BEUC The European Consumer Organisation

The Consumer Voice in Europe

Mr. Salvatore D'Acunto
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Health technology and Cosmetics
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
European Commission
Rue de la Loi 200
B – 1049 Brussels

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Brussels, 13 November 2019

Subject: Consumer concern over delay of EU database on Medical Devices

Dear Mr. D'Acunto,

On behalf of BEUC, I write to express our severe regret in the European Commission's decision to delay the launch of the new European database on medical devices (EUDAMED) by two years. EUDAMED is an essential element to fulfil the objectives of the Medical Devices Regulation (MDR) to enhance vigilance, market surveillance and transparency, including through better access to information for the public. Therefore, we are strongly concerned that the delay of EUDAMED could undermine consumer protection.

Medical devices – from plasters to dental filling material, and from heart valves to X-ray machines – significantly contribute to consumers' health and well-being. Unsafe medical devices can however disrupt consumers' lives, a fact made tragically evident by the PIP breast implants fraud and the metal-on-metal hip implants case. These and other more recent scandals affecting the sector have eroded consumer confidence in medical devices and in the supervision of competent authorities. That trust must urgently be restored.

EUDAMED has a great potential to pave the way towards trust restoration, as it enhances vigilance, postmarket surveillance and transparency when it comes to medical devices. The decision to delay EUDAMED therefore threatens to undermine timely implementation of new rules, and thus, the safety of the devices. We strongly regret that the Commission has not been able to respect the foreseen deadline to set up EUDAMED.

Given that a period of two years is a significant hold-up of a long overdue improvement, we urge the Commission to publicly clarify the following:

- what will the Commission do to ensure that EUDAMED is fully operational in 2022, including how the Commission will ensure that EUDAMED is not further delayed in future.
- until the launch of EUDAMED, what steps does the Commission foresee to compensate for the contribution EUDAMED was meant to improve vigilance, postmarket surveillance and transparency.

We would very much welcome an opportunity to meet with you to exchange on these concerns as well as to discuss how EUDAMED could be designed to improve transparency for consumers.

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

Yours sincerely,

Pelle Moos
Senior Safety and Health Policy Officer, Team leader