European Alliance for
Responsible R&D and Affordable Medicines

Transparency is needed to reap the full benefits of the EU's investment in its Vaccines Strategy

The COVID-19 crisis represents an unprecedented challenge for societies in the European Union as well as at a global level. The European vaccines strategy's Advance Purchase Agreements (APAs) mechanism has been used by the EU to procure vaccines for COVID-19. We welcome the effort of the European Commission and all Member States speaking with one voice as a promising step towards reducing the harm caused by the COVID-19 pandemic.

At the same time, we notice that high hopes for the potential benefits of early access to vaccine(s) result in substantial political, as well as economic pressure being exerted on the European Medicines Agency and on the European Commission to approve and procure vaccines against COVID-19 as fast as possible. The signatory organisations call for more transparency on the governance of the APAs. At this crucial stage in the development of one of the main elements of the EU's response to COVID-19, trust and accountability need to be upheld in order to safeguard and promote public health, the quality of healthcare systems, patient and consumer safety. Therefore, the signed organisations call for:

Transparency on the amounts as well as on the destination of the EU's spending on COVID-19 vaccines

- Public funds and other forms of public support for the ongoing COVID-19 R&D must be accounted for and factored into a fair final price for the possible vaccines and treatments.
- We call for an analytical break down of the more than €2 billion funds already committed by the EU as advance payments as well as a forecast of who the recipients of the additional funding will be.
- Member States and the European Commission need to outline in detail all forms of public support and flexibilities granted to pharma companies since the onset of the COVID-19 public health emergency. In case of additional funding, the destination of any top-up should be outlined too.

High standards of regulatory assessment of COVID-19 products

- The procurement process and the conclusion of APAs cannot preclude the results of the assessment of the possible vaccines by Europe's regulators. A robust and complete regulatory assessment of any potential vaccines and treatments against COVID-19 is critical to defend public health, to protect patient safety, to guarantee confidence in vaccines and strengthen public trust in the regulatory system.
- We stand firmly by the European regulators who should be allowed to conduct their mission free of any external influence. The current crisis and the understandable pressure to have access to a vaccine cannot replace the need to respect the European regulatory infrastructure.

Transparency of the vaccines joint procurement process

- We call for the publication of already signed and future contracts with pharmaceutical companies as well as detailed information on the financial aspects of these contracts.
- We call for the publication of the clinical trial results of the vaccines that were procured using the joint procurement process, as well as the criteria for selecting vaccines to be included in APAs.

Transparent liability clauses to make sure that responsibilities are fairly shared between manufacturers and the public sector

- We call for the publication of the respective liability-indemnity provisions inserted in the AstraZeneca deal and in the deals to follow.
- We need to know what the safeguards are, to guarantee a payback or refund in case of non-fruition of vaccines.

Signatory organisations

- AIM – International Association of Mutual Benefit Societies
- CPME – Standing Committee of European Doctors
- ECL – Access to Medicines Task Force, Association of European Cancer Leagues
- EPHA – European Public Health Alliance
- ESIP – European Social Insurance Platform
- European Alliance for Responsible R&D and Affordable Medicines