Question for written answer E-003764/2023
to the Commission
Rule 138
Joanna Kopcińska (ECR)

Subject: List and transposition mechanism of critical medicines categories

On 12 December 2023, the Commission, together with the European Medicines Agency (EMA), published the first Union list of critical medicines. The list contains more than 200 active substances for human use that have been identified as critical for the functioning of healthcare systems and for which continuity of supply must be an absolute priority in order to prevent shortages in the EU/EEA. According to the methodology used to establish this list (EMA/432940/2023), two key criteria have been taken into account: the therapeutic indication and the availability of appropriate alternatives.

Given that a potential shortage of a critical medicine may be due to either a lack of a finished active substance or a disruption in the supply chain process, what specific mechanism has been proposed for the flexible transfer of labels of a list of critical medicines (‘critical medicine’, ‘high-risk medicine’, ‘medicine for which an alternative exists’) that would accurately reflect the emergence of potential gaps in product supply chains that would result in a particular medicine being transferred to another critical category?

Submitted:26.12.2023