

### Factsheet n°8 – COVID-19 Vaccination

### **Facts and Figures**

- On 11 March, a total of 42 726 242COVID-19 vaccine doses had been administered in the FU.<sup>1</sup>
- At the current pace, no EU country comes close to the Commission's COVID-19 vaccination target of 70% by the end of September.<sup>2</sup>
- Mid-January, more than 39 million doses of COVID-19 vaccines had been administered in at least 49 higher-income countries. Just 25 doses had been given in one lowest-income country.<sup>3</sup>
- According to a RECOVER survey, between 44% and 66% of respondents in the participating countries would accept a COVID-19 vaccine, if it is found to be safe and effective and provided free-of-charge.<sup>4</sup>
- The European Commission supports COVID-19 vaccines development through the €2.75 billion Emergency Support Instrument<sup>5</sup>, but estimates on actual payments and expenditure on COVID-19 vaccines vary substantially.<sup>6</sup>

#### **AIM Recommendations**

### - Ensure access to vaccination for all at European and global level

AIM welcomes and encourages the coordinated approach to the distribution of vaccines across EU Member States, monitored and led by the European Commission. The joint procurement of vaccines against COVID-19 is an unprecedented example of good EU collaboration. It is faithful to the principle of solidarity on which the Union was build and allows for increased leverage when negotiating with the pharmaceutical industry. At the same time, it is important that the European Union as well as the European Commission learn the lessons from the first implementation of its vaccines strategy and of the huge delivery problems encountered at the moment, including vaccines' development, production and distribution.

Equitable access to vaccination should also be ensured within countries themselves. Barriers for access to vaccination should be overcome, including for people without residence or with insecure legal status. In that vein, the vaccine should be accessible to all, free of charge.

Efforts to accelerate vaccine availability at global level must be stepped up, equity must be promoted between countries and international cooperation mechanisms established to that end.

<sup>&</sup>lt;sup>1</sup> https://qap.ecdc.europa.eu/public/extensions/COVID-19/vaccine-tracker.html#uptake-tab

<sup>&</sup>lt;sup>2</sup> https://www.politico.eu/article/coronavirus-vaccination-live-data-tracker/

<sup>&</sup>lt;sup>3</sup> https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-148th-session-of-the-executive-board

<sup>&</sup>lt;sup>4</sup> Coutries: France, Germany, Belgium, Italy, Spain, Sweden, and Ukraine <a href="https://www.recover-europe.eu/wp-content/uploads/2021/02/Social-science-policy-brief">https://www.recover-europe.eu/wp-content/uploads/2021/02/Social-science-policy-brief</a> Vaccination v5.pdf

<sup>&</sup>lt;sup>5</sup> https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/coronavirus-vaccines-strategy en

https://www.touteleurope.eu/actualite/vaccins-contre-le-covid-19-quel-role-joue-l-union-europeenne.html

AIM subscribes to the EU excluding from its transparency and authorisation mechanism for exports of COVID-19 vaccines "(...) vaccine supplies for humanitarian aid or destined to countries under the COVAX facility, as well as our neighbourhood." The COVAX Facility's goal to vaccinate at least 20% of the population in the recipient countries is not enough to secure access to the COVID-19 vaccine in low and middle-income countries. We need stronger commitments from the European Union in this respect. On top of grant funding, the EU and its Member States alike must, at a later stage, commit to share its excess doses with the COVAX Facility.

### Invest in vaccine preparedness

The current issues related to vaccines supply mean that the EU is considering having a stronger role. Current vaccines business models cannot adequately prepare us against pandemics as private business models generate revenue on volume sold to fight actual diseases. They are ill-suited to bring products to the market that aren't destined to be used and sold as soon as they are approved.

Still, in comparison with the huge economic loss due to COVID, investment in vaccines preparedness is cost-effective. We need global coordination to invest outside of pandemic times into "vaccines candidates", ready to be customized and enter clinical trials once a pandemic breaks out. Vaccines for COVID-19 benefited from research done on countermeasures against Mers and Sars, for instance. Efforts to develop such candidates are estimated to cost tens of billions of euros. Relevant action can only be taken at global level, probably through a collaboration between public and private investment, given the scale of the issue and the stakes in it.

## Attach strong access and transparency conditions to public funding for COVID-19 vaccines

The EU has committed funds to support the development of medicinal products to fight COVID-19, including vaccines. Strong access clauses must be included in funding contracts, in order to make sure that everyone can access the much-needed products developed through these funding programmes.

In this respect, intellectual property (IP) protection deserves a specific attention as it maintains prices high, which can reduce access. In order to effectively protect against COVID-19, vaccines prices must allow for global access, in order to contain the pandemic and its crippling effects on societies and economies across the world. The European Commission should give full attention and support to current international efforts to pool intellectual property rights in order to allow for competitive and accelerated production of COVID-19 treatments. However, waiving IP protection alone is not likely to lead to access, as distribution and manufacturing challenges are also key barriers to access to vaccines.

