BEUC The European Consumer Organisation

The Consumer Voice in Europe

Ms. Stella Kyriakides
Commissioner for Health and Food Safety

Ms. Mariya Gabriel
Commissioner for Innovation, Research, Culture, Education and Youth

European Commission
Rue de la Loi 200
B – 1049 Brussels

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Brussels, 27 March 2020

Subject: Concerns over lack of attention to affordability in EU research funding for COVID-19 treatments and the Medical Devices Regulation delay

Dear Commissioner Kyriakides,
Dear Commissioner Gabriel,

On behalf of BEUC, The European Consumer Organisation, I would like to express our support for the Commission's ongoing efforts to deal with the COVID-19 outbreak. In the last weeks, thousands of European citizens have lost their lives, many are hospitalised with severe symptoms or quarantined at home. In some areas, the worse could be yet to come. The situation is dire.

Our member organisations are relentlessly working to assist consumers in this difficult time.[1] Fake news about cures are reaching laypeople, while necessary products such as hand sanitizers and masks are being sold on online platforms at rocketing prices.

The priority right now at the EU level must be dealing with the crisis. At the same time, the EU must be mindful to ensure that the health, rights and interests of Europeans are protected both in the short run and thereafter. In this regard, we are concerned about two recent developments:

Lack of attention to affordability in EU research funding for COVID-19 treatments

Developing effective treatments, vaccines and diagnostic tools is urgently needed to tackle the outbreak. We welcome the European Commission's ambitious support to research on COVID-19 through various instruments, such as Horizon 2020 and the Innovative Medicines Initiative (IMI) partnership. This will certainly contribute to the availability of vaccines and treatments in the shortest possible timelines. However, the Commission does not appear to commit to promote R&D models that contribute not only to the identification of pharmaceutical responses to COIVD-19, but also to their affordability for the European population. In the current situation of public health emergency, this is even more incomprehensible.

One way of ensuring affordability is by attaching conditionalities to public research funding. Non-exclusive licensing can help achieve broader access to health technologies. When exclusive licenses are negotiated, adequate safeguards should be in place to prevent abuses. Grant agreements can also include specific commitments on affordability.

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[1] More information about BEUC members' actions on COVID-19 can be found here https://www.beuc.eu/press-media/news-events/coronavirus-covid-19-outbreak-advice-consumer-groups.

We urge the European Commission to make the most out of the EU research funding programme and other instruments so COVID-19 therapies and diagnostics are widely available at the lowest possible prices for public healthcare systems. This will facilitate that they can be provided for free to the population.

Lack of preparedness for the new rules on medical devices

BEUC regrets the decision to propose a delay of the Medical Devices Regulation (MDR) just two months before its application date and without broader outreach to other affected stakeholders. We fully understand that due to the COVID-19 crisis all resources must be pulled towards the resolution of the health emergency. However, the MDR came into force in 2017 and all stakeholders has had three years to make a transition to the new rules. Furthermore, the MDR already foresees a grace period for certain devices (both higher and lower risk) to remain on the market without recertification until 2024, significantly easing up the burden on the system. The decision to delay the MDR can therefore only be explained by the fact that the three-year transition period was not used to thoroughly prepare for the new rules, which was also earlier illustrated by the decision to delay Eudamed by two years.

We understand that emergency situations lead to adaptation of situations, and where relevant to delay or suspension of application of existing rules. However, all derogations from the existing regulatory framework should be proportionate and should be duly justified. Lack of preparedness by all actors to apply long-known rules is a worrying sign that does not match the conditions of proportionality.

We urge the European Commission, governments, industry and other involved stakeholders to ensure the safety and well-being of patients and consumers and be fully ready by the new deadline. Following the medtech industry call to postpone the In Vitro Diagnostic Medical Devices Regulation, we call on the Commission to enforce the foreseen deadline of May 2022.

We look forward to following up with your Commission services on these questions. In the meantime, let us stress again our support in these difficult times.

Yours sincerely,

Monique Goyens
Director-General