BEUC The European Consumer Organisation

The Consumer Voice in Europe

Ms. Stella Kyriakides
European Commissioner for Health and Food Safety
European Commission
Rue de la Loi 200

B – 1049 Brussels

Ref.: BEUC-X-2020-107/MGO/cm

Brussels, 3 November 2020

Subject: Timely implementation of EU's In-Vitro Diagnostics Regulation is a must to keep consumers safe

Dear Commissioner Kyriakides,

On behalf of BEUC, The European Consumer Organisation, I write to express our concern over re-occurring discussions to delay the In-Vitro Diagnostics Regulation (IVDR). Full implementation of the IVDR is slated for 2022. However, manufacturers are expressing doubts about the timely implementation of the Regulation and are calling for its postponement, justified by the COVID-19 outbreak and an overlap with the implementation of the Medical Devices Regulation (MDR), scheduled for May 2021. We urge the European Commission to maintain its existing commitment to respect the legal deadline, as the delay of new rules must be avoided.

We fully understand that due to COVID-19, all resources must be pooled towards the resolution of the health emergency. However, the IVDR entered into force in 2017. By May 2022, all stakeholders will therefore have had five years to make the transition to the new rules. The delay of the Eudamed database by two years, and the MDR delay by one year sadly illustrated that the transition period was not used correctly to prepare for the new rules.

Despite the seriousness of the burden posed by the pandemic on all stakeholders, it cannot be used as a continuous excuse to delay much-needed higher safety standards and a transparency framework for medical devices and in-vitro diagnostics. Safe, reliable and trustworthy diagnostics and medical devices are needed both to deal with COVID-19 and to ensure the health and well-being of all European patients and consumers looking beyond the pandemic.

Given that the delay to MDR and Eudamed has already hampered long-overdue improvement, we urge the Commission to ensure:

- Timely and diligent implementation of the IVDR by May 2022;
- Thorough implementation of the MDR by the new deadline of May 2021, without any further delay;
- A fully operational Eudamed database by May 2022.

We would very much welcome an opportunity to meet virtually with you to exchange on these concerns and other health-related matters.

We thank you in advance for taking the above into consideration.

For your information, we have also sent a copy of this letter to Vice-President Schinas.

Yours sincerely,

Monique Goyens,
Director General