Priority question for written answer P-002489/2023
to the Commission
Rule 138
Evelyn Regner (S&D)

Subject: Eurogine contraceptive coil

A production defect affected several batches of contraceptive coils made by the Spanish manufacturer Eurogine: because of material fatigue, the coils broke prematurely, which in some cases caused women considerable pain and harm to their health and even led to unwanted pregnancies.

As a result of a product warning issued by the Spanish authorities, the defective batches had been known about since spring 2018. In Austria, women continued to be fitted with those coils until the product defect was publicised after a newspaper investigation in autumn 2020 and, consequently, a public warning was issued by the Austrian Federal Agency for Healthcare Safety. If there had been a functioning chain of communication, the Austrian Medicines Authority could also have become aware of what was a fundamental product defect two and a half years earlier and could have acted accordingly. Major complications and considerable suffering for countless women could thus have been prevented in the simplest way possible. Women's health must be taken seriously.

1. Who is responsible for ensuring that fundamental, known product defects are reported to all central bodies in the Member States?

2. How can such a failure by Eurogine and the Spanish Medicines Authority to notify all their central purchasers and partner authorities be explained?

3. What are the consequences for the bodies responsible, and how will it be ensured that the chain of communication functions properly in future instances?

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