

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,

The legislative proposal of the Austrian 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) effectively introduces an export ban.

While GIRP supports the control of exports of medicines in the event of shortages, export restrictions must be adopted based on transparent, publicly available and non-discriminatory criteria that are known in advance by economic operators, in such a way as to ensure that any restrictions imposed are not placed arbitrarily, as set out by the European Commission and Member States in the Paper on the obligation of continuous supply to tackle the problem of shortages of medicines of 25 May 2018.

In this paper, restrictions of supply for specific listed medicinal products may be considered suitable if:

- the list applies only to pharmaceuticals for which a shortage is likely or certain, such as those medicines where the volume available does not meet current needs of patients in the Member State;
- the list is established through criteria that are known in advance;
- the list takes into account the availability of alternative treatments in the Member State;
- the list is revised on a regular basis taking into account the latest occurrences or risks of shortages of medicines for public health;
- the decisions implementing its application are taken within a reasonable time period;
- and - the decisions are open to be contested before the relevant administrative bodies or courts of justice.

Bearing in mind the guidance in the European Commission and Member States Paper on the obligation of continuous supply to tackle the problem of shortages, the legislative proposal of the Austrian Federal Minister for Labour, Social Affairs, Health and Consumer Protection on ensuring the supply of medicines, raises some concerns for GIRP. The proposal does not appear to be consistent with the guidance paper referenced above.

As patients are the most affected by shortages, GIRP has published recommendations on proportionate and effective ways to address shortages, in order to soften their impact and improve availability.^{1, 2}

Yours faithfully,

Martin FitzGerald
Deputy Director General

1 GIRP recommendations on ways to address shortages http://girp.eu/sites/default/files/documents/recommendations_on_ways_to_address_shortages_0.pdf

2 GIRP reflection paper on shortages http://girp.eu/sites/default/files/documents/girp_medicine_shortages_reflection_paper.pdf