Question for written answer E-000572/2023
to the Commission
Rule 138
Nathalie Colin-Oesterlé (PPE)

Subject: Rules on female sanitary products

Female sanitary products are regulated as medical devices in many countries such as the US, meaning that there is a high level of standards with specific norms, certifications and tests such as:

• pre-clinical trials;

• clinical trials;

• monitoring once on the market.

In the EU, sanitary products are currently regulated by Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, which provides for a much lower level of requirements than outside the EU. For example, without the medical CE marking, individual female hygiene products can be made available in public places without the information leaflets, traceability and the outer packaging that guarantees the product's integrity. This undermines the safety of European women.

The regulatory difference creates an inequality in competition on the international market and exposes European women to a number of dangers and risks:

• toxic shock syndrome (amputation, death);

• contamination with endocrine disruptors and carcinogens and mutagens.

Could the scope of Regulation (EU) 2017/745 (Annex 16) on medical devices not be extended to sanitary products to redress this market imbalance and better protect European women?

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