Question for written answer E-005219/2020
to the Commission
Rule 138
Petra De Sutter (Verts/ALE)

Subject: Implementation of the new In Vitro Diagnostics Regulation (IVDR) (EU 2017/746)

The application date of Regulation (EU) 2017/746 (IVDR)[1] is set for May 2022. The IVDR brings major changes for laboratories, health professionals, industry and patients. However, many elements still have to be put in place to ensure a smooth transition.

The diagnostic sector is concerned that all necessary guidance will not be available on time, particularly regarding the conditions for Laboratory Developed Tests (LDTs). Health institutions depend heavily on LDTs where no appropriate CE-marked tests are available. For example, the rapid development and implementation of LDTs has played a major role in fighting the COVID-19 pandemic[2].

1. How will the Commission accelerate the IVDR implementation process and ensure all necessary elements (including essential guidance) are available to stakeholders well ahead of the application date?

2. When will the medical device coordination group's IVD WG taskforce, which will draft the Guidance on Conditions for In-House Devices, be set up and how will the Commission ensure that the input of the diagnostic sector is considered at an early stage?

3. Which specific issues will be addressed in this guidance, and how will the Commission ensure that all stakeholders' questions are answered?

[1] OJ L 117, 5.5.2017, p. 176 (https://eur-lex.europa.eu/eli/reg/2017/746/oj).
[2] https://www.degruyter.com/view/journals/cclm/ahead-of-print/article-10.1515-cclm-2020-0804/article-10.1515-cclm-2020-0804.xml (https://www.degruyter.com/view/journals/cclm/ahead-of-print/article-10.1515-cclm-2020-0804/article-10.1515-cclm-2020-0804.xml)