ROMANIA

Newsletter

Year 20, No. 4 (80), 4th quarter 2018

National Agency for Medicines and Medical Devices

ISSN 1583-347X

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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

Published in: The Official Journal No. 1.031 of 5 December 2018

***) 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);

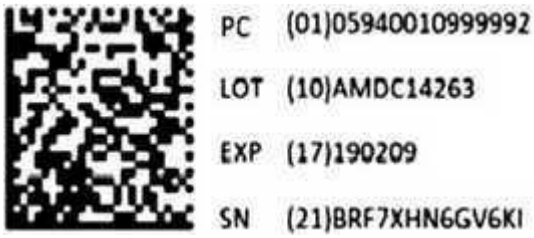
b) ***Serial Number (SN)***: variable alphanumeric field containing up to 20 digits;

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:
FNC10105940010999992 10AMDC14263FNC11719020921BRF7XHN6G V6KI

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.

DECISION
No. 3/24.10.2018
on approval of the Romanian version of the Good Pharmacovigilance Guidelines - Module XVI, Addendum I – Educational Material

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 757/13.06.2018, convened on summons by the NAMMD President in the ordinary session of 24.10.2018, in accordance with provisions of Article 12 (5) of Decision of the Romanian Government no.734/2010 on organisation and operation of the National Agency for Medicines and Medical Devices, as amended,

hereby adopts the following

DECISION

Single article – The Romanian version of the Good Pharmacovigilance Practice – Module XVI – Addendum I – Educational material, is hereby approved according to the Annex which is integral part of this decision.

PRESIDENT
of the Scientific Council
of the National Agency
for Medicines and Medical Devices,

Prof. Anca-Dana Buzoianu, MD, PhD

ANNEX
to Scientific Council Decision
no. 3 /24.10.2018

Note:

The Annex to this Decision is a translation into Romanian and an adaptation of the document EMA/61341/2015, "Guideline on good pharmacovigilance practices (GVP) – Module XVI Addendum I – Educational materials" published by the Heads of Medicines Agencies and the European Medicines Agency. Adaptation consists in reference to respective Romanian healthcare regulatory provisions, transposing EU regulations. Therefore, for the Annex to this Decision, please see https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-good-pharmacovigilance-practices-gvp-module-xvi-addendum-i-educational-materials_en.pdf

DECISION

No. 4/24.10.2018

on Notification by Marketing Authorisation and Manufacturing Authorisation Holders of quality defects to the National Agency for Medicines and Medical Devices

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 757/13.06.2018, convened on summons by the NAMMD President in the ordinary session of 14.06.2018, in accordance with provisions of Article 12 (5) of Decision of the Romanian Government no.734/2010 on organisation and operation of the National Agency for Medicines and Medical Devices, as amended,

hereby adopts the following

DECISION

Article 1. – The template for defective product report is hereby approved for medicinal products for human use authorised through national, mutual recognition and decentralised procedures according to Annex 1 which is integral part of this decision.

Article 2. – The Guideline on use of the defective product report to notify a quality defect to the NAMMD is hereby approved for medicinal products for human use authorised through national, mutual recognition and decentralised procedures according to Annex 2 which is integral part of this decision.

PRESIDENT
of the Scientific Council
of the National Agency
for Medicines and Medical Devices,

Prof. Anca-Dana Buzoianu, MD, PhD

RAPORTARE NECONFORMITATE DE CALITATE

Tipul medicamentului: Medicament de uz uman

Data transmiterii:

1. DETALIILE PERSOANEI CARE TRANSMITE RAPORTUL

Nume	Companie	Reprezentant
		Altele (daca este cazul):
Adresa	E-mail	Numar de telefon

2. DETALIILE PRODUSULUI

	Produs	DCI	Tip APP	No. APP	Concentratie
1					

Forma farmaceutica	Calea de administrare	Forma de prezentare / ambalaj

Fabricantul seriei		Locul de eliberare a seriei		Detinatorul de APP	
Nume		Nume		Nume	
Adresa		Adresa		Adresa	

	Marimea seriei	No. de unitati afectate	Data de expirare	Data de fabricatie	Distributia produsului	Numarul de serie	Limba de inscriptionare a ambalajului
1.1							

3. DETALIILE NECONFORMITATII DE CALITATE

Descrierea neconformitatii de calitate

Categoria neconformitatii de calitate	Descrierea neconformitatii de calitate

Locul unde a avut loc neconformitatea

Nume		Adresa	

4. DETALII PRIVIND INVESTIGATIILE and ACTIUNILE EFECTUATE

Rezumatul investigatiilor

Autoritatea/Autoritatile competenta/e anuntata/e

Reactii/evenimente adverse identificate (raportare conform cerintelor de farmacovigilenta aplicabile)

Actiuni propuse	Justificarea actiunilor propuse

Alta actiune(daca este cazul):

Tipul de retragere propus	Consecintele actiunilor propuse asupra pietei

In cazul in care actiunile agreate vor conduce la intreruperea distributiei produsului pe piata, va rugam sa notificati NAMMD

Descrierea cauzei identificate/ suspectate	Detalii privind posibila cauza identificata

	Actiuni corective/preventive propuse	Data implementarii actiunilor corective/preventive propuse
1		

Furnizati cat de repede posibil raportul investigatiei, inclusiv planul de masuri corective/preventive, raportul de evaluare a riscurilor asupra sanatatii, fotografii, rezultate ale testarii and orice alte documente, daca este necesar

Atasati documente	Atasati raportul investigatiei and alte documente relevante

Categoria companiei
fabricant
deținător de autorizație de punere pe piață
deținător de autorizație de distribuție paralelă
distribuitor angro
alt tip (vă rugăm precizați)

Tip APP
Medicament autorizat prin procedura nationala
Medicament autorizat prin procedura descentralizata
Medicament autorizat prin procedura de recunoastere mutuala

Categoria neconformitatii de calitate
1. Probleme de control de laborator în procesul de fabricatie
2. Contaminarea produsului sau probleme referitoare la sterilitate
3. Probleme de etichetare a produsului
4. Probleme de ambalare a produsului
5. Probleme referitoare la aspectul fizic al produsului

descrierea cauzei neconformitatii de calitate
mediul inconjurator
echipament
eroare umana
materiale
metoda
nedeterminata
altele

Tipul neconformitatii de calitate
1.1 Probleme de control de laborator în procesul de fabricatie
1.2 Rezultate în afara specificațiilor
2.1 Contaminare chimică a produsului
2.2 Contaminare microbiologică a produsului
2.3 Contaminare fizica a produsului
2.4 Contaminare cu fluide biologice a produsului

Actiunea propusa
Supendarea punerii pe piață a produsului
Nicio acțiune de retragere
Carantină
Retragere clasa I
Retragere clasa a II-a
Retragere clasa a III-a

Nivelul retragerii
depozitul companiei
distribuitor angro
pacient
farmacie comunitara/de spital
niciuna

Consecintele retragerii
Niciuna/disponibile alte serii
posibila lipsa de stoc
altele, va rugam specificati

2.5 Lipsa sterilității produsului	Altele (vă rugăm precizați în câmpul de pe rândul următor).
2.6 Suspiciune de transmitere a unui agent infecțios prin intermediul produsului	
3.1 Probleme ale aspectului fizic legate de etichetarea produsului	
3.2 Probleme legate de codul de bare	
3.3 Probleme legate de data de expirare a produsului	
3.4 Probleme legate de numărul de identificare al produsului	
3.5 Probleme cu etichetarea	
3.6 Eticheta unui produs aplicată pe alt produs	
3.7 Probleme cu numărul de lot al produsului	
4.1 Probleme cu ambalarea sub forma de blister	
4.2 Probleme cu sistemul de închidere al produsului	
4.3 Probleme cu amestecarea produselor	
4.4 Probleme cu recipientul produsului	
4.5 Probleme cu sigiliul ambalajului	
4.6 Probleme cu sistemul de picurare	
4.7 Probleme cu ambalajul secundar al produsului	

4.8 Probleme cu ambalarea produsului
4.9 Probleme cu cantitatea de produs ambalat
5.1 Probleme cu acoperirea tabletslor
5.2 Probleme cu formarea de depozite de substanță
5.3 Probleme cu forma de dozare a produsului
5.4 Gelificarea produsului
5.5 Probleme legate de aspectul fizic al produsului

DEFECTIVE PRODUCT REPORT

Medicine Type	Date of submission:
human use	

1. REPORTER DETAILS		
Reporter	Company	Representing
		Other (if applicable):
Address	E-mail	Direct phone number

2. Product details						
1	Product		INN	MA type	MA no.	Strength
Pharmaceutical form		Route of administration			Presentation/packaging	
Manufacturer of the batch		Site of batch release			MA holder	
Name		Name			Name	
Address		Address			Address	

1.1	Batch size	Units affected	Batch no	Expiry date	Manufacturing date	Product distribution	Pack langauges(s)

3. DEFECT DETAILS			
Defect description			
Defect category		Defect descriptor	
Site where the defect occurred			
Name		Address	

4. INVESTIGATION AND ACTION DETAILS

Summary of the investigation

Competent Authority(ies) contacted

Adverse reaction/evence and reoccurrence identified (report according to applicable pharmacovigilance requirements)

Proposed action	Justification of the proposed action

Other (if applicable):

Proposed depth of the recall	Consequences of proposed action on the market

In the event that the agreed action intended to take is leading to disruption in product supply, please notify NAMMD

Description of the root cause identified/expected	Expected root cause details

	Proposed/taken CAPA to prevent reoccurence	CAPA implementation timeline
1		

Please provide in timely fashion: investigation report including CAPAs, health hazard risk assessment report, photos, test results and any other documentation, if needed

Attach files Please attach the investigation and any other relevant documentation

Type of company
manufacturer
MAH
parallel distributor/parallel importer
wholesaler
other (please specify)

MA type
NAP
DCP
MRP

Defect type
1. Manufacturing laboratory controls issue
2. Product contamination and sterility issues
3. Product label issues
4. Product packaging issues
5. Product physical issues

Description of the defect cause
environmental
equipment
human error
materials
method
not determined
others

Defect type
1.1 Manufacturing laboratory controls issue
1.2 Out of specification test results
2.1 Product contamination chemical
2.2 Product contamination microbial
2.3 Product contamination physical
2.4 Product contamination with body fluid
2.5 Product sterility lacking
2.6 Suspected transmission of an infectious agent via product
3.1 Physical product label issue

Proposed action
Market suspension
No recall
Quarantine
Recall Class I
Recall Class II
Recall Class III
Others (please specify below).

Level of withdrawal
company warehouse
wholesaler
patient
pharmacy/hospital
none

Consequences of withdrawal
none, other batches/presentations available
possible shortage
others, please specify

3.2 Product barcode issue
3.3 Product expiration date issue
3.4 Product identification number issue
3.5 Product label issue
3.6 Product label on wrong product
3.7 Product lot number issue
4.1 Product blister packaging issue
4.2 Product closure issue
4.3 Product commingling
4.4 Product container issue
4.5 Product container seal issue
4.6 Product dropper issue
4.7 Product outer packaging issue
4.8 Product packaging issue
4.9 Product packaging quantity issue
5.1 Product coating issue
5.2 Product deposit
5.3 Product dosage form issue
5.4 Product gel formation
5.5 Product physical issue

ANNEX No. 2
to SCD no. 4/24.10.2018

Guideline on use of the defective product report for medicinal products for human use authorised through national, mutual recognition and decentralised procedures

Holders of marketing and manufacturing authorisations shall notify the NAMMD on suspected/confirmed quality defects. Notification is made using the reporting form approved in line with Annex 1 of this Scientific Council Decision (hereafter Reporting).

Product quality defects reports related to Nationally Authorised Products (NAPs) and Mutual Recognition Procedure/ Decentralised Procedure (MRP/DCP) are required to be sent to the relevant National Competed Authority (i.e. in Romania, the NAMMD).

Therefore, the Annex to this Decision is a translation into Romanian and an adaptation of the document EMA document EMA/INS/GMP/35037/2017 "How to use the defective product report to notify a quality defect to European Medicines Agency", at https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/how-use-defective-product-report-notify-quality-defect-european-medicines-agency_en.pdf

Most of the fields of the main features present in the new quality defect report are self-explanatory; however, in case of data fields that are not clear, please contact the Romanian competent authority at secretariat@anm.ro.

DECISION
No. 5/24.10.2018

on approval of the Romanian version of Standard terms approved by the European Pharmacopoeia Commission for combination packs

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 757/13.06.2018, convened on summons by the NAMMD President in the ordinary session of 24.10.2018, in accordance with provisions of Article 12 (5) of Decision of the Romanian Government no.734/2010 on organisation and operation of the National Agency for Medicines and Medical Devices, as amended,

hereby adopts the following

DECISION

Article 1 - The Romanian version of Standard terms approved by the European Pharmacopoeia Commission for combination packs is hereby approved, as provided in the database of the *European Directorate for the quality of Medicines – EDQM.*

PRESIDENT
of the Scientific Council
of the National Agency
for Medicines and Medical Devices,

Prof. Anca-Dana Buzoianu, MD, PhD

		Combinations packs = Ambalaje de combinații			
No. CRT	**Status**	**Standard terms**		**Definitions**	
		English	***Romanian***	***English***	***Romanian***
1	Current NEW	***Capsule, hard + tablet***	***Capsulă + tablet***	Combination package consisting of a hard capsule and a tablet. Comment If there is more than one hard capsule in the combination pack, this term becomes 'Capsules, hard + tablet' (and similarly if there is more than one tablet).	Ambalajul unei combinations care consta dintr-o capsula and un tablet . Comentariu: daca exista mai mult decat o capsula in ambalajul combinatiei, acest termen standard (TS) devine "Capsule+tablet" (in mod similar in cazul in care exista mai mult decat un tablet , adica "Capsule +tablets"
2	Current NEW	***Capsule, soft + tablet***	***Capsulă moale + tablet***	Combination package consisting of a soft capsule and a tablet. Comment If there is more than one soft capsule in the combination pack, this term becomes 'Capsules, soft + tablet' (and similarly if there is more than one tablet).	Ambalajul unei combinations care consta dintr-o capsula moale and un tablet . Comentariu: daca exista mai mult decat o capsula moale in ambalajul combinatiei, acest TS devine "Capsule moi+tablet" (in mod similar in cazul in care exista mai mult decat un tablet , adica "Capsule moi +tablets"
3	Current NEW	***Cream + pessary***	***Cremă + ovul***	Combination package consisting of a cream and a pessary.	Ambalajul unei combinations compus dintr-o crema and un ovul.

4	Current NEW	***Cream + vaginal capsule, soft***	***Crema + capsula moale vaginala***	Combination package consisting of a cream and a vaginal capsule, soft. Comment If there is more than one vaginal capsule, soft, in the combination pack, this term becomes 'Cream + vaginal capsules, soft'.	Ambalajul unei combinaţii compus dintr-o crema and o capsula moale vaginala. Comentariu: daca exista mai mult decat o capsula moale vaginala in ambalajul combinatiei, acest termen standard devine "Crema + capsule moi, vaginale"
5	Current NEW	***Cream + vaginal tablet***	***Cremă + tablet vaginal***	Combination package consisting of a cream and a vaginal tablet. Comment If there is more than one vaginal tablet in the combination pack, this term becomes 'Cream + vaginal tablets'.	Ambalajul unei combinations care consta dintr-o crema and tablet vaginal. Comentariu: daca exista mai mult decat un tablet vaginal in ambalajul combinatiei, acest TS devine "Crema +tablets vaginale".
6	Current NEW	***Cutaneous solution + medicated sponge***	***Soluție cutanată + burete medicamentos***	Combination package consisting of a cutaneous solution and a medicated sponge	Ambalajul unei combinations care consta dintr-o solution for cutanata and un burete medicamentos.
7	Current NEW	***Effervescent granules + film-coated tablet***	***Granule efervescente + tablet filmat***	Combination package consisting of effervescent granules and a film-coated tablet. Comment If there is more than one film-coated tablet in the combination pack, this term becomes 'Effervescent granules + film-coated tablets'.	Ambalajul unei combinations care consta din granule efervescente and un tablet filmat. Comentariu: daca exista mai mult decat un tablet filmat in ambalajul combinatiei, acest TS devine "Granule efervescente +film-coated tablets"

8	Current NEW	***Effervescent tablet + film-coated tablet***	***Tablet efervescent + tablet filmat***	Combination package consisting of an effervescent tablet and a film-coated tablet. Comment If there is more than one effervescent tablet in the combination pack, this term becomes 'Effervescent tablets + film-coated tablet' (and similarly if there is more than one film-coated tablet).	Ambalajul unei combinations care consta dintr-un tablet efervescent and un tablet filmat. Comentariu: daca exista mai mult de un tablet efervescent in ambalajul combinatiei, acest TS devine "Tablets efervescente + tablet filmat" (si in mod similar daca exista mai mult decat un tablet filmat).
9	Current NEW	***Film-coated tablet + pessary***	***Tablet filmat + ovul***	Combination package consisting of a film-coated tablet and a pessary. Comment If there is more than one film-coated tablet in the combination pack, this term becomes 'Film-coated tablets + pessary' (and similarly if there is more than one pessary).	Ambalajul unei combinations care consta dintr-un tablet filmat and un ovul. Comentariu: daca exista mai mult de un tablet filmat in ambalajul combinatiei, acest TS devine "Film-coated tablets + ovul " (si in mod similar daca exista mai mult decat un ovul).
10	Current NEW	***Film-coated tablet + tablet***	***Tablet filmat + tablet***	Combination package consisting of a film-coated tablet and a tablet. Comment If there is more than one film-coated tablet in the combination pack, this term becomes 'Film-coated tablets + tablet' (and similarly if there is more than one tablet).	Ambalajul unei combinations care consta dintr-un tablet filmat and un tablet. Comentariu: daca exista mai mult de un tablet filmat in ambalajul combinatiei, acest TS devine "Film-coated tablets + tablet " (si in mod similar daca exista mai mult decat un tablet).

