;
- "SAMPLE – when the product has been sampled by national authorities;
- "FREE SAMPLE" - for packages provided as free samples;
- "LOCKED" - for packages which may not be supplied to the public;
- "INTENDED FOR DESTRUCTION" - for packages intended for destruction;
- "STOLEN" - for packages identified as reported stolen.