European Commission - Press release

Infringement: Parallel trade of medicines: Commission closes infringement proceedings and complaints against Poland, Romania and Slovakia

Brussels, 17 May 2018

The European Commission decided today to close its infringement procedures and the treatment of complaints in the area of parallel trade of medicines for human use against Poland, Romania and Slovakia.

From the start, the Juncker Commission has been focusing on its political priorities and pursuing them vigorously. This political approach is also reflected in the Commission's handling of infringement cases. The Communication "EU law: Better results through better application" sets out the Commission's approach to prioritising cases in a strategic manner, carefully weighing the various public and private interests involved.

Parallel imports and exports of medicinal products is a lawful form of trade within the Single Market. Member States may, however, in certain cases restrict parallel trade, as long as the measures are justified, reasonable and proportionate to ensure a legitimate public interest. For example, to ensure an adequate and continuous supply of pharmaceuticals to the population.

The lack of appropriate and continued supplies of human medicinal products to pharmacies is a serious and growing problem that has occurred in recent years in a number of Member States and can gravely impact the treatment of patients. The Commission acknowledges that parallel trade in medicines may be one of the reasons for the occurrence of shortages of a number of medicinal products for human use.

Reconciling the respect to the free movement of goods with the right of access to healthcare to patients is a fine balancing act. After careful assessment, the Commission has concluded on the need to look for other ways than infringements to adequately solve this complex situation in order to swiftly and efficiently deal with an issue that might have negative impact on the health of European citizens.

The Commission considers that a structured dialogue including all relevant parties should rapidly take place. The Commission remains committed to supporting Member States in their efforts to ensure that citizens have timely access to affordable, preventive and curative healthcare of good quality. To do so, it will gather more information from the Member States and other stakeholders to discuss the implementation of the public service obligation and export restrictions within the Commission Working Group on Pharmaceuticals (Human Pharmaceutical Committee).

Background:

Parallel trade allows wholesalers to buy medicinal products in one Member State (typically where prices of medicines are lower too), and sell into other Member States (where prices are higher). Parallel imports and exports of medicinal products are compatible with the free movement of goods (Article 34 of TFEU).

However, restrictions may exceptionally be introduced if justified by overriding requirements of public interest, such as the protection of human health and life, and there are no other less restrictive means available to achieve that objective (Article 36 of TFEU).

The issue of shortages of human medicines in the EU was discussed during the informal meeting of ministers for health matters held in Bratislava on 3 and 4 October 2016.

The Commission notes that the European Parliament adopted its resolution on EU options for improving access to medicines on 2 March 2017. In this resolution, the Parliament called on the Commission and the Council of the EU to analyse the causes of shortages of medicines to monitor compliance with EU rules on the obligation to ensure continuous supply (Article 81 of Directive 2001/83/EC). This is inextricably linked to the affordability of human medicines to patients and related pricing policies in different Member States for which they have exclusive competence.

On 8 December 2017, the Council held an exchange of views on the pharmaceutical policy in the EU. There, the Commission stressed its commitment to support Member States to ensure the right of citizens to have timely access to affordable, preventive and curative healthcare of good quality.

For More Information:

- On the key decisions of the May 2018 infringements package, please refer to the full MEMO/18/3446.
- On the general infringements procedure, see MEMO/12/12.
- On the EU infringements procedure.

IP/18/3459

Press contacts:

Lucia CAUDET (+32 2 295 61 82)
Maud NOYON (+32 2 298 03 79)
Victoria VON HAMMERSTEIN-GESMOLD (+32 2 295 50 40)

General public inquiries: Europe Direct by phone 00 800 67 89 10 11 or by email