11	Current NEW	***Gastro-resistant tablet + rectal suspension***	***Tablet gastrorezistent + suspensie rectală***	Combination package consisting of a gastro-resistant tablet and a rectal suspension. Comment If there is more than one gastro-resistant tablet in the combination pack, this term becomes 'Gastro-resistant tablets + rectal suspension'	Ambalajul unei combinations care consta dintr-un tablet gastrorezistent and o suspensie rectala. Comentariu: daca exista mai mult de un tablet gastrorezistent in ambalajul combinatiei, acest TS devine "Tablets gastrorezistente + suspensie rectala".
12	Current NEW	***Tablet + vaginal tablet***	***Tablet + tablet vaginal***	Combination package consisting of a tablet and a vaginal tablet. Comment If there is more than one vaginal tablet in the combination pack, this term becomes 'Tablet + vaginal tablets' (and similarly if there is more than one 'oral' tablet).	Ambalajul unei combinations care consta dintr-un tablet and un tablet vaginal. Comentariu: daca exista mai mult de un tablet vaginal in ambalajul combinatiei, acest TS devine "Tablet + tablets vaginale (si in mod similar daca exista mai mult decat un tablet).
13	Current NEW	***Vaginal capsule, soft + vaginal cream***	***Capsulă moale vaginală + cremă vaginală***	Combination package consisting of a vaginal capsule, soft, and a vaginal cream. Comment If there is more than one vaginal capsule, soft, in the combination pack, this term becomes 'Vaginal capsules, soft + vaginal cream'.	Ambalajul unei combinations care consta dintr-o capsula moale vaginala and o crema vaginala . Comentariu: daca exista mai mult de o capsula moale vaginala in ambalajul combinatiei, acest TS devine "Capsule moi vaginale +crema vaginala".

14	Current NEW	***Vaginal cream + vaginal tablet***	***Cremă vaginală + tablet vaginal***	Combination package consisting of a vaginal cream and a vaginal tablet. Comment If there is more than one vaginal tablet in the combination pack, this term becomes 'Vaginal cream + vaginal tablets'	Ambalajul unei combinations care consta dintr-o crema vaginala and un tablet vaginal. Comentariu: daca exista mai mult de un tablet vaginal in ambalajul combinatiei, acest TS devine "Crema vaginala + tablets vaginale".
Legends:		**Current – NEW = PhEur Commission approved ST,**			
		Romanian version submitted for approval on NAMMD Scientific Council meeting of 24.10.2018.			

Definition (EMA guideline)		
Combination pack =ambalajul unei combinations care consta din mai multe medicamente , sau mai multe forme farmaceutice ale aceluiasi medicament, fiind prezentata sub o singura trade name, atunci cand medicamentele / formele farmaceutice individuale sunt destinate administrarii simultane sau secventiale	***(Trade name) (strength SA1 + strength SA2) (FF1+FF2)***	**Medabon 200mg+0,20mg, tablet + vaginal tablets** (mifepristone + misoprostol)
		Seasonique 150micrograme / 30micrograms + 10micrograms, film coated tablets + film coated tablets (levonorgestrel/etinslestradiol + etinilestradiol)
Multi pack = ambalaj multiplu compus din cateva ambalaje individuale ale unui medicament cu aceeasi concentratie	***(Trade name) (strength) (FF)***	**Penthrox 99,9%, 3 ml inhalation vapor, lichid** (methoxyflurane) Multiple pack containing 10 boxes with one bottle of 3 ml PENTHROX + 1 one PENTHROX Inhaler +1 Activated Carbon chamber
Fixed (dose) combinations = combinations (in doze) fixe care se limiteaza la substantele active continute in aceeasi forma farmaceutica de administrare		
Concluzie		
Fixed (dose) combinations # combinations packs !!!		
Fixed (dose) combinations fixe # combination packs		
Active substance combinations # pharmaceutical forms combinations!!!		
CAUTION: Product information sometimes uses inaccurate phrases as proposed by the Applicant (e.g. COMBIPACK for MULTI PACK) !! In such cases, PhEur Commission approved STs should be used (MULTI PACK = MULTIPLE PACKAGEGING)		

Medicinal product batches recalled/withdrawn during the 4th quarter 2018

No.	Product recalled/ withdrawn	Pharm. form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall/withdrawal	Action proposed	Recall/ Withdrawal date
1	CEFOZON 1g	powder for solution for i.m./i.v. injection/ infusion	1 g	cefoperazone	Felsin Farm S.R.L. Romania/ E.I.P.I.C.O. Med S.R.L., Romania	1701920	confirmed quality nonconformity (yellowish-white precipitate upon immediate dissolution in the solvent and foam when administered in 100 ml 0.9% saline solution for infusion, increasing flow time of the solution for infusion)	Recall and destruction	04.10.2018
2	OZURDEX	intravitreal implant	700 µg	dexamethasone	Allergan Pharmaceuticals International Ltd. Ireland	E78726	silicon particles found in several implants	Voluntary recall from community / hospital (clinic) pharmacy and destruction	04.10.2018
3	CLOSTILBEGYT 50 mg x 10 tabl.	tablets	50 mg	clomiphene	Egis Pharmaceuticals PLC, Hungary	all marketed batches	temporary discontinuation of marketing and removal from the CaNaMed Index and the Public Index starting with 01.01.2019	Voluntary recall and destruction	28.12.2018
4	EGILOK 25 mg x 20 tabl.	tablets	25 mg	metoprolol	Egis Pharmaceuticals PLC, Hungary	all marketed batches	temporary discontinuation of marketing and removal from the CaNaMed Index and the Public Index starting with 01.01.2019	Voluntary recall and destruction	28.12.2018

No.	Product recalled/ withdrawn	Pharm. form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall/withdrawal	Action proposed	Recall/ Withdrawal date
5	EGIRAMLON 10 mg/10 mg x 100 caps.	capsule	10 mg/ 10 mg	combinations (ramipril+ amlodipine)	Egis Pharmaceuticals PLC, Hungary	all marketed batches	temporary discontinuation of marketing and removal from the CaNaMed Index and the Public Index starting with 01.01.2019	Voluntary recall and destruction	28.12.2018
6	EGIRAMLON 10 mg/5 mg x 100 caps.	capsule	10 mg/ 5 mg	combinations (ramipril+ amlodipine)	Egis Pharmaceuticals PLC, Hungary	all marketed batches	temporary discontinuation of marketing and removal from the CaNaMed Index and the Public Index starting with 01.01.2019	Voluntary recall and destruction	28.12.2018
7	EGIRAMLON 5 mg/10 mg x 100 caps.	capsule	5 mg/ 10 mg	combinations (ramipril+ amlodipine)	Egis Pharmaceuticals PLC, Hungary	all marketed batches	temporary discontinuation of marketing and removal from the CaNaMed Index and the Public Index starting with 01.01.2019	Voluntary recall and destruction	28.12.2018
8	EGIRAMLON 5 mg/5 mg x 100 caps.	capsule	5 mg/ 5 mg	combinations (ramipril+ amlodipine)	Egis Pharmaceuticals PLC, Hungary	all marketed batches	temporary discontinuation of marketing and removal from the CaNaMed Index and the Public Index starting with 01.01.2019	Voluntary recall and destruction	28.12.2018
9	ESCITIL 10 mg x 28 film-coated tabl.	film-coated tablets	10 mg	escitalopram	Egis Pharmaceuticals PLC, Hungary	all marketed batches	temporary discontinuation of marketing and removal from the CaNaMed Index and the Public Index starting with 01.01.2019	Voluntary recall and destruction	28.12.2018
10	EXPLEMED 10 mg x 28 tabl.	tablets	10 mg	aripiprazole	Egis Pharmaceuticals PLC, Hungary	all marketed batches	temporary discontinuation of marketing and removal from the CaNaMed Index and the Public Index starting with 01.01.2019	Voluntary recall and destruction	28.12.2018

