

The Consumer Voice in Europe

ENSURING ACCESS TO SAFE, EFFECTIVE AND AFFORDABLE COVID-19 VACCINES



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Why it matters to consumers

Europe and the world need a COVID-19 vaccine to address the current pandemic. For a vaccine to meet people's needs and expectations, it will have to be approved based on robust evidence on safety and efficacy and be affordable for all. Ensuring adequate public communication on the vaccine and swift compensation in the event of safety incident will be crucial to boost vaccination confidence and uphold consumers' rights.

Introduction

COVID-19 has shaken the world. The pandemic is impacting people's lives on many levels. When the virus hit Europe, the European Union did not have in place all the measures that are needed to respond to it effectively. Nevertheless, new, relevant initiatives have since been put in place, such as the EU Strategy for COVID-19 vaccines.

BEUC welcomes the European Commission's initiative on vaccines. **To ensure that the Strategy meets the needs and expectations of patients and consumers, their views must guide its implementation.**

In this paper, we outline how to roll out the Strategy in ways that best help consumers. The recommendations below are addressed to the EU institutions, the European Medicines Agency and Member States' competent authorities.¹

BEUC recommendations for equitable access to safe and effective COVID-19 vaccines

To enable timely access to safe and effective vaccines, the EU Strategy for COVID-19 vaccines provides financial support to vaccine developers to boost research and their production capacity. It also calls for using existing regulatory flexibilities to accelerate the marketing authorisation process.

To ensure that the Strategy is fit for purpose, each one of its pillars must uphold some core principles:

1. Public research funding should go hand in hand with accessibility conditions

As the Commission's communication on the Strategy rightly mentions, vaccine developers have received significant financial support from the public sector. Millions of euros have been disbursed from the EU budget for vaccine development and production, through

¹ The recommendations follow a letter sent by BEUC to Commissioner Kyriakides. See '[Access to a COVID-19 vaccine must go hand in hand with adequate consumer compensation in case of harm](#)', September 2020.

Horizon 2020 and the European Investment Bank.² In addition, the European Commission has authorised Member States to support companies' research efforts through State Aid. To maximise the impact of these welcomed initiatives:

- The European Commission should actively encourage those entities that already received funding to maximise access to research results in line with the Manifesto for EU COVID-19 Research.³ The Commission should publish an overview of beneficiaries' adherence to the Manifesto's call for non-exclusive licenses.
- Future EU funding for vaccine development should be disbursed with binding affordability related conditions - as it has been done in some Horizon 2020 calls for proposals (e.g. for the development of medical supplies).
- Member States must ensure that vaccine developers that receive State Aid grant non-exclusive licenses, as required in the 'State Aid Temporary Framework to support the economy in the context of the Covid-19 outbreak'.⁴
- In the mid-term, there should be a public evaluation of the experience with these clauses at the EU and national levels. If areas of improvement are identified, they should inform future action to ensure that affordability related clauses in research grants are framed in ways that maximise access to end products.
- The implementation of Horizon Europe should be informed by a general policy on EU research funding and the accessibility of end products across therapeutic areas and uses.
- The EU and Member States need to pay more attention to research on infectious diseases. This would avoid repeating mistakes of the past, as too often such funding dropped as epidemics and pandemics were fading away - leaving populations more vulnerable to future health threats.⁵

2. Vaccines' quality, safety and efficacy must be ensured

Regulators need to carefully manage the urgent need for a vaccine on the one hand, and for robust evidence on its safety and efficacy on the other. Boosting confidence in immunisation programmes will be crucial, given that levels of vaccine scepticism are higher in Europe than in other parts of the world.⁶

As the European Medicines Agency (EMA) starts the rolling review of data on COVID-19 vaccines, we call for:

2.1. Robust evidence generation and transparency of study results

- The approval of any COVID-19 vaccine must be underpinned by strong evidence on safety and efficacy. The evidence must be robust enough as to generate broad consensus and acceptance among the scientific and medical community.
- Pharmaceutical companies must actively monitor the safety of the vaccine and conduct robust studies in a timely manner to complete evidence generation.
- The Commission's welcome call for independent studies on vaccines' safety and effectiveness should be matched with adequate research funding at the EU and national levels.

² European Commission, *Coronavirus research and innovation*, [website], https://ec.europa.eu/info/research-and-innovation/research-area/health-research-and-innovation/coronavirus-research-and-innovation_en (accessed 26 October 2020).

³ European Commission, 'Manifesto for EU COVID research. Maximising the accessibility of research results in the fight against COVID-19', September 2020.

