BEUC The European Consumer Organisation

The Consumer Voice in Europe

MAKING THE MOST OF EU ADVANCE PURCHASES OF MEDICINES

BEUC assessment of COVID-19 vaccine contracts and recommendations for improvement

Contact: Ancel·la Santos - health@beuc.eu

BUREAU EUROPÉEN DES UNIONