MINISTRY OF HEALTH

ORDER No. 1.772
of 24 May 2023
on approval of the conditions for temporary authorisation of the distribution of an unauthorised medicinal product, purchased by the Ministry of Health from the Global Drug Facility (GDF) with financing from the Global Fund, in order to be used within national public health programmes

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On seeing the Approval report no. AR/9.300/2023 of the General Directorate of Public Health and Health Programmes within the Ministry of Health,

taking into account the provisions of:

- Art. 703 (21) of Law 95/2006 on healthcare reform, republished, as further amended and supplemented;
- Government Decision no. 423/2022 on approval of national health programmes, as further amended and supplemented;

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

the minister of health hereby issues the following order:

Art. 1 – This Order establishes the conditions for temporary authorisation by the National Agency for Medicines and Medical Devices of Romania, hereinafter referred to as the NAMMDR, of the distribution of an unauthorised medicinal product, purchased by the Ministry of Health from the Global Drug Facility (GDF) with financing from the Global Fund, hereinafter referred to as a medicinal product purchased from the Programme, in order to be used within national public health programmes, in line with the provisions of Art. 703 (21) of Law 95/2006 on healthcare reform, republished, as further amended and supplemented.

Art. 2 – The following do not fall under the scope of this Order:

a) medicinal products with a marketing authorisation valid in Romania, in line with Art. 704 of Law 95/2006, republished, as further amended and supplemented;

b) Medicinal products subject to a clinical trial carried out in Romania and those used outside the approved therapeutic indications.

Art. 3 - (1) The NAMMDR issues a temporary authorisation for the distribution of a medicinal product purchased from the Programme, in line with Art. 703 (21) of Law 95/2006, republished as further amended and supplemented, only if:

a) there is a supporting document regarding the inclusion of the requested medicinal product, in line with the provisions of Art. 703 (2^1) of Law 95/2006, republished, as further amended and supplemented, issued by the specialised departments within the Ministry of Health, specifying the required quantity provided by the competent institutions or specialised commissions within the Ministry of Health;

b) the medicinal product is authorised in at least one state of the European Economic Area or in a third country.

(2) The temporary authorisation for distribution, issued for a medicinal product purchased from the Programme, is valid until the quantity for which it was issued is used up.

(3) Medicinal products authorised according to this Order, which are issued exclusively by the closed-circuit pharmacy/closed-circuit office, are exempted from the legal provisions in force regarding the packaging/labelling of medicinal products authorised to be placed on the market.

Art. 4 - The wholesale distributor, holder of a temporary distribution authorisation of a medicinal product purchased from the Programme, has the obligation to accompany each delivery to the beneficiaries of the latest approved version of the leaflet and the summary of the product characteristics, attached to the marketing authorisation in the country of origin and their authorised translation into Romanian.

Art. 5 - (1) The Ministry of Health, through its specialised department, forwards to the wholesale distributor, provided for in Art. 6, the supply and the purchase agreement/contract/order regarding the medicinal product, the form of presentation, the concentration and the quantity, in order to obtain the temporary distribution authorization for a medicinal product purchased from the Programme.

(2) The NAMMDR issues the temporary distribution authorisation for a medicinal product purchased from the Programme within a maximum of 10 working days from the registration of the documentation in line with Art. 7.

Art. 6 - The temporary distribution authorisation of a medicinal product purchased from the Programme can only be issued for the wholesale distributor who is a signatory of the framework agreement/service contract for storage, preservation and release of products purchased by the Ministry of Health or received through donations or sponsorships, authorized by the NAMMDR, in line with Annex 1.

Art. 7 - (1) In order to obtain the temporary distribution authorisation, the wholesale distributor provided for in Art. 6 submits to the NAMMDR, within no more than five working days after receipt of the supply and the framework agreement/purchase contract

from the Ministry of Health through the specialised departments, in line with Art. 5 (1), a documentation including:

a) the standard request form according to Annex 2;

b) the medical justification and the amount communicated by the General Directorate of Public Health and Health Programmes of the Ministry of Health;

c) marketing authorisation in one of the states of the European Economic Area or from the third country where it is authorised;

d) the good manufacturing practice certificates for the manufacturers involved in the manufacture of the medicinal product: the manufacturer(s) of the finished product, the manufacturer(s) involved in the primary and secondary packaging of the finished product, the manufacturer(s) involved in the secondary packaging of the finished product, the manufacturer/manufacturers involved in testing the batch of the finished product and the manufacturer(s) involved in releasing the batch of the finished product;

e) the quality specifications of the medicinal product (on release and during the period of validity), quality and compliance certificates for a medicinal product batch. In the case of biological products, the summary of the protocol of the batch will be sent, demonstrating the existence of specific information collected by the manufacturer during the production and quality control of a batch of vaccine/blood derivative, signed by the responsible person of the manufacturer;

f) The proof that they have specialised staff responsible for the pharmacovigilance activity and the required means for immediate notification of the NAMMDR regarding all suspected adverse reactions, reported in Romania, and for the collection of additional information obtained after follow-up of these adverse reactions.

