Question for written answer E-001017/2023 to the Commission

Rule 138

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Subject: Underrepresentation of women in neurological research – increasing women's

participation

Research on sex- and gender-related differences in risk factors, disease progression and treatment responses in neurology is lagging behind, even when women are often disproportionally affected by neurological disorders. Women are significantly underrepresented in clinical research as sex and gender differences are not a focus in the design and analysis of clinical trials.

Underrepresentation of women in neurological research can be associated with suboptimal health outcomes, as men and women respond differently to the same prescribed medication.

- 1. Does the Commission intend to promote any measures facilitating the adoption of frameworks for increased inclusion of women in clinical research, including neurological research, particularly in cases where there is evidence of a lack of treatment efficacy and/or increased side effects in women?
- 2. In the US, the Food and Drug Administration (FDA) monitors women's participation in clinical research on approved therapies and publishes annual reports¹. While the EU Clinical Trials Regulation will improve data transparency, is the Commission planning to adopt similar measures that would facilitate the implementation of monitoring and accountability frameworks, including monitoring of sex-specific efficacy and side effects during drug development?

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FDA Annual Drug Trials Snapshots: https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots