European Parliament
2014-2019

Committee on Petitions

31.1.2018

NOTICE TO MEMBERS

Subject: Petition No 0636/2017 by J.L.B. (Spanish) on the tendering system for medicinal products in the Autonomous Community of Andalusia

1. Summary of petition

The petitioner says that the tendering system for medicinal products in the Autonomous Community of Andalusia does not guarantee freedom of choice for patients and pharmacists, since they cannot choose medicines freely and only those medicinal products that are successful in the tenders can be dispensed. This restricts competition and hinders the free movement of goods, according to the petitioner.

2. Admissibility

Declared admissible on 7 November 2017. Information requested from Commission under Rule 216(6).

3. **Commission reply**, received on 31 January 2018

In addition to the EP summary, it should be noted that:

a) the petitioner alleges that the operational and administrative limitations introduced by the Andalusian Health Service lead to shortages of medicines with the consequent need to switch patients to a different prescription, which may have an adverse impact on the health of the patient.

b) a further point raised by the petitioner questions the quality of medicinal products administered by the Andalusian Health Service as some of these products originate from countries such as Bangladesh, Vietnam and India.

The Commission's observations

a) In accordance with the Treaty on the Functioning of the European Union (TFEU), Title XIV, Article 168(7), the Member States are responsible for the definition of their health policy and for the organisation and delivery of health services and medical care. Their responsibilities include the management of health care and the allocation of resources assigned to them. The Union has no competence in the area of health services and medical care, and the existing EU pharmaceutical legislation does not cover the area of tendering.

   In the specific context of shortages, the Commission is collaborating with the Member States, the Heads of Medicines Agencies and the European Medicines Agency in order to facilitate sharing of best practices between the Member States with a view to assuring continuous supply of medicines through effective implementation of Article 81 of Directive 2001/83/EC.

b) According to the EU legislation on medicinal products, no medicinal products may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authority of that Member States or the European Commission. For the granting of the marketing authorisation, the medicinal products shall fulfil strict requirements of quality, safety and efficacy. This applies equally to medicines imported from third countries.

Conclusion

As the EU legislation clearly places the competence and responsibility for the organisation of health care on the Member States, the Commission is not in the position to intervene in favour of the petitioner.