# ORDER

## of the Minister of Health No. 269/2017 of 14 March 2017

## on mandatory provision of medicinal product adequate and continuous stocks

ISSUING BODY: The Ministry of Health

published in: the Official Gazette No. 183 of 15 March 2017

On seeing the Approval Report No. FB 2.193/2017 of the Directorate for Policies on Medicinal Products and Medical Devices,

Taking into account provisions of Article no. 699 (19) and of Article no. 804 (2) of Law no. 95/2006 on healthcare reform republished as amended,

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

the Minister of Health hereby issues the following order:

**Article 1**

For the purposes of this order, terms and concepts used herein shall have the following meaning:

a) beneficiaries – healthcare units under contract with health insurance houses, conducting national healthcare programs, and pharmacies;

b) justified order – request by fax or email for medicinal product delivery, containing information on the name and the quantity thereof, as well as batch, number and date relating to a medical prescription, placed by a pharmacy with contracted wholesalers, or, as the case may be, request by e-mail or fax for delivery of medicines, placed based on the contract between healthcare facilities under contract with health insurance houses or facilities conducting national healthcare programmes and a Marketing Authorisation Holder or their legal representative in Romania, hereinafter referred to as MAH, or wholesale distributor, providing for contract obligations clearly specifying medicinal product names, quantities and delivery deadlines under the contract;

c) Temporary list of medicinal products under surveillance - list of all trade names related to a medicinal product, as defined by International Non-Proprietary

Name, hereinafter referred to as INN, pharmaceutical form and strength, under temporary ban of intra-Community supply and export;

d) intra-Community delivery – supply of medicinal products included in the List within the meaning of subparagraph e), delivered or transported from Romania to a Contracting State in the European Economic Area by the supplier or by the delivery recipient or a different body on their behalf;

e) enlisted medicinal products – trade names of medicinal products whose respective INNs are included in the List of International Non-Proprietary Names of on-prescription medicinal products provided to insurants, irrespective of personal contribution within the healthcare insurance system, as well as International Non-Proprietary Names (INNs) of medicinal products provided in the frame of national healthcare programmes, approved by Government Decision No. 720/2008, as amended;

f) national alert – decrease under the average monthly turnover for 7 consecutive days of nationwide stocks for the medicinal product category with the same INN, pharmaceutical form and strength;

g) average monthly turnover – monthly average turnover of the respective medicinal product for the past three months, representing the minimum necessary to meet public healthcare needs;

h) exceptional circumstances - situations notified by the MAH to the National Agency for Medicines and Medical Devices, hereinafter referred to as the NAMMD, in accordance with the law, on matters of quality/safety, failure to supply active substances, withdrawal of the Certificate of compliance with the European Pharmacopoeia or of the Good Manufacturing Practice Certificate, temporary discontinuation of manufacture;

i) buffer stock - quantity of enlisted medicinal products, available in the wholesaler's stock between two successive supplies, representing the minimum adequate and continuous stocks able to meet any justified order placed with the respective wholesaler;

j) term of delivery - maximum 24 hours for justified orders related to a medical prescription for acute and subacute conditions or 48 hours, respectively, or justified orders related to a medical prescription for chronic conditions.

**Article 2**

(1) The average monthly turnover is calculated based on information submitted to the Ministry of Health via the Electronic System for Inventory Reporting, hereinafter ESIR, as regulated by Order of the Minister of Health no. 1345/2016

on daily reporting of stocks and trade operations carried out with medicinal products for human use included in the National catalogue of prices for medicinal products authorised for marketing in Romania by medicinal product distributors, importers, authorised manufacturers and closed- and open-circuit pharmacies.

(2) MAHs shall permanently warrant compliance with the public service obligation by providing a monthly minimum level equal to the average monthly turnover as defined under Article 10 g) for each listed medicinal product they hold an authorisation for marketing in Romania.

(3) Wholesalers shall permanently warrant compliance with the public service obligation by setting up buffer stocks equal to the average monthly turnover for each enlisted product they distribute.

(4) Wholesalers shall meet any justified orders submitted by contract beneficiaries, within terms of delivery pursuant to Article 1 j).

(5) Beneficiaries shall submit justified orders to contracted wholesalers at least once for each wholesaler until their order is met.

(6) Beneficiaries shall ensure meeting of justified orders within the terms of delivery pursuant to Article 1 j). As proof of justified order, units dispensing medicinal products to the public may retain the medical prescription for not longer than 48 hours, on written consent by the patient.

(7) Wholesalers shall notify the received justified order to the MAH or other wholesalers under contract from whom they had purchased the medicinal product subject to the justified order.

(8) When unable to meet a justified order, wholesalers shall communicate the justified order to the MAH or other wholesalers under contract. MAH or, where appropriate, wholesalers under contract are required to meet the justified order received or notify the ordering party that they fall under the scope of one of the situations referred to in Article 1 (h), notified to the NAMMD.