Equally, the negotiation of vaccines contracts has been done in complete secrecy, which cannot be the standard way of handling such issues. The publication of half of the signed advance purchase agreements is a modest step in the right direction. The contracts are heavily redacted, which prevents any transparent reading of their content. We call on the European Union to be a strong advocate of transparency of contracts and of access clauses in the future. AIM signed along with many NGOs numerous joint statements arguing in favour of more transparency. As the European Union is currently poised for playing a greater role along with the private sector in bringing countermeasures to the

market, this role should also give the EU leverage to ban the practice of secret contracts between the public and private sector.<sup>7, 8</sup>

#### Devote sufficient resources to vaccination roll-outs

The various COVID-19 vaccines have different characteristics when it comes to their storage and transport requirements. Vaccines have temperature requirements and thus specific transport needs (cold chains). Logistical, storage and transport capacities need to be adapted to those specificities.

On top of that, Member States should ensure that vaccination services have the necessary resources to carry out their task, from sufficient skilled workforce to medical and protective equipment. In low-and-middle income countries, challenges related to logistics, skills and access to equipment are more acute than in the rest of the world. There is tension regarding the supply of not only vaccines doses but also of all the equipment that healthcare systems need to effectively vaccinate their population.

AIM welcomes the proposal made by the European Commission to extend the mandate of the European Medicines Agency (EMA) in order to tackle shortages of both medicines and medical devices.

### Ensure quality, safety and efficacy of COVID19 vaccines

The urgency of the need to supply the necessary countermeasures cannot preclude the results of their assessment 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. European regulatory infrastructure needs to be respected at all times.

The COVID-19 vaccines have been developed and brought to the market at an unprecedented speed. Post-authorisation surveillance systems for these vaccines should be strengthened at EU level. Member States should share their national surveillance data on unintended side-effects, if relevant, with other Member States and the European Authorities, such as the European Medicines Agency (EMA). Protecting patients and safeguarding public health indeed requires new post-marketing information to be centrally collected and quickly identified and evaluated so that efficient measures can be taken in a timely manner.<sup>9</sup>

To this end, AIM welcomes the proposal on the standardisation of epidemiological data collection and reporting with the aim to improve the surveillance of rates of new infections made by the European Commission in its regulation on serious cross-border health threats regarding epidemiological surveillance as well as the proposal to extend the mandate of the ECDC. When using information from electronic patient records, data protection regulations must be respected. In case of reporting obligations due to infection protection laws, the reporting may only be done anonymously.

<sup>&</sup>lt;sup>7</sup> Joint Statement – Transparency is needed to reap the full benefits of the EU's investment in its Vaccines Strategy - <a href="https://www.aim-mutual.org/wp-content/uploads/2020/09/Joint-statement-Transparency-is-needed-to-reap-the-full-benefits-of-the-EU-vaccines-strategy.pdf">https://www.aim-mutual.org/wp-content/uploads/2020/09/Joint-statement-Transparency-is-needed-to-reap-the-full-benefits-of-the-EU-vaccines-strategy.pdf</a>

<sup>&</sup>lt;sup>8</sup> Transparency is a fundamental pillar for the success of the EU's vaccines strategy - <a href="https://epha.org/wp-content/uploads/2020/12/jointtransparency-statement-final.pdf">https://epha.org/wp-content/uploads/2020/12/jointtransparency-statement-final.pdf</a>

<sup>&</sup>lt;sup>9</sup> https://ec.europa.eu/health/sites/health/files/vaccination/docs/2020 strategies deployment en.pdf

## - Tackle vaccine hesitancy and fear through targeted, comprehensive and efficient communication

If national and regional targeting are proven to have a better impact on citizens and to be more efficient when it comes to tackling vaccine hesitancy<sup>10</sup>, AIM is of the opinion that general guidance and data/statistics could be provided at EU level. That data should be totally transparent and include information on important aspects such as reported side effects. Only through transparency can the trust of citizens in vaccination be upheld. EU guidelines on how to tackle hesitancy could be especially beneficial to Member States with limited resources.

Clear, accurate and trustful information should be provided to the public, with a specific target on vulnerable groups such as people with low literacy levels. Social media and influencers can have a key role to play when it comes to achieving high vaccination rates amongst some groups. As such, their potential should be further exploited, especially when Member States start vaccinating younger citizens.

General practitioners are often patients' first contact point. Therefore, they should be properly informed and trained on vaccine safety, efficacy, effectiveness, contraindications, and possible adverse events, but also on how to properly communicate to their patients without inducing fear. So must be other professionals administering the vaccine.

All stakeholders have their role to play at different levels: decision-makers, general practitioners and other healthcare professionals, communities, NGOs, media, individuals, etc. In this vein, AIM has published a series of questions and answers regarding COVID-19 vaccination, to contribute to tackle hesitancy.<sup>11</sup>

# - Implement common liability rules for very rare, but possible complications from COVID19 vaccines at EU level.

Vaccines are administered to people who are usually healthy. Therefore, a higher degree of safety is often expected for vaccines than for other pharmaceuticals or other healthcare interventions. To ensure the safety of vaccines but also citizens' trust in them, it is important to improve spontaneous reporting of adverse event(s) following immunization (AEIF) and pooling of AEIF data globally in order to reduce time to identify rare vaccine reactions. AIM encourages the European Commission to implement common liability rules for very rare, but possible complications from COVID19 vaccines at EU level. A need for standard methodologies for active surveillance and a standard reporting format for AEIF should be developed. This would help ensure a proper monitoring of vaccines after their use.

<sup>&</sup>lt;sup>10</sup> See AIM position paper on <u>Vaccine Hesitancy</u>

<sup>&</sup>lt;sup>11</sup> AIM Q&A can be found here.