

Ref.: BEUC-X-2020-080/MGO/ste

07 September 2020

Subject: Access to a COVID-19 vaccine must go hand in hand with adequate consumer compensation in case of harm

Dear Commissioner Kyriakides,

I write to you on behalf of BEUC, the European Consumer Organisation, in response to some urgent developments regarding the application of liability rules to COVID-19 vaccine manufacturers.

Timely access to a safe and effective vaccine is crucial to overcome the current pandemic. BEUC wholeheartedly congratulates the European Commission for its efforts supporting vaccine development and facilitating joint procurement by Member States. However, it is also essential to ensure that the deployment of vaccines goes hand in hand with high safety standards, fully preserves the interests of the population and provides the industry with the right set of signals to take the maximum precautionary measures to prevent harm from happening in the first place.

Media have recently reported about liability exemptions that the pharmaceutical industry is pushing for when marketing their products.¹ This raises serious concerns about the extent to which citizens will be protected, and on the possibility that pharmaceutical companies end up making economic profits from the sale of their products without also being held accountable when things go wrong.

The EU and the Member States are today doing a lot to help the industry develop COVID-19 vaccines by providing funding for their R&D activities and strengthening their production capacities. In addition, governments might bear liability risks associated with the vaccines. While we understand that some special liability arrangements may be necessary under certain conditions, it is crucial that risks are properly shared between Member States and the pharmaceutical industry.

Considering the ongoing discussions between the European Commission, the Member States and the industry on advance purchase agreements for COVID-19 vaccines, it is crucial that:

- **The terms and conditions of any agreements concluded with vaccine developers (including possible liability arrangements) are fully transparent.** The relevant documents should be accessible to all interested parties, including civil society organisations.

1/2

¹ Mancini DP, Peel M. Drugmakers call for legal indemnity in frantic race to find Covid vaccine. Financial Times, 26 August 2020

- **Everyone has access to clear and easily accessible information about vaccines.** In this regard, package leaflets should be available in all relevant languages with information on the correct use of the vaccine and its safety aspects. Electronic leaflets should complement, but by no means replace, paper-based versions. Indeed, adequate information for recipients on the safe use of vaccines is a crucial element for a vaccine to be safe.
- **Consumers should benefit from quick and effective compensation schemes if they suffer an adverse reaction.** There should be clearly identifiable go-to points individuals may turn to in order to obtain compensation.
- **Vaccine developers need to remain in principle liable for the products they develop.** If the current extraordinary circumstances and urgent need for a vaccine may call for certain forms of liability arrangements, these arrangements should remain limited in scope and time, be proportionate and be disclosed to the public.
- **Vaccine developers should be required to maintain strict post-marketing surveillance activities** and continuously report on the possible adverse reactions that they may observe with their products. It should also be possible for regulators to turn to vaccines developers when the company fails to fulfil its obligations.
- **Consumer organisations should be consulted about the implementation of the EU Strategy for COVID-19 vaccines,** particularly on aspects as important as liability schemes.

The fight against the COVID-19 pandemic requires a joint effort from all stakeholders. We sincerely hope to be given an opportunity to be involved as stakeholders in the roll out of the EU Strategy for COVID-19 vaccines, so that we can share with you and the other parties our concerns and recommendations to respond to consumer needs, concerns and expectations.

Whilst we address the present letter in reaction to some urgent developments, we will be sharing with you shortly complementary recommendations, based on the full feedback from our members, on how the Strategy can best help consumers.

Please be informed that this letter will be made public.

Yours sincerely,

Monique Goyens
BEUC Director General