(9) Where wholesalers are unable to meet the justified order, beneficiaries shall notify the NAMMD, in electronic format, to lipsamedicament@anm.ro as well as, for electronic medical prescriptions, the respective healthcare insurance houses to which they are allocated.

(10) MAHs, wholesalers and beneficiaries are exempt from compliance with the public service obligation in exceptional circumstances defined under Article 1 h).

Article 3

(1) Emergence of a nation-wide alert under Article 1 f) is publicly reported and communicated to the Ministry of Health through the ESIR.

(2) Within 3 days following emergence of the national alert, the Ministry of Health includes the category of medicinal products with the same INN, pharmaceutical form and strength into the Temporary list of medicinal products under surveillance.

(3) The Temporary list of medicinal products under surveillance is approved and updated as necessary by order of the Minister of Health and posted on the website of the Ministry of Health and the NAMMD.

(4) Immediately following the national alert signal, the Ministry of Health requests the NAMMD to confirm whether the cause of the alert falls within one of the exceptional situations provided for in Article 1 h).

(5) In case of NAMMD confirmation that the cause of the national alert level falls within the exceptional situations provided for in Article 1 h), the Ministry of Health eliminates the medicinal product category with the same INN, pharmaceutical form and strength from the Temporary list of medicinal products under surveillance.

(6) On depletion of stocks of medicinal products covered by an exceptional circumstance pursuant to Article 1 h), the MAH shall notify the National Health Insurance House thereof.

(7) Where the NAMMD does not confirm that the cause of the national alert falls within the exceptional circumstances pursuant to Article 1 h), the category of medicinal products with the same INN, pharmaceutical form and strength is preserved in the Temporary list of medicinal products under surveillance until restoration and retention for 14 consecutive days from the date of the respective category's inclusion into this list of national stocks in excess of the average monthly turnover.

(8) For medicines included in the Temporary list of medicinal products under surveillance, MAHs are required to notify the NAMMD and the Ministry of Health no later than 3 days after the date of Temporary list publication on the Ministry of Health web page under the "Decision-making transparency" section related to wholesalers contracted to ensure distribution of respective medicinal products; the same information is posted by the NAMMD and the Ministry of Health on their own web sites.

**Article 4**

In case of Ministry of Health reporting by means of the ESIR of decrease for 7 consecutive days of wholesaler stocks of products in the list below the average monthly turnover of the respective wholesaler, the Ministry of Health shall notify the NAMMD, who shall immediately initiate an inspection procedure according to the law.

**Article 5**

(1) 10 days before conduct of an intra-Community delivery, transactions between two or more representative offices of the same company in different countries included, the MAH, the wholesaler or pharmacies shall notify the NAMMD by submission of the filled-in self declaration in respect of compliance with the public service obligation, in accordance with the annex integral to this order.

(2) Data identifying the respective medicinal product (i.e. trade name, pharmaceutical form, INN, package size, quantity, batch) covered by the notification referred to in (1) shall be posted on the NAMMD website within 5 days from notice submission.

(3) For legal entities authorised for parallel conduct of medicinal product dispensing to the public and wholesale activities, records shall make specific notice whether the medicinal products are received or held in stock as retailer or as wholesaler. Where medicinal products are received or held in stock as retailer, these may not be subject to wholesale distribution.

Article 6

This Order shall be published in the Official Gazette of Romania, Part I.

The Ministry of Health

Florin-Dorel Bodog

Bucharest, 14 March 2017.

No. 269.

ANNEX

**NOTIFICATION OF INTRA-COMMUNITY DELIVERY**

**Medicinal products for human use**

Name of the wholesaler .....

Address .....

Unique registration code (CUI) .....

Wholesale distribution authorisation no. .....

Retail distribution authorisation for the same CUI YES NO

Trade name of the medicinal product (pursuant to MA) .....

INN .....

Pharmaceutical form.....

Strength .....

Package size .....

CIM Code: .....

ATC Code .....

MAH .....

Quantity .....

Purchased from .....

Country intended for distribution .....

Stocks on notification (excluding the quantity notified above.....

I, the undersigned ... ... ... ... ... ... ... ... ... ... ... .... in my capacity as ... ... ... ... ... ... ... ... ... ... .... of the wholesaler ... ... ... ... ... ... ... ... ... ... ... ... ... ... ... ... ... ... ..., holder of Wholesale Distribution Authorisation no. ... ... ... ... ... ... ... ... .., fully aware of legal provisions relating to false statements, hereby declare under my own responsibility that all orders received for the medicinal product covered by

this notification have been met, and that the notified intra-Community delivery does not affect my public service obligation.

Legal representative,

---