Question for written answer E-001090/2024
to the Commission
Rule 138
Andreas Glück (Renew)

Subject: The PFAS restriction proposal and the safety of European patients

In January 2023, the authorities of five countries submitted the most far-reaching restriction proposal ever put forward under the REACH Regulation. This proposal targets the whole group of per- and polyfluoroalkyl substances (PFAS), comprising over 10 000 substances.

According to the restriction proposal, active pharmaceutical ingredients (APIs) used for human and veterinary medicines benefit from a derogation. However, PFAS are essential in the supply and value chains involved in developing, manufacturing and packaging medicines. In many cases, there are no alternatives due to their required chemical properties like chemical resistance, heat resistance, durability, lubricity and biocompatibility.

Without additional broad-based derogations, the manufacturing of medicines and their APIs in the EU are endangered, undermining the goal of open strategic autonomy and exposing European patients to shortages in the supply of pharmaceutical products.

1. How will the Commission ensure the goal of open strategic autonomy and the security of supply of pharmaceutical products for humans and animals in Europe?

2. Is the Commission considering a broad-based derogation for all aspects of the manufacturing of medicines in order to avoid the disruption of complex supply chains and negative consequences for patient safety in the EU?

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