⁴ For information on BEUC's views on this initiative, see our letter to Executive Vice-President Vestager 'The consumers' perspective on State aid and COVID-19', April 2020.

⁵ Test Santé, 'Pourquoi nous n'étions pas mieux préparés au COVID-19', Num 157, June 2020.

⁶ Wellcome, 'Wellcome Global Monitor. How does the world feel about science and health?', Wellcome Trust, June 2019.

- All vaccine developers should publish their clinical trials protocols, as some companies have already done.⁷ The publication of these documents should be made a requirement when companies receive public support for drug development.
- Competent authorities need to ensure that all COVID-19 vaccine trials conducted in Europe are adequately registered in the EU Clinical Trials Register.⁸ They should encourage trial sponsors to post the results soon after the conclusion of the trial.⁹
- The EMA's commitment to increase transparency regarding its COVID-19 activities is welcome.¹⁰ Publishing clinical study reports, with minimum redactions on commercial confidentiality, right after the decision on marketing authorisation is paramount. Likewise, it is important that pre-submission exchanges between the Agency and vaccine developers are well-detailed in European Public Assessment Reports.

2.2. Optimal vaccine information to consumers

- Consumers must have easy access to all information on the safe use of vaccines and their effects. As a general principle, electronic product information should complement, but not replace, the paper package leaflet.
- Following the adoption of a Memorandum of Understanding¹¹ between the Commission and Member States on labelling and packaging flexibilities, the EMA and Heads of Medicines Agencies (HMA) must ensure that:
 - Flexibilities in relation to packaging and labelling are only authorised based on reasoned justification provided by vaccine manufacturers (no 'one size fits all' approach).
 - Regulatory decisions to accept or deny exemptions required by companies are published on the agencies' websites.
 - There are deadlines in place that limit the duration of granted flexibilities.
 - Consumers must have access to printed versions of paper leaflets – without omissions of particulars – in their language when they get the vaccine. Pharmaceutical companies could either distribute these printouts among vaccine dispensing centres or provide compensation for printing costs. Ways to ensure consumer access to product information should be detailed in an EMA/HMA guidance.
- Consumer representatives should be consulted on public communication campaigns on the vaccine. Close collaboration on this among Member States and with the EMA will be essential too.

⁷ D. Grady and K. Thomas, '[Moderna and Pfizer Reveal Secret Blueprints for Coronavirus Vaccine Trials](#)', *The New York Times*, 17 September 2020 (accessed 26 October 2020).

⁸ A 2018 independent evaluation of sponsors' compliance with requirements to report results on the EU Clinical Trials Register revealed that 'EU registry data commonly contains inconsistencies that might prevent even regulators assessing compliance.', In B. Goldacre et. al, 'Compliance with requirement to report results on the EU Clinical Trials Register: cohort study and web resource', *BMJ*, 2018; 362: k3218

⁹ The COVID-19 pandemic requires exceptional transparency measures. Vaccine developers should publish the summary results of clinical trials right after the end of the trial (as opposed to waiting 12 months to do so, as current rules allow).

¹⁰ For example, the decision to publish full risk management plans for COVID-19 products, instead of summaries. More about additional transparency related commitments by the EMA [here](#)

¹¹ European Commission, '[Memorandum of Understanding \(MoU\) with Member States on regulatory flexibility for COVID-19 vaccines](#)', 27 September 2020.

3. Advance purchase agreements must be transparent, and vaccine affordability and equitable access ensured

BEUC welcomes the initiative on Advance Purchase Agreements (APAs) outlined in the Strategy as it can help ensure quicker vaccine availability. By entering in joint negotiations with pharmaceutical companies, governments increase their bargaining power and thus have a better chance to negotiate favourable supply and pricing conditions.

However, the way these negotiations have been conducted so far raises some concerns. To start with, there is little transparency on the terms and conditions being agreed with each company, on the negotiation process itself and the list of negotiators. In addition, the media reported that some companies pushed for liability exemptions to avoid bearing the costs for potential damages arising from supplied vaccines.¹²

To make the best of Advance Purchase Agreements:

- The European Commission and Member States must shed light on APAs negotiation processes and contracts, as required already by MEPs.¹³ Information on liability arrangements should be made public immediately to allow a more informed debate on this important matter. Likewise, we need transparency on the amount of advanced payments among other.¹⁴ Full APA contracts could be published at a later stage, together with a detailed overview of how the funds from the Emergency Support Instrument have been disbursed.
- In exchange for EU's financial assistance, pharmaceutical companies should commit to offer fair prices for any approved vaccine (in the context of the advanced purchases and thereafter). Companies should be transparent about R&D and production costs.
- The Commission must ensure that the distribution of vaccines doses across countries is fully transparent and there is equitable access.

