

**Question for written answer E-002450/2023
to the Commission**
Rule 138
Joanna Kopcińska (ECR)

Subject: Shortages of paediatric drugs in winter 2023-24

Despite the initiatives announced earlier this year (i.e. extending the EMA's mandate, enhancing HERA's operations and making key changes to the restructuring of pharmaceutical law) and the much-talked-about ways to solve the shortage of medicines in Europe, the situation is not improving, and the shortage and absence of medicines are becoming an increasingly serious health challenge in the EU.

There is a major risk that a situation could arise this autumn and winter in which important antibiotics and other vital medicines are in very short supply. This risk could be particularly high when it comes to all paediatric medicines.

1. In view of the above, and given that EMA's stronger mandate now includes a coordinating role to monitor and identify actions to alleviate medicine shortages in preparation for crises, within this operational framework, what additional precautions is the Commission planning to take in the run-up to autumn and winter in order to prevent shortages of paediatric medicines?
2. When can Member States expect a recommendation on the proposed measures, bearing in mind that the preparation system must be preceded by a buffer of several months in order for drug safety procedures to be introduced?
3. Does the Commission have plans to draw up a list of urgent paediatric medicines for autumn and winter 2023-24, and are there recommendations for an equal and fair process to stockpile the medicines needed in the Member States?

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