EUROPEAN COMMISSION

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His Excellency
Mr. Alexander Schallenberg
Federal Minister for European and
International Affairs
Minoritenplatz 8
A - 1014 Vienna

Subject: **Notification 2024/0037/AT**

The draft Ordinance of the Federal Minister for Social Affairs, Health, Care and Consumer Protection concerning the stockpiling of medicinal products for human use.

Delivery of comments pursuant to article 5(2) of Directive (EU) 2015/1535.

Dear Sir,

Within the framework of the notification procedure laid down in Directive (EU) 2015/1535 ([1]), the Austrian authorities notified to the Commission on 24 January 2024 the draft Ordinance of the Federal Minister for Social Affairs, Health, Care and Consumer Protection concerning the stockpiling of medicinal products for human use (Notification No 2024/0037/AT) (hereinafter "the notified draft").

As explained in the notification documents, the purpose of the notified draft is to safeguard the supply of medicinal products and prevent shortages through imposing a stockpiling and reporting obligation on marketing authorisation holders distributing their medicinal products in Austria. The stockpiling obligation consists of maintaining a stock of a medicinal product corresponding to 4 months' demand of this product. The reporting obligation consists of reporting annual demand for the medicinal product in question and

[1] ()Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).

of notifying whenever there is a shortfall below the mandated minimum storage quantity per medicinal product. The notified measures target prescription only, generic medicinal products that are absolutely necessary to ensure the medical care to patients if, either their unavailability poses a serious and significant risk to patients due to lack of treatment alternative, or if they have already been affected by shortages, or if a sharp increase of demand for them is to be expected. The medicines fulfilling the above criteria are listed in the annex to the notified draft.

The examination of the draft has prompted the Commission to issue the following comments.

The Commission recalls that Article 35 of the Treaty on the Functioning of the European Union (TFEU) prohibits national restrictions on exports. Member States may take measures that affect exports only if those measures are justified on one of the grounds listed under Article 36 TFEU, or other mandatory requirements established by the case-law of the Court of Justice of the European Union. Such individual measures need to be justified, i.e. be appropriate, necessary and proportionate to the public objective pursued.

In addition, the Commission highlights that Article 81, second paragraph of Directive 2001/83/EC ([2]) prescribes the following:

"The holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered."

The third paragraph of Article 81 of Directive 2001/83/EC provides that the arrangements for implementing that Article should be justified on grounds of public health protection and be proportionate in relation to the objective of such protection, in compliance with the Treaty rules, particularly those concerning the free movement of goods and competition.

A stockpiling obligation imposed on the marketing authorisation holders distributing the medicines in Austria may prevent them from moving freely the stock concerned to the other Member States.

According to settled case-law of the Court of Justice, a national measure restricting the exercise of the fundamental freedoms guaranteed by the Treaty may be allowed only if it pursues a legitimate objective in the public interest, is appropriate to ensuring the attainment of that objective and does not go beyond what is necessary to attain the objective pursued (see, to that effect, C-340/14 and C-341/14 *Trijber and Harmsen*, paragraph 70).

However, legislation capable of restricting a fundamental freedom guaranteed by the TFEU, such as the free movement of goods, can be justified only if it is appropriate for securing the attainment of the legitimate objective pursued and does not go beyond what is necessary in order to attain it (see, to that effect, in the context of human health, C-141/07 *Commission v Germany*, paragraph 48, C-421/09 *Humanplasma*, paragraph 34).

As a preliminary remark, the Commission would like to acknowledge that shortages are a serious issue, recognised by the Commission, including in the recently adopted

[2] () Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

Communication on shortages in the EU ([3]). Shortages are experienced by all Member States of the EU.

Addressing shortages of medicinal products is one of the objectives of the proposals for revision of EU pharmaceutical legal framework ([4]). The Proposal for the Regulation *laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency* ([5]) contains in its Chapter X a number of measures that aim at improving availability and ensuring the security of supply of medicinal products. These measures rely on extended notification and reporting obligations of the marketing authorisation holders and increased cooperation of the Member States at the EU level in management and prevention of shortages. Regulation (EU) 123/2022 *on a reinforced role of the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices* ([6]) constituted the first step in strengthening the collaboration on management and prevention of shortages.

The Commission is informed, through the notification process established by Directive (EU) 2015/1535, that some Member States introduced stockpiling obligations to which the impact assessment accompanying the notified draft also refers. These facts cannot however be relied upon to justify the introduction of similar measures as it is important to recall that any unilateral Member State measure, may have negative effect on the availability of the medicines on the markets of other Member States.

In this regard, the Commission would like to make the following comments regarding the notified draft.

Firstly, the medicines that the notified draft targets, covered by Section 2, paragraph 4, point 2, are prone to shortages across the EU. In particular, many EU Member States experience acute seasonal shortages of some of the antibiotics included in the Annex. This led the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) in the European Medicines Agency to issue, in preparation for the autumn/winter season 2023/2024, a recommendation ([7]) on the availability of certain antibiotics. The MSSG recommendation highlighted the need to avoid stockpiling. Given the lessons from COVID-19, it is important to ensure that during seasonal epidemiological peaks when the demand for certain medicines increases across the EU and shortages are experienced by many Member States, the medicines available on the EU market reach the patients that need them the most.([8]) In this context, the Commission would invite the Austrian authorities to consider opening a possibility of releasing stockpiles resulting from the notified draft in case of urgent demand in another Member State, in particular through application of the voluntary solidarity mechanism as agreed in

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[3] ()Communication from the Commission to the European Parliament, the Council, the European Economic and social Committee and the Committee of the Regions, Addressing medicine shortages in the EU, COM(2023)672 final.

[4] ()Proposal for a Regulation (COM(2023)193 final) and a Directive (COM(2023) 192 final) adopted by the Commission on 26 April 2023.

[5] () 26.4.2023, COM(2023)193 final.

[6] () *OJ L 20, 31.1.2022, p. 1.*

[7] ()Recommendation of the Executive Steering Group on shortages and Safety of Medicinal Products on the availability of a subset of antibiotics of 14.07.2023.

[8] ()Guidelines on the optimal and rational supply of medicines to avoid shortages during the COVID-19 outbreak (2020/C 116 I/01)

MSSG in October 2023 ([9]). Such possibility seems precluded under the notified draft, as proposed.

Secondly, to avoid that compliance with the stockpiling obligation, as proposed in the notified draft, negatively affects the availability of the products in scope of the measure on other EU markets, marketing authorisation holders may be required to increase the production. The notified draft proposes 10 months *vacatio legis* for the measure. In order to avoid the negative impact of the measure, it is important to ascertain that the proposed timeline is sufficient for the industry to ensure the compliance. As stems from the impact assessment accompanying the notified draft, the Austrian authorities relied on a presumption that the marketing authorisation holders have, already now, a stock corresponding to 3 months' demand. It is not clear what gave the ground to such presumption and whether the possible impact of establishment of the stockpile obligation on the other EU markets has been considered.

Thirdly, according to Section 2, paragraph 7, the list of medicines covered by the notified draft will be subject to a revision "*at least every two years*". It is not clear what would trigger the revision and what would be the transitory period before the measures announced in the notified draft become applicable to the medicines in the new revised annex. Hence, it is unclear whether the marketing authorisation holders responsible for the products that would be added to the list, would have sufficient time to ensure that, if necessary, the required additional volumes result from increased production rather than from quotas initially destined for the markets of other Member States.

Finally, the Commission would like to recall that, as noted in its Communication on shortages in the EU, national stockpiling can impact the availability of medicines in other EU Member States. Therefore, it calls for the common strategic approach to medicines stockpiling to be developed jointly by the Commission and the Member States in 2024.

The Commission invites the Austrian authorities to take into account the above comments.

Yours faithfully,

For the Commission

Sandra GALLINA

Director-General
Directorate-General for Health and Food Safety

[9] ()MSSG Solidarity mechanism process (europa.eu)