(2) The temporary distribution authorisation of a medicinal product purchased from the Programme can be suspended if it is found that the conditions under which it was granted are no longer respected. The suspension is maintained until the identified deficiencies are remedied, without extending the authorisation term.

(3) The temporary distribution authorisation of a medicinal product purchased from the Programme is withdrawn in the following situations:

a) deficiencies found according to paragraph (2) cannot be remedied;

b) There is noncompliance with any of the obligations of the wholesale distributor provided by Art. 8.

(4) After obtaining the temporary distribution authorisation of a medicinal product purchased from the Programme, the wholesale distributor submits to the NAMMDR the request for exemption from the legal provisions in force regarding the packaging/labelling of medicinal products authorised to be placed on the market, other than those provided for in the Rules regarding the procedure for granting an exemption from the obligation of the

submission of certain information on the label and in the leaflet and from the obligation that the leaflet be in Romanian, in the case of medicinal products for human use which are not intended for direct delivery to the patient, approved by Order of the Minister of Public Health no. 872/2006.

Art. 8 – The wholesale distributor, holder of a temporary distribution authorisation of a medicinal product purchased from the programme, must comply with the following obligations:

a) to immediately inform the NAMMDR about the safety or quality problems, including those caused by a possible falsification, about which he was notified;

b) not to advertise the medicinal product;

c) to keep specific records/documents regarding its distribution, according to the provisions of Art. 9;

d) to notify the NAMMDR of the actual imported/traded quantity of the respective medicinal product at each entry/exit, the medicinal product stock and any other issues arising in its supply, by the 15th day of each month, as well as anytime within one working day after the NAMMDR request, for the entire period of validity of the temporary distribution authorisation of a medicinal product purchased from the Programme;

e) to make sure that the use of the medicinal product for which the temporary distribution authorisation of a medicinal product purchased from the Programme was issued is only done on Romanian territory;

f) to immediately notify the NAMMDR regarding all suspected adverse reactions reported in Romania, and to submit to the NAMMDR the additional information obtained based on the follow-up of these adverse reactions.

Art. 9 - The records/documents provided for in Art. 8 c) must be kept for a period of at least 5 years from the date of expiry of the temporary distribution authorisation of a medicinal product purchased from the Programme and contain the following information:

a) the external supplier of the medicinal product;

b) and list of beneficiaries to whom the medicinal product was provided;

c) the quantity of each delivery;

d) the series of the medicinal product;

e) the storage/transport conditions of the medicinal product;

f) the details of any adverse reaction known to the supplier;

g) details of any reports of falsification of the medicinal product known to the supplier.

Art. 10 - The NAMMDR can request the wholesale distributor at any time the status of the records/documents mentioned in Art. 9 and may order any measure related to the medicinal product purchased from the Programme, related to its quality, safety or effectiveness, which would reduce a potential risk for the patient's health or for public health.

Art. 11 – Annexes 1 and 2 are integral parts of this Order.

Art. 12 - The Ministry of Health, the specialized commissions within the Ministry of Health and the NAMMDR shall carry out the provisions of this Order.

Art. 13 - This Order shall be published in the Official Gazette of Romania, Part I.

On behalf of the Minister of Health,
Alexandru-Florin Rogobete,
Secretary of state

Annex 1

THE MINISTRY OF HEALTH

THE NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES OF ROMANIA

No. ..... of .....

AUTHORISATION

for temporary distribution of an unauthorised medicinal product, purchased by the Ministry of Health from the Global Drug Facility (GDF) with financing from the Global Fund, in order to be used within national public health programmes

On seeing request no. ..... of ....., submitted to the National Agency for Medicines and Medical Devices of Romania,

Considering the provisions of Art. 7 (5) of Law 134/2019 on reorganisation of the National Agency for Medicines and Medical Devices and amendment of further ruling provisions, as further amended and supplemented, and of Art. 703 (21) of Law 95/2006 on healthcare reform, republished, as further amended and supplemented,

wholesale distributor ..... is authorised for the distribution of ..... (name of the medicinal product), containing ....., *(international non-proprietary name)*

(trade name, pharmaceutical form and strength),

Marketing Authorisation Holder in country of origin ..... and country of origin ....., amount of ....., in order to respond to the request of the specialised department .....

(name of the specialised department)

of the Ministry of Health no. ..... of ..... .

This authorisation is valid for ..... months.

President

of the National Agency for Medicines and Medical Devices of Romania,

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