No.	Product recalled/ withdrawn	Pharm. form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall/withdrawal	Action proposed	Recall/ Withdrawal date
11	EXPLEMED 15 mg x 28 tabl.	tablets	15 mg	aripiprazole	Egis Pharmaceuticals PLC, Hungary	all marketed batches	temporary discontinuation of marketing and removal from the CaNaMed Index and the Public Index starting with 01.01.2019	Voluntary recall and destruction	28.12.2018
12	KETILEPT 100 mg x 60 film-coated tabl.	film-coated tablets	100 mg	quetiapine	Egis Pharmaceuticals PLC, Hungary	all marketed batches	temporary discontinuation of marketing and removal from the CaNaMed Index and the Public Index starting with 01.01.2019	Voluntary recall and destruction	28.12.2018
13	KETILEPT 200 mg x 60 film-coated tabl.	film-coated tablets	200 mg	quetiapine	Egis Pharmaceuticals PLC, Hungary	all marketed batches	temporary discontinuation of marketing and removal from the CaNaMed Index and the Public Index starting with 01.01.2019	Voluntary recall and destruction	28.12.2018
14	KETILEPT 300 mg x 60 film-coated tabl.	film-coated tablets	300 mg	quetiapine	Egis Pharmaceuticals PLC, Hungary	all marketed batches	temporary discontinuation of marketing and removal from the CaNaMed Index and the Public Index starting with 01.01.2019	Voluntary recall and destruction	28.12.2018
15	LUCETAM 800 mg x 20 film-coated tabl.	film-coated tablets	800 mg	piracetam	Egis Pharmaceuticals PLC, Hungary	all marketed batches	temporary discontinuation of marketing and removal from the CaNaMed Index and the Public Index starting with 01.01.2019	Voluntary recall and destruction	28.12.2018
16	LUCETAM 1200 mg x 20 film-coated tabl.	film-coated tablets	1200 mg	piracetam	Egis Pharmaceuticals PLC, Hungary	all marketed batches	temporary discontinuation of marketing and removal from the CaNaMed Index and the Public Index starting with 01.01.2019	Voluntary recall and destruction	28.12.2018

No.	Product recalled/ withdrawn	Pharm. form	Strength	INN	Manufacturer/ MAH	Batch	Grounds for recall/withdrawal	Action proposed	Recall/ Withdrawal date
17	LUCETAM 400 mg x 20 film-coated tabl.	film-coated tablets	400 mg	piracetam	Egis Pharmaceuticals PLC, Hungary	all marketed batches	temporary discontinuation of marketing and removal from the CaNaMed Index and the Public Index starting with 01.01.2019	Voluntary recall and destruction	28.12.2018
18	PERITOL 4 mg x 20 tabl.	tablets	4 mg	cyproheptadine	Egis Pharmaceuticals PLC, Hungary	all marketed batches	temporary discontinuation of marketing and removal from the CaNaMed Index and the Public Index starting with 01.01.2019	Voluntary recall and destruction	28.12.2018
19	TELMISARTAN/HIDROCLOROTIAZIDA EGIS 80 mg/12.5 mg x 28 tabl.	tablets	80 mg/ 12.5 mg	combinations (telmisartan+ hydrochlorothiazide)	Egis Pharmaceuticals PLC, Hungary	all marketed batches	temporary discontinuation of marketing and removal from the CaNaMed Index and the Public Index starting with 01.01.2019	Voluntary recall and destruction	28.12.2018

Applications for marketing authorisation/marketing authorisation renewal submitted to the NAMMD during the 3rd quarter 2018

During the 3rd quarter of 2018, 170 marketing authorisation/renewal applications for medicinal products corresponding to the following therapeutic groups have been submitted as follows:

A01 – STOMATOLOGICAL PREPARATIONS
A02 – DRUGS FOR ACID RELATED DISORDERS
A03 – DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS
A06 – LAXATIVES
A07 – ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS
A10 – DRUGS USED IN DIABETES
B01 – ANTITHROMBOTIC AGENTS
B03 – ANTIANEMIC PREPARATIONS
B05 – BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS
C01 – CARDIAC THERAPY
C02 – ANTIHYPERTENSIVES
C08 – CALCIUM CHANNEL BLOCKERS
C09 – AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM
C10 – LIPID MODIFYING AGENTS
G03 – SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM
H02 – CORTICOSTEROIDS FOR SYSTEMIC USE
H03 – THYROID THERAPY
H05 – CALCIUM HOMEOSTASIS
J01 – ANTIBACTERIALS FOR SYSTEMIC USE
J05 – ANTIVIRALS FOR SYSTEMIC USE
J07 – VACCINES
L01 – ANTINEOPLASTIC AGENTS
L02 – ENDOCRINE THERAPY
L04 – IMMUNOSUPPRESSANTS
M01 – ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS
N01 – ANESTHETICS
N02 – ANALGESICS
N03 – ANTIEPILEPTICS
N04 – ANTI-PARKINSON DRUGS
N06 – PSYCHOANALEPTICS
R01 – NASAL PREPARATIONS
R02 – THROAT PREPARATIONS
R05 – COUGH AND COLD PREPARATIONS
R06 – ANTIHISTAMINES FOR SYSTEMIC USE
S01 – OPHTHALMOLOGICALS
V01 – ALLERGENS
V03 – ALL OTHER THERAPEUTIC PRODUCTS
V08 – CONTRAST MEDIA

Medicinal products authorised for marketing during the 3rd quarter 2018

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number		
ABACAVIRUM/ LAMIVUDINUM	ABACAVIR/ LAMIVUDINA MYLAN	film-coated tabl.	600mg/300mg	MYLAN S.A.S.	FRANCE	10824	2018	01
ACIDUM ACETYLSALICYLICUM/ PSEUDOEPHEDRINUM	ASPIRIN COMPLEX HOT DRINK	gran. for oral susp.	500mg/30mg	BAYER S.R.L.	ROMANIA	11005	2018	01
ACIDUM IBANDRONICUM	QUODIXOR	film-coated tabl.	150mg	ALVOGEN IPCO S.A.R.L.	LUXEMBOURG	10837	2018	01
ACIDUM ZOLENDRONICUM	ACID ZOLEDRONIC ACCORD	sol. for inf.	0.04mg/ml	ACCORD HEALTHCARE LIMITED	TURKEY	10979	2018	01
AMBROXOLUM HYDROCHLORIDE	FLAVAMED	oral sol.	15mg/5ml	BERLIN CHEMIE AG	GERMANY	10869	2018	01
AMLODIPINUM BESILATUM/ ATORVASTATINUM CALCIUM	ATORDAPIN	film-coated tabl.	10 mg/10 mg	KRKA D.D. NOVO MESTO	SLOVENIA	10894	2018	01
AMLOPIDINUM/ ATORVASTATINUM	ATORDAPIN	film-coated tabl.	5mg/10mg	KRKA D.D. NOVO MESTO	SLOVENIA	10893	2018	01
ARGIPRESSINUM	REVERPLEG	conc. for sol perf.	40UI/2ml	ORPHA - DEVEL HANDELS UND VERTRIEBS GMBH	AUSTRIA	10862	2018	01
ATOMOXETINUM	ATOFAB	capsule	10mg	G.L. PHARMA GMBH	AUSTRIA	10884	2018	01
ATOMOXETINUM	ATOFAB	capsule	18mg	G.L. PHARMA GMBH	AUSTRIA	10885	2018	01
ATOMOXETINUM	ATOFAB	capsule	25mg	G.L. PHARMA GMBH	AUSTRIA	10886	2018	01
ATOMOXETINUM	ATOFAB	capsule	40mg	G.L. PHARMA GMBH	AUSTRIA	10887	2018	01
ATOMOXETINUM	ATOFAB	capsule	60mg	G.L. PHARMA GMBH	AUSTRIA	10888	2018	01

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number		
AZELASTINUM	ALLERGODIL	eye drops, sol	0.5 mg/ml	MEDA PHARMA GmbH	GERMANY	10969	2018	01
AZELASTINUM/ FLUTICASONUM	DYMISTA	nasal spray, susp.	137 µg/ 50 µg/doza	MEDA PHARMA GmbH	AUSTRIA	11003	2018	01
AZELASTINUM/ FLUTICASONUM	SYNAZE	nasal spray, susp.	137 µg/ 50 µg/doza	MEDA PHARMA GmbH	AUSTRIA	11004	2018	01
BENZILPENICILINA SODICA	PENICILINA G SODICA ATB	powd. for sol. for inj.	400000UI	ANTIBIOTICE S.A.	ROMANIA	10904	2018	01
BENZOYLIS PEROXIDUM + CLINDAMYCINUM PHOSPHATE	DUAC	gel	10 mg/g+ 30mg/g	GLAXOSMITHKLINE (GSK) S.R.L.	ROMANIA	10957	2018	01
BETAXOLOLUM	BETAXOLOL PMCS	tabl.	20mg	PRO.MED.CS PRAHA a.s.	CZECH REPUBLIC	10913	2018	01
BORTEZOMIBUM	BORTEZOMIB SANDOZ	powd. for sol. for inj.	1mg	SANDOZ S.R.L.	ROMANIA	10838	2018	01
BORTEZOMIBUM	BORTEZOMIB SANDOZ	powd. for sol. for inj.	3.5mg	SANDOZ S.R.L.	ROMANIA	10839	2018	01
BORTEZOMIBUM	BORTEZOMIB MYLAN	powd. for sol. for inj.	1mg	MYLAN S.A.S.	FRANCE	10882	2018	01
BORTEZOMIBUM	BORTEZOMIB MYLAN	powd. for sol. for inj.	3.5mg	MYLAN S.A.S.	FRANCE	10883	2018	01
BOSENTANUM MONOHYDRATUM	BOPAHO	film-coated tabl.	125mg	ZENTIVA S.A.	ROMANIA	10823	2018	01
BUDESONIDE/ FORMOTEROL FUMARATE	AIRBUFO FORSPIRO	powd. for inh.	160 µg/4.5 µg	SANDOZ S.R.L.	ROMANIA	10917	2018	01

