PHAGO
VERBAND DER ÖSTERREICHISCHEN ARZNEIMITTELVOLLGROSSHÄNDLER

Austrian Ordinance of the Federal Minister for Labour, Social Affairs, Health and Consumer Protection on ensuring the supply of medicines notified to the Commission on 18 October 2019 (2019/516/A)

Dear Sir or Madam,

As a preliminary point, we – the Austrian pharmaceutical full-line wholesalers - would like to establish that we welcome measures whose purpose is to improve the supply of medicines. In principle, we take a positive view of increased transparency and a temporary export restriction for certain supply-critical medical products.

However, in our opinion, the process outlined in this ordinance draft is not sufficiently specified and objectivised and therefore not suitable for helping to ensure the supply of medical products to Austrian patients.

Concerns pertaining to Union legislation

Articles 34 and 35 TFEU (Treaty on the Functioning of the European Union) principally prohibit quantitative import and export restrictions, as well as all measures to the same effect, between the EU member states.

However, according to Art. 36 TFEU, import, export and transit prohibitions or restrictions are permissible if they are justified due to reasons of public ethics, order and safety, the protection of the health and life of people, animals or plants, of national cultural assets of an artistic, historical or archaeological value, or of business and commercial property. These prohibitions or restrictions may not, however, represent either a means of deliberate discrimination or a veiled restriction of trade between the member states.

The obligation set out in § 57a par. 1 MPA (Medicinal Products Act) for an appropriate and continuous supply of specific medical products is implemented by Art. 81 par. 2 of Directive 2004/27/EC[1].

Art. 81 par. 3 Directive 2004/27/EC stipulates that the (national) regulations for the implementation of Art. 81 must be in accordance with the regulations of the EU contracts, especially with the regulations pertaining to the free movement of goods and

[1] Directive 2004/27/EC of the European Parliament and the council of 31.03.2004 for the amendment of the Directive 2001/83/EC for the establishment of a Community code for human medicines.

free competition, must be justified on the grounds of the protection of public health and must be proportionate to this objective.

The ordinance draft based on § 57a par. 2 MPA with the **export prohibition contained in § 4 represents an intervention into the free movement of goods**,[2] whose Union legislation permissibility is to be assessed in relation to Art. 36 TFEU.

The **European Commission**, in its *paper on the obligation of continuous supply to tackle the problem of shortages of medicines* of 25.05.2018, addressed the permissibility of restrictions of the free movement of goods in conjunction with ensuring the domestic supply of medicines:

According to this, member states may in principle implement measures pertaining to public interest in the protection of human health, in order to prevent restrictions of the supply of medicines to the population.

However, these measures must be necessary, appropriate and proportionate:

- Measures are to be restricted to medicines that are already or probably will be in short supply, whereby **alternative medical supply options are to be taken into account**.
- Export restrictions are to be based exclusively on **transparent, publicly accessible and non-discriminating criteria** that those potentially affected by a restriction are **sufficiently aware of in advance** and **cannot be set arbitrarily**.
- The restrictions stipulated by national authorities must be **legally contestable (according to administrative law)**.

Applied to this particular case, this means:

- The inclusion of a specific medicine in the list to be published and therefore the export prohibition in the case of § 1 of the ordinance draft depends entirely on the behaviour of the product licence holder.

  The strict wording of § 1 par. 3 of the ordinance draft obstructs the national authorities in the verification of the fulfilment of the conditions.[3]

  The ordinance draft can therefore **not sufficiently impede the arbitrary behaviour of the product licence holder**.
- The criteria for the presence of a restriction of the sales capacity or of patient requirements (§ 1 par. 1 ordinance draft) or a restriction of the supply (§ 3 par. 2 ordinance draft) are **too unspecific**.
- The ordinance draft does not specify whether the list is to be qualified as a legal ordinance. It is therefore unclear whether there is sufficient **legal protection**.

In conclusion, **the ordinance draft does not fulfil the Union legislation requirements of Art. 36 TFEU** for a justification of the restriction of the free movement of goods.

[2] The same applies to the explanations of the ordinance draft, but which are based on a appropriate measure in the public interest.

[3] Contrary to this, the statement of facts of § 2 and § 3 par. 2 of the ordinance draft explicitly orders verification by a national authority.

Summary

This ordinance draft contravenes Union legislation because it

- lacks sufficiently determined and foreseeable conditions that can be officially verified for export prohibitions for specific medical products, as well as
- a transparent procedure in which all those potentially affected by an export ban are entitled to participate;
- in addition, it lacks adequate legal protection.

For the stated reasons, the Association of Austrian Pharmaceuticals Full-Line Wholesalers therefore rejects the ordinance draft in the present form.

Kind regards

Dr. Monika Vögele
Secretary General

Dr. Andreas Windischbauer
President

PHAGO
Association of Austrian Pharmaceuticals Wholesalers
Am Belvedere 8 :: 1100 Vienna :: Tel. +43/1/71 72 8 794:: E-mail office@phago.at :: Web www.phago.at
Central Register of Associations no. 188110543 :: VAT reg. no. ATU 47067203 :: Place of jurisdiction Vienna Commercial Court :: Bank details Oberbank, IBAN AT291515004211001930, BIC OBKLAT2L