4. Vaccine users who suffer damage must get quick and adequate compensation

Liability exemptions pushed for by the industry have raised many concerns. In the context of the 2009 H1N1 flu ('swine flu'), drug producers already fought for – and in some cases obtained – liability clauses shielding them from the obligation to remedy the damage associated with vaccines.

In 2010, a Resolution of the Parliamentary Assembly of the Council of Europe clearly stressed that Member States should “ensure that the private sector does not gain undue profit from public health scares and it is not allowed to absolve itself of liabilities with a view of privatising proofing while sharing the risks”.¹⁵

In some Member States, such liability exemptions were negotiated behind closed doors.¹⁶ This lack of accountability undermined public confidence.¹⁷ The EU should learn from the past and avoid making the same mistake.

¹² DP. Mancini DP and M. Peel, '[Covid-19 vaccine makers lobby EU for legal protection](#)'. *Financial Times*, 26 August 2020.

¹³ European Parliament, '[COVID-19 vaccines: MEPs seek answers from industry representatives. Press release](#)', 22 September 2020 (accessed 27 October 2020).

¹⁴ Other crucial information includes for example vaccine prices and the duration of agreed terms and conditions, the number of doses that correspond to each country and how much will be left for them to pay, IP rights and any licensing arrangements.

¹⁵ Parliamentary Assembly of the Council of Europe, '[Resolution 1749 \(2010\) Final version, Handling of the H1N1 pandemic: more transparency needed](#)', at par.8.6

¹⁶ See for e.g. in France, '[La grippe A \(H1N1\)v : Retours sur « la première pandémie du XXIe siècle. \(rapport\)](#)'.

¹⁷ As the Parliamentary Assembly of the Council of Europe noted “the Assembly fears that this lack of transparency and accountability will result in a drop in confidence in the advice given by major public health institutions. This may prove disastrous

BEUC's key recommendations on liability:

- Drug producers must remain liable for the products that they develop.
- Vaccine users must have easy access to adequate compensation in case of safety incident.
- A public fund is the best way forward to ensure swift compensation. This is because when it comes to vaccines, the burden of proof remains very high, making the compensation process before courts very complex and lengthy for the injured individuals.^{18, 19}
- The European Commission should identify best practices on compensation funds, in consultation with patient and consumer groups. Such public schemes are already in place in several Member States for vaccine damage claim (e.g. in Denmark or France²⁰).
- The Commission and Member States should design a common EU framework for a compensation scheme, which could be implemented either directly at the EU level or through Member States. This would help ensure that all Europeans have access to swift and quick compensation.
- The financing of the compensation fund should come directly from vaccine manufacturers. Their financial contribution should be calculated based on the number of vaccines that they sell. For each vaccine sold, one share of the price should fuel the compensation fund.

5. Global context

To tackle the COVID-19 pandemic it is essential that people around the world can afford access to safe and effective vaccines. BEUC strongly supports the EU vaccines Strategy commitment to universal access. To maximise impact at the global level, the EU should:

- Promote plurilateral trade negotiations on medical goods, for improved medicines availability and affordability. Such an initiative could be positive as long as it includes the consumer interest, is conducted transparently and allows engagement from civil society.
- Support the possibility for Member States to import medicines produced elsewhere under a compulsory license, by reversing the opt-out of article 31bis of the World Trade Organization agreement on trade related aspects of intellectual property rights (TRIPS). Situations like the COVID-19 pandemic show how important it is to ensure that Member States can import cheaper versions of urgently needed medicines.
- Seek synergies with international initiatives on joint procurement to ensure equitable access at the global level.

END

in the case of a next disease of pandemic scope, which may turn out to be much more severe than the H1N1 influenza" (see reference 11).

¹⁸ Although the CJEU cleared circumstantial methods of proof to establish the link between a vaccine and a disease, the Court also prevented Member States from making it too easy for claimants as the latter still have to provide "sufficiently serious, specific and consistent" proof to establish the defect and the causal link (CJEU, *Sanofi Pasteur*, case C-621-15, 21 June 2017, (ECLI:EU:C:2017:484).

¹⁹ In addition, the application of product liability rules in times of emergency and pandemic is likely to raise important questions before courts, with a risk of divergent decisions across Europe and additional delays before obtaining compensation.

²⁰ In France, the *Office National d'Indemnisation des Accidents Médicaux* ("ONIAM") is the scheme in charge of ensuring compensation in case of damage arising out from mandatory vaccines (www.oniam.fr).



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