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number		
BUDESONIDUM	CORTIMENT	prol. release tabl.	9 mg	FERRING GmbH	GERMANY	10851	2018	01
CALCIUM ACETATE ANHYDROUS/ MAGNEZIUM CARBONATE	OSVAREN	film-coated tabl.	435mg/235mg	FRESENIUS MEDICAL CARE GMBH	GERMANY	10963	2018	01
CAPECITABINUM	CAPECITABINA DR REDDY'S	film-coated tabl.	500 mg	DR. REDDY'S LABORATORIES ROMANIA SRL	ROMANIA	10958	2018	01
CEFADROXILUM	CEXYL	gran. for oral susp.	125 ml/5 ml	SANDOZ S.R.L.	ROMANIA	10899	2018	01
CEFADROXILUM	CEXYL	gran. for oral susp.	250 ml/5 ml	SANDOZ S.R.L.	ROMANIA	10900	2018	01
CEFADROXILUM	CEXYL	caps.	500 mg	SANDOZ S.R.L.	ROMANIA	10901	2018	01
CEFADROXILUM	CEXYL	film-coated tabl.	1000 mg	SANDOZ S.R.L.	ROMANIA	10902	2018	01
CEFIXIMUM	XIFIA	film-coated tabl.	400mg	INN-FARM d.o.o.	SLOVENIA	10962	2018	01
CELECOXIBUM	ACLEXA	caps.	100mg	KRKA D.D. NOVO MESTO	SLOVENIA	10953	2018	01
CELECOXIBUM	ACLEXA	caps.	200mg	KRKA D.D. NOVO MESTO	SLOVENIA	10954	2018	01
CELECOXIBUM	CELECOXIB ACTAVIS	tabl.	100 mg	ACTAVIS GROUP PTC	ISLANDA	10955	2018	01
CELECOXIBUM	CELECOXIB ACTAVIS	tabl.	200mg	ACTAVIS GROUP PTC	ISLANDA	10956	2018	01
CETIRIZINUM DIHYDROCHLORIDE	REACTIN	caps.	10mg	MCNEIL HEALTHCARE LIMITED	IRELAND	10928	2018	01
CICLOSERINA	CICLOSERINA Atb	caps.	250mg	ANTIBIOTICE S.A.	ROMANIA	10903	2018	01
CLARITHROMYCINUM	LEKOKLAR	gran. for oral susp.	125mg/5ml	SANDOZ S.R.L.	ROMANIA	10950	2018	01
CLARITHROMYCINUM	LEKOKLAR	gran. for oral susp.	250mg/5ml	SANDOZ S.R.L.	ROMANIA	10951	2018	01

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number		
CLINDAMYCIN PHOSPHATE/ TRETINOIN	ACNATAC	gel	10 mg/g + 0.25 mg/g	MEDA PHARMA GmbH	GERMANY	10896	2018	01
CLOPIDOGRELUM	CLOPIDOGREL DR. REDDY'S	film-coated tabl.	75mg	DR. REDDY'S LABORATORIES	ROMANIA	10871	2018	01
COMBINATIONS	VIACORLIX	film-coated tabl.	7mg/5mg/ 2.5mg	LES LABORATORIES SERVIER	FRANCE	10852	2018	01
COMBINATIONS	STEROFUNDIN ISO	sol. for inj.		B. BRAUN MELSUNGEN AG	GERMANY	10877	2018	01
DESOGESTRELUM	DESIRETT	film-coated tabl.	75mcg	EXELTIS MAGYARORSZAG KFT.	HUNGARY	10864	2018	01
DESOGESTRELUM	CERAZETTE	film-coated tabl.	0.075 mg	MERCK SHARP & DOHME ROMANIA SRL	ROMANIA	10970	2018	01
DOCETAXELUM	TOLNEXA	conc. for sol. for inf.	20mg/ml	KRKA D.D. NOVO MESTO	SLOVENIA	10828	2018	01
DUTASTERIDUM	ASIUM	soft caps.	0.5mg	TERAPIA S.A.	ROMANIA	11006	2018	01
EPLERENONUM	APLERIA	film-coated tabl.	25mg	KRKA D.D. NOVO MESTO	SLOVENIA	10971	2018	01
EPLERENONUM	APLERIA	film-coated tabl.	50mg	KRKA D.D. NOVO MESTO	SLOVENIA	10972	2018	01
ESCITALOPRAMUM OXALATE	ESCITALOPRAM TORRENT	film-coated tabl.	5mg	HEUMANN PHARMA GmbH & Co. GENERICA KG	GERMANY	10829	2018	01
ESCITALOPRAMUM OXALATE	ESCITALOPRAM TORRENT	film-coated tabl.	10mg	HEUMANN PHARMA GmbH & Co. GENERICA KG	GERMANY	10830	2018	01
ESCITALOPRAMUM OXALATE	ESCITALOPRAM TORRENT	film-coated tabl.	15mg	HEUMANN PHARMA GmbH & Co. GENERICA KG	GERMANY	10831	2018	01

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number		
ESCITALOPRAMUM OXALATE	ESCITALOPRAM TORRENT	film-coated tabl.	20mg	HEUMANN PHARMA GmbH & Co. GENERICA KG	GERMANY	10832	2018	01
EVEROLIMUS	EVEROLIMUS ALVOGEN	tabl.	2.5mg	ALVOGEN MALTA OPERATIONS	MALTA	10879	2018	01
EVEROLIMUS	EVEROLIMUS ALVOGEN	tabl.	5mg	ALVOGEN MALTA OPERATIONS	MALTA	10880	2018	01
EVEROLIMUS	EVEROLIMUS ALVOGEN	tabl.	10mg	ALVOGEN MALTA OPERATIONS	MALTA	10881	2018	01
EVEROLIMUS	EVEROLIMUS MYLAN	tabl.	2.5mg	MYLAN B.V.	NETHERLANDS	10987	2018	01
EVEROLIMUS	EVEROLIMUS MYLAN	tabl.	5mg	MYLAN B.V.	NETHERLANDS	10988	2018	01
EVEROLIMUS	EVEROLIMUS MYLAN	tabl.	10mg	MYLAN B.V.	NETHERLANDS	10989	2018	01
FLUOXETINUM HYDROCHLORIDE	FLUOXIN	caps.	20 mg	VIM SPECTRUM S.R.L.	ROMANIA	10964	2018	01
FULVESTRANTUM	FULVESTRANT SUN	sol. for inj. (pre-filled syringes)	250mg	SUN PHARMACEUTICAL INDUSTRIES EUROPE B.V.	NETHERLANDS	10934	2018	01
GLICLAZIDUM	GLICLAZIDA KRKA	modif. release tabl.	60mg	KRKA D.D. NOVO MESTO	SLOVENIA	10872	2018	01
GLICLAZIDUM	GLYCLADA	modif. release tabl.	60mg	KRKA D.D. NOVO MESTO	SLOVENIA	10873	2018	01
HUMAN COAGULATION FACTOR VIII	BERIATE	powd. and solv. for sol. for inj.	250UI	CSL BEHRING GmbH	GERMANY	10923	2018	01
HUMAN COAGULATION FACTOR VIII	BERIATE	powd. and solv. for sol. for inj.	500UI	CSL BEHRING GmbH	GERMANY	10924	2018	01
HUMAN COAGULATION FACTOR VIII	BERIATE	powd. and solv. for sol. for inj.	1000UI	CSL BEHRING GmbH	GERMANY	10925	2018	01

