

(English version)

**Question for written answer E-003561/23
to the Commission
Elisabetta De Blasis (ECR), Pietro Fiocchi (ECR)
(6 December 2023)**

Subject: Gender medicine in European health systems

Gender medicine has long been considered a type of ‘medicine for the reproductive organs’. In fact, hormones and habits, often dictated by gender social norms, are both key factors in the body’s response to pathogens and drugs. Significant differences between men and women have been found in both non-communicable diseases (cancer and autoimmune and cardiovascular diseases) and infectious diseases.

In Italy, a plan for the introduction and distribution of gender medicine has now been formally established, by means of Article 3(1) of Law No 3/2018. However, many medicines are imported from third countries and there is still no legislation at EU level to support experiments vis-a-vis differences in biology, genetics and habits. To date, the only action plan to have been drawn up was by the European Gender Medicine Network, and it is for a ‘soft law’ which, although important, does not coordinate action by Member States on the matter.

Within the scope of its powers:

1. What plans will the Commission take to coordinate Member States’ action on gender medicine?
2. Does it plan to introduce any changes to the rules on pharmacological testing that take account of gender differences and use more representative samples?

Submitted: 6.12.2023

**Answer given by Ms Kyriakides on behalf of the European Commission
(5 April 2024)**

Regarding medicines development depending on the gender, the Clinical Trials Regulation ⁽¹⁾ includes provisions related to the justification for the gender allocation of subjects.

The authorisation of a given clinical trial is a Member State responsibility. The Commission evaluates the evolution of clinical research in Europe with a series of metrics collected through the Clinical Trials Information System (CTIS).

One key performance indicator is on gender representation in clinical trials: male/female/both gender categories. When looking at clinical trials authorised since 31 January 2022, at the end of September 2023, the gender of subjects was distributed as follows: 70 clinical trials (5%) with only women, 88 clinical trials (7%) with only men and 1140 clinical trials (88%) with both genders.

As regards research and innovation (R&I), the EU strengthened the integration of sex- and gender-based analysis into the contents of research and innovation projects supported by the framework Programmes for R&I ⁽²⁾.

Unless specifically indicated in a given topic that the integration of the gender dimension into R&I content is not required, all Horizon Europe ⁽³⁾ R&I projects funded under the Cluster 1 ‘Health’ ⁽⁴⁾ or the Cancer Mission ⁽⁵⁾ need to look at potential differences in sex and gender.

Furthermore, Horizon Europe partnerships like the European Partnership for Personalised Medicine strongly encourage to integrate sex and gender considerations into proposals submitted for funding ⁽⁶⁾.

This should help understand why certain groups are more susceptible to develop certain conditions and develop tailored interventions for eventual better outcomes. The sex and gender considerations have been highlighted in several scientific publications ⁽⁷⁾.

⁽¹⁾ Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, OJ L 158, 27.5.2014, p. 1-76.

⁽²⁾ The integration of the gender dimension in Horizon Europe is expressly provided for in Article 7 (6) of the Horizon Europe Regulation.

⁽³⁾ https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe_en

⁽⁴⁾ https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/cluster-1-health_en

⁽⁵⁾ https://research-and-innovation.ec.europa.eu/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe/eu-missions-horizon-europe/eu-mission-cancer_en

⁽⁶⁾ Call from the European partnership for personalised medicines <https://anr.fr/fileadmin/aap/2024/aap-ep-permed-2024.pdf>

⁽⁷⁾ ‘Accounting for sex and gender makes for better science’ <https://www.nature.com/articles/d41586-020-03459-y>; ‘Nature journals raise the bar on sex and gender reporting in research’ <https://www.nature.com/articles/d41586-022-01218-9>