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number		
HUMAN COAGULATION FACTOR VIII	BERIATE	powd. and solv. for sol. for inj.	2000UI	CSL BEHRING GmbH	GERMANY	10926	2018	01
HUMAN NORMAL IMMUNOGLOBULIN	OCTAGAM 10%	sol. for inf.	100mg/ml	OCTAPHARMA (IP) LIMITED	UK	10959	2018	01
IMATINIBUM	IMATINIB GLENMARK	film-coated tabl.	100mg	GLENMARK PHARMACEUTICALS S.R.O.	CZECH REPUBLIC	10932	2018	01
IMATINIBUM	IMATINIB GLENMARK	film-coated tabl.	400mg	GLENMARK PHARMACEUTICALS S.R.O.	CZECH REPUBLIC	10933	2018	01
IMATINIBUM MESYLATUM	IMATINIB ZENTIVA	film-coated tabl.	100mg	ZENTIVA k.s.	CZECH REPUBLIC	10853	2018	01
IMATINIBUM MESYLATUM	IMATINIB ZENTIVA	film-coated tabl.	400mg	ZENTIVA k.s.	CZECH REPUBLIC	10854	2018	01
IMATINIBUM MESYLATUM	IMATINIB MYLAN	caps.	100mg	GENERICS UK LTD	UK	10931	2018	01
INDAPAMIDUM	INDAPAMIDA BILLEV	prol. release tabl.	1.5 mg	BILLEV PHARMA ApS	DENMARK	10827	2018	01
LAMIVUDINUM/ ZIDOVUDINUM	LAMIVUDINA/ ZIDOVUDINA ACCORD	film-coated tabl.	150/300mg	ACCORD HEALTHCARE LIMITED	UK	10878	2018	01
LENALIDOMIDUM	LENALIDOMIDA ALVOGEN	caps.	2.5mg	ALVOGEN MALTA OPERATIONS	MALTA	10935	2018	01
LENALIDOMIDUM	LENALIDOMIDA ALVOGEN	caps.	5mg	ALVOGEN MALTA OPERATIONS	MALTA	10936	2018	01
LENALIDOMIDUM	LENALIDOMIDA ALVOGEN	caps.	7.5mg	ALVOGEN MALTA OPERATIONS	MALTA	10937	2018	01
LENALIDOMIDUM	LENALIDOMIDA ALVOGEN	caps.	10mg	ALVOGEN MALTA OPERATIONS	MALTA	10938	2018	01
LENALIDOMIDUM	LENALIDOMIDA ALVOGEN	caps.	15mg	ALVOGEN MALTA OPERATIONS	MALTA	10939	2018	01

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number		
LENALIDOMIDUM	LENALIDOMIDA ALVOGEN	caps.	20mg	ALVOGEN MALTA OPERATIONS	MALTA	10940	2018	01
LENALIDOMIDUM	LENALIDOMIDA ALVOGEN	caps.	25mg	ALVOGEN MALTA OPERATIONS	MALTA	10941	2018	01
LENALIDOMIDUM	LENALIDOMIDA LABORMED	caps.	2.5mg	LABORMED PHARMA S.A.	ROMANIA	10942	2018	01
LENALIDOMIDUM	LENALIDOMIDA LABORMED	caps.	5mg	LABORMED PHARMA S.A.	ROMANIA	10943	2018	01
LENALIDOMIDUM	LENALIDOMIDA LABORMED	caps.	7.5mg	LABORMED PHARMA S.A.	ROMANIA	10944	2018	01
LENALIDOMIDUM	LENALIDOMIDA LABORMED	caps.	10mg	LABORMED PHARMA S.A.	ROMANIA	10945	2018	01
LENALIDOMIDUM	LENALIDOMIDA LABORMED	caps.	15mg	LABORMED PHARMA S.A.	ROMANIA	10946	2018	01
LENALIDOMIDUM	LENALIDOMIDA LABORMED	caps.	20mg	LABORMED PHARMA S.A.	ROMANIA	10947	2018	01
LENALIDOMIDUM	LENALIDOMIDA LABORMED	caps.	25mg	LABORMED PHARMA S.A.	ROMANIA	10948	2018	01
LERCANIDIPINUM HYDROCHLORIDE	LERCANIDIPINA MYLAN 10 mg	film-coated tabl.	10 mg	JENSON PHARMA SERVICE LTD	UK	10918	2018	01
LERCANIDIPINUM HYDROCHLORIDE	LERCANIDIPINA MYLAN 20 mg	film-coated tabl.	20 mg	JENSON PHARMA SERVICE LTD	UK	10919	2018	01
LEVETIRACETAMUM	LEVETIRACETAM ACCORD	oral sol.	100mg/ml	ACCORD HEALTHCARE LIMITED	UK	10826	2018	01
LEVOFLOXACINUM HEMIHYDRATE	LEVOFLOXACINA ACTAVIS	sol. for inf.	5 mg/ml	ACTAVIS GROUP PTC EHF	ISLANDA	10922	2018	01

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number		
LEVOFLOXACINUM HEMIHYDRATE	CENOMAR	sol. for inj.	5 mg/ml	STADA ARZNEIMITTEL AG	GERMANY	10929	2018	01
LOSARTANUM POTASSIUM + HYDROCHLOROTHIAZIDE	LOSARTAN HCT ARENA	film-coated tabl.	50mg/12.5mg	ARENA GROUP S.A.	ROMANIA	10909	2018	01
LOSARTANUM POTASSIUM + HYDROCHLOROTHIAZIDE	LOSARTAN HCT ARENA	film-coated tabl.	100mg/25mg	ARENA GROUP S.A.	ROMANIA	10910	2018	01
MEMANTINUM HYDROCHLORIDE	MEMANTINA TORRENT	oral sol.	10 mg/ml	TORRENT PHARMA GmbH	GERMANY	10911	2018	01
MEMANTINUM HYDROCHLORIDE	MEMANTINA DR. REDDY'S 10 mg	film-coated tabl.	10mg	DR. REDDY'S LABORATORIES ROMANIA SRL	ROMANIA	10912	2018	01
MEMANTINUM HYDROCHLORIDE	MEMANTINA TEVA	oral sol.	10mg/ml	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	10927	2018	01
MESALAZINUM	SALOFALK	suppos.	1g	DR. FALK PHARMA GmbH	GERMANY	10973	2018	01
METAMIZOLUM SODIUM	LOCAMIN	oral sol.	500mg/ml	STADA ARZNEIMITTEL AG	GERMANY	10914	2018	01
METAMIZOLUM SODIUM	ALVOTOR	oral drops, sol.	500mg/ml	TORRENT PHARMA S.R.L.	ROMANIA	10915	2018	01
METAMIZOLUM SODIUM	ALVATOR	oral drops, sol.	500 mg/ml	TORRENT PHARMA GmbH	ROMANIA	10915	2018	01
METAMIZOLUM SODIUM	ALGOCALMIN	tabl.	500 mg	ZENTIVA S.A.	ROMANIA	10965	2018	01
METHADONUM	MISYO	conc. for oral sol.	10mg/ml	INN-FARM d.o.o.	SLOVENIA	10898	2018	01
METOCLOPRAMIDUM CLORHIDRATUM	METOCLOPRAMID	sol. for inj.	10 mg	TERAPIA S.A.	ROMANIA	10968	2018	01

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number		
METOPROLOLUM TARTRATE	METOPROLOL TARTRAT AUROBINDO	film-coated tabl.	50mg	AUROBINDO PHARMA LIMITED	MALTA	10859	2018	01
METOPROLOLUM TARTRATE	METOPROLOL TARTRAT AUROBINDO	film-coated tabl.	100mg	AUROBINDO PHARMA LIMITED	MALTA	10860	2018	01
NETILMICINUM	NETTACIN	eye drops, sol	0.3%	S.I.F.I. S.p.A	ITALY	10811	2018	01
NETILMICINUM	NETTACIN	eye ointment	3mg/g	S.I.F.I S.p.A	ITALY	10966	2018	01
NETILMICINUM	NETTACIN	eye drops, sol	3 mg/ ml	S.I.F.I. S.p.A	ITALY	10967	2018	01
OLANZAPINUM	OLANZAPINA AUROBINDO	tabl.	5mg	AUROBINDO PHARMA LIMITED	MALTA	10993	2018	01
OLANZAPINUM	OLANZAPINA AUROBINDO	tabl.	10mg	AUROBINDO PHARMA LIMITED	MALTA	10994	2018	01
OLANZAPINUM	OLANZAPINA AUROBINDO	tabl.	15mg	AUROBINDO PHARMA LIMITED	MALTA	10995	2018	01
OMEGA 3 ACID ETHYL ESTER 90	TEVOCOR	caps.	1000 mg	TEVA UK Ltd	UK	10916	2018	01
OMEPRAZOLUM	OMEPRAZOL SANDOZ	gastrores. caps.	10mg	SANDOZ S.R.L.	ROMANIA	10875	2018	01
OMEPRAZOLUM	OMEPRAZOL SANDOZ	gastrores. caps.	20mg	SANDOZ S.R.L.	ROMANIA	10876	2018	01
PANTOPRAZOLE SODIUM	PANTOPRAZOL KRKA	gastrores. tabl.	20mg	KRKA D.D. NOVO MESTO	SLOVENIA	10865	2018	01
PANTOPRAZOLE SODIUM	PANTOPRAZOL KRKA	gastrores. tabl.	40mg	KRKA D.D. NOVO MESTO	SLOVENIA	10866	2018	01
PERINDOPRILUL TOSILATE + AMLODIPINE	AMLESSA	tabl.	4mg/5mg	KRKA D.D. NOVO MESTO	SLOVENIA	10889	2018	01

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number		
PERINDOPRILUL TOSILATE + AMLODIPINE	AMLESSA	tabl.	4mg/10mg	KRKA D.D. NOVO MESTO	SLOVENIA	10890	2018	01
PERINDOPRILUL TOSILATE + AMLODIPINE	AMLESSA	tabl.	8mg/5mg	KRKA D.D. NOVO MESTO	SLOVENIA	10891	2018	01
PERINDOPRILUL TOSILATE + AMLODIPINE	AMLESSA	tabl.	8mg/10mg	KRKA D.D. NOVO MESTO	SLOVENIA	10892	2018	01
PERINDOPRILUM ARGININE/AMLODIPINUM	PRESTANCE	tabl	5 mg/5 mg	LES LAB. SERVIER IND.	FRANCE	10997	2018	01
PERINDOPRILUM ARGININE/AMLODIPINUM	PRESTANCE	tabl	5 mg/10 mg	LES LAB. SERVIER IND.	FRANCE	10998	2018	01
PERINDOPRILUM ARGININE/AMLODIPINUM	PRESTANCE	tabl	10 mg/5 mg	LES LAB. SERVIER IND.	FRANCE	10999	2018	01
PERINDOPRILUM ARGININE/AMLODIPINUM	PRESTANCE	tabl	10 mg/ 10 mg	LES LAB. SERVIER IND.	FRANCE	11000	2018	01
PLANTE	CYSTINOL	draj.	265 mg	3F PLANTAMED SRL	ROMANIA	10867	2018	01
PLANTE	FEMIBEN	caps.	4 mg	3F PLANTAMED SRL	ROMANIA	10868	2018	01
PLANTE	DROPIZOL	oral sol.	10mg/ml	PHARMANOVIA A/S	DENMARK	10930	2018	01
PRAMIPEXOLUM	MEDOPEXOL	tabl.	0.18mg	MEDOCHEMIE LTD	CYPRUS	10857	2018	01
PRAMIPEXOLUM	MEDOPEXOL	tabl.	0.7mg	MEDOCHEMIE LTD	CYPRUS	10858	2018	01
PRODUSE BIOLOGICE	HUMULIN R FLACON	sol. for inj.	100IU/ml	ELI LILLY AND COMPANY LTD.	UK	10812	2018	01
PRODUSE BIOLOGICE	HUMULIN R CARTUS	sol. for inj.	100IU/ml	ELI LILLY AND COMPANY LTD.	UK	10813	2018	01
PRODUSE BIOLOGICE	HUMULIN N CARTUS	sol. for inj.	100IU/ml	ELI LILLY AND COMPANY LTD.	UK	10814	2018	01
PRODUSE BIOLOGICE	HUMULIN M3 CARTUS	sol. for inj.	100IU/ml	ELI LILLY AND COMPANY LTD.	UK	10815	2018	01

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number		
PRODUSE BIOLOGICE	HUMULIN R KwikPen	sol. for inj.	100IU/ml	ELI LILLY AND COMPANY LTD.	UK	10816	2018	01
PRODUSE BIOLOGICE	HUMULIN N KwikPen	sol. for inj.	100IU/ml	ELI LILLY AND COMPANY LTD.	UK	10817	2018	01
PRODUSE BIOLOGICE	HUMULIN M3 KwikPen	sol. for inj.	100IU/ml	ELI LILLY AND COMPANY LTD.	UK	10818	2018	01
PRODUSE RADIOFARMACEUTICE	FID-MIBI	kit for radiopharm. prep.	1 mg	FIDELIO FARM. S.R.L	ROMANIA	10949	2018	01
RIFAXIMINUM	TIXTELLER	film-coated tabl.	550 mg	ALFASIGMA SPA	ITALY	10895	2018	01
RIVASTIGMINUM	RIVASTIGMINA ARENA	caps.	1.5mg	ARENA GROUP S.A.	ROMANIA	10905	2018	01
RIVASTIGMINUM	RIVASTIGMINA ARENA	caps.	3mg	ARENA GROUP S.A.	ROMANIA	10906	2018	01
RIVASTIGMINUM	RIVASTIGMINA ARENA	caps.	4.5mg	ARENA GROUP S.A.	ROMANIA	10907	2018	01
RIVASTIGMINUM	RIVASTIGMINA ARENA	caps.	6mg	ARENA GROUP S.A.	ROMANIA	10908	2018	01
ROPINIROLUM HYDROCHLORIDE	ROPINIROL AUROBINDO	prol. release tabl.	2mg	AUROBINDO PHARMA LIMITED	MALTA	10974	2018	01
ROPINIROLUM HYDROCHLORIDE	ROPINIROL AUROBINDO	prol. release tabl.	4mg	AUROBINDO PHARMA LIMITED	MALTA	10975	2018	01
ROPINIROLUM HYDROCHLORIDE	ROPINIROL AUROBINDO	prol. release tabl.	8 mg	AUROBINDO PHARMA LIMITED	MALTA	10976	2018	01
ROPIVACAINUM HYDROCHLORIDE	ROPIVACAINA BIOQ PHARMA	sol. for inf.	2mg/ml	BIOQ PHARMA B.V.	BELGIUM	10825	2018	01
ROSUVASTATINUM + EZETIMIBUM	LIPOCOMB CALCIU	caps.	10/10mg	EGIS PHARMACEUTICALS PLC	HUNGARY	10960	2018	01
ROSUVASTATINUM + EZETIMIBUM	LIPOCOMB CALCIU	caps.	20/10mg	EGIS PHARMACEUTICALS PLC	HUNGARY	10961	2018	01

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number		
ROSUVASTATINUM CALCIUM	ROSUVASTATINA TEVA	film-coated tabl.	10mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	10920	2018	01
ROSUVASTATINUM CALCIUM	ROSUVASTATINA TEVA	film-coated tabl.	20mg	TEVA PHARMACEUTICALS S.R.L.	ROMANIA	10921	2018	01
ROSUVASTATINUM CALCIUM	ROSUVASTATINA AUROBINDO	film-coated tabl.	5mg	AUROBINDO PHARMA B.V.	NETHERLANDS	10983	2018	01
ROSUVASTATINUM CALCIUM	ROSUVASTATINA AUROBINDO	film-coated tabl.	10mg	AUROBINDO PHARMA B.V.	NETHERLANDS	10984	2018	01
ROSUVASTATINUM CALCIUM	ROSUVASTATINA AUROBINDO	film-coated tabl.	20mg	AUROBINDO PHARMA B.V.	NETHERLANDS	10985	2018	01
ROSUVASTATINUM CALCIUM	ROSUVASTATINA AUROBINDO	film-coated tabl.	40mg	AUROBINDO PHARMA B.V.	NETHERLANDS	10986	2018	01
SOLIFENACINUM SUCCINATUM	VESISTAD	film-coated tabl.	5mg	STADA M&D SRL	ROMANIA	11001	2018	01
SOLIFENACINUM SUCCINATUM	VESISTAD	film-coated tabl.	10mg	STADA M&D SRL	ROMANIA	11002	2018	01
TAFLUPROSTUM	SAFLUTAN	eye drops, sol	15mcg/ml	SANTEN OY	FINLAND	10861	2018	01
TEICOPLANINUM	TEICOPLANINA MYLAN	powd. and solv. for sol. for inj.	100mg	MYLAN S.A.S.	FRANCE	10990	2018	01
TEICOPLANINUM	TEICOPLANINA MYLAN	powd. and solv. for sol. for inj.	200mg	MYLAN S.A.S.	FRANCE	10991	2018	01
TEICOPLANINUM	TEICOPLANINA MYLAN	powd. and solv. for sol. for inj.	400mg	MYLAN S.A.S.	FRANCE	10992	2018	01
TELMISARTANUM	TELMISARTAN EGIS	film-coated tabl.	20mg	EGIS PHARMACEUTICALS PLC	HUNGARY	10843	2018	01

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number		
TELMISARTANUM	TELMISARTAN EGIS	film-coated tabl.	40mg	EGIS PHARMACEUTICALS PLC	HUNGARY	10844	2018	01
TELMISARTANUM	TELMISARTAN EGIS	film-coated tabl.	80mg	EGIS PHARMACEUTICALS PLC	HUNGARY	10845	2018	01
TELMISARTANUM HYDROCHLOROTHIAZIDUM	TELMISARTAN/HYDROCHLOROTHIAZIDA BILLEV	tabl.	40 mg/ 12.5 mg	BILLEV PHARMA ApS	DENMARK	10840	2018	01
TELMISARTANUM HYDROCHLOROTHIAZIDUM	TELMISARTAN/HYDROCHLOROTHIAZIDA BILLEV	tabl.	80 mg/ 12.5 mg	BILLEV PHARMA ApS	DENMARK	10841	2018	01
TELMISARTANUM HYDROCHLOROTHIAZIDUM	TELMISARTAN/HYDROCHLOROTHIAZIDA BILLEV	tabl.	80 mg/25 mg	BILLEV PHARMA ApS	DENMARK	10842	2018	01
TENOFOVIRUM DISOPROXILUM	TENOFOVIR DISOPROXIL CIPLA	film-coated tabl.	245mg	CIPLA (EU) LIMITED	UK	10874	2018	01
TESTOSTERONUM	TESTAVAN	transdermal gel	20mg/g	FERRING CONTROLLED THERAPEUTICS LIMITED	UK	10863	2018	01
TRAMADOLUM HYDROCHLORIDE/ DEXKETOPROFENUM	SKUDEXA	gran. for oral sol.	75/25mg	MENARINI INTERNATIONAL OPERATIONS S.A.	LUXEMBOURG	10870	2018	01
TRIFLUSALUM	PLATROX	caps.	300mg	GLENMARK PHARMACEUTICALS S.R.O.	CZECH REPUBLIC	10897	2018	01
TRIMETAZIDINUM	TRIMETAZIDINA MYLAN	prol. release tabl.	35 mg	MYLAN B.V.	FRANCE	10980	2018	01
VALSARTANUM	VALSARTAN TORRENT	film-coated tabl.	40 mg	TORRENT PHARMA GmbH	GERMANY	10833	2018	01
VALSARTANUM	VALSARTAN TORRENT	film-coated tabl.	80 mg	TORRENT PHARMA GmbH	GERMANY	10834	2018	01
VALSARTANUM	VALSARTAN TORRENT	film-coated tabl.	160 mg	TORRENT PHARMA GmbH	GERMANY	10835	2018	01

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number		
VALSARTANUM	VALSARTAN TORRENT	film-coated tabl.	320mg	TORRENT PHARMA GmbH	GERMANY	10836	2018	01
VALSARTANUM + HYDROCHLORITHIAZIDE	VALSARTAN HIDROCLOROTIAZIDA TORRENT	film-coated tabl.	80mg/12.5mg	TORRENT PHARMA GmbH	GERMANY	10846	2018	01
VALSARTANUM + HYDROCHLORITHIAZIDE	VALSARTAN HIDROCLOROTIAZIDA TORRENT	film-coated tabl.	160mg/ 12.5mg	TORRENT PHARMA GmbH	GERMANY	10847	2018	01
VALSARTANUM + HYDROCHLORITHIAZIDE	VALSARTAN HIDROCLOROTIAZIDA TORRENT	film-coated tabl.	160mg/25mg	TORRENT PHARMA GmbH	GERMANY	10848	2018	01
VALSARTANUM + HYDROCHLORITHIAZIDE	VALSARTAN HIDROCLOROTIAZIDA TORRENT	film-coated tabl.	320mg/ 12.5mg	TORRENT PHARMA GmbH	GERMANY	10849	2018	01
VALSARTANUM + HYDROCHLORITHIAZIDE	VALSARTAN HIDROCLOROTIAZIDA TORRENT	film-coated tabl.	320mg/25mg	TORRENT PHARMA GmbH	GERMANY	10850	2018	01
VENIN DE ALBINA	ALUTARD SQ	sol. for inj		ALK - ABELLO A/S	DENMARK	10819	2018	01
VENIN DE ALBINA	ALUTARD SQ	sol. for inj		ALK - ABELLO A/S	DENMARK	10820	2018	01
VENIN DE VIESPE	ALUTARD SQ	sol. for inj		ALK - ABELLO A/S	DENMARK	10821	2018	01
VENIN DE VIESPE	ALUTARD SQ	sol. for inj		ALK - ABELLO A/S	DENMARK	10822	2018	01
VORICICONAZOLUM	VORICONAZOL SANDOZ	film-coated tabl.	50mg	SANDOZ S.R.L.	ROMANIA	10855	2018	01
VORICICONAZOLUM	VORICONAZOL SANDOZ	film-coated tabl.	200mg	SANDOZ S.R.L.	ROMANIA	10856	2018	01
XILOMETAZOLINUM HYDROCHLORIDE/ DEXPANTHENOLUM	SEPTANAZAL	nasal spray, sol.	1mg/50mg/ml	KRKA D.D. NOVO MESTO	SLOVENIA	10977	2018	01

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number		
XILOMETAZOLINUM HYDROCHLORIDE/ DEXPANTHENOLUM	SEPTANAZAL PENTRU COPII	nasal spray, sol.	0.5mg/ 50mg/ml	KRKA D.D. NOVO MESTO	SLOVENIA	10978	2018	01
ZOFENOPROLUM CALCIUM + HYDROCHLOROTHIAZIDE	ZOMEN PLUS	film-coated tabl.	30/12.5mg	MENARINI MANUFACTURING LOGISTICS AND SERVICES	ITALY	10952	2018	01
ZOLPIDEMUM TARTRATE	ZADOBRA	film-coated tabl.	5mg	ALKALOID d.o.o. LJUBLJANA	SLOVENIA	10981	2018	01
ZOLPIDEMUM TARTRATE	ZADOBRA	film-coated tabl.	10mg	ALKALOID d.o.o. LJUBLJANA	SLOVENIA	10982	2018	01

Centrally authorised medicinal products notified for marketing in Romania during the 3rd quarter 2018

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number		
ABEMACICLIBUM	VERZENIOS 50 mg	film-coated tabl.	50mg	ELI LILLY NEDERLAND B.V.	NETHERLANDS	1307	2018	03
ABEMACICLIBUM	VERZENIOS 100 mg	film-coated tabl.	100mg	ELI LILLY NEDERLAND B.V.	NETHERLANDS	1307	2018	06
ABEMACICLIBUM	VERZENIOS 150 mg	film-coated tabl.	150mg	ELI LILLY NEDERLAND B.V.	NETHERLANDS	1307	2018	09
ADALIMUMABUM	HULIO	sol. for inj. in pre-filled syringe	40mg/0,8ml	MYLAN S.A.S.	FRANCE	1319	2018	07
ADALIMUMABUM	HULIO	sol. for inj. in pre-filled syringe	40mg	MYLAN S.A.S.	FRANCE	1319	2018	01
ADALIMUMABUM	HULIO	sol. for inj. in pre-filled pen	40mg	MYLAN S.A.S.	FRANCE	1319	2018	04
ADALIMUMABUM	HYRIMOZ 40 mg	sol. for inj. in pre-filled pen	40mg/0,8ml	SANDOZ GMBH	AUSTRIA	1286	2018	05
DURVALUMABUM	IMFINZI 50 mg/ml	conc. for sol. for inf.	50mg/ml	ASTRAZENECA AB	SWEDEN	1322	2018	02
ERENUMABUM	AIMOVIG 70 mg	sol. for inj. in pre-filled syringe	70mg	NOVARTIS EUROPHARM LIMITED	IRELAND	1293	2018	03
ERENUMABUM	AIMOVIG 70 mg	sol. for inj. in pre-filled pen	70mg	NOVARTIS EUROPHARM LIMITED	IRELAND	1293	2018	01
LENALIDOMIDUM	LENALIDOMIDE ACCORD 2.5 mg	caps.	2.5mg	ACCORD HEALTHCARE LIMITED	UK	1316	2018	02
LENALIDOMIDUM	LENALIDOMIDE ACCORD 5 mg	caps.	5mg	ACCORD HEALTHCARE LIMITED	UK	1316	2018	04
LENALIDOMIDUM	LENALIDOMIDE ACCORD 7.5 mg	caps.	7.5mg	ACCORD HEALTHCARE LIMITED	UK	1316	2018	05
LENALIDOMIDUM	LENALIDOMIDE ACCORD 10 mg	caps.	10mg	ACCORD HEALTHCARE LIMITED	UK	1316	2018	07

INN	Trade name	Pharm. form	Strength	MAH	Country	MA number		
LENALIDOMIDUM	LENALIDOMIDE ACCORD 15 mg	caps.	15mg	ACCORD HEALTHCARE LIMITED	UK	1316	2018	09
LENALIDOMIDUM	LENALIDOMIDE ACCORD 20 mg	caps.	20mg	ACCORD HEALTHCARE LIMITED	UK	1316	2018	10
LENALIDOMIDUM	LENALIDOMIDE ACCORD 25 mg	caps.	25mg	ACCORD HEALTHCARE LIMITED	UK	1316	2018	11
PATISIRANUM	ONPATTRO 2 mg/ml	conc. for sol. for inf.	2mg/ml	ALNYLAM NETHERLANDS B.V.	NETHERLANDS	1320	2018	01
PEGFILGRASTIMUM	PELGRAZ 6 mg	sol. for inj. in pre-filled syringe	6mg	ACCORD HEALTHCARE LIMITED	UK	1313	2018	01
TISAGENLECLEUCEL	KYMRIAH	dispers. for inf.		NOVARTIS EUROPHARM LIMITED	IRELAND	1297	2018	01
TRASTUZUMABUM	TRAZIMERA 150 mg	powd. for conc. for sol. for inf.	150mg	PFIZER EUROPE MA EEIG	BELGIUM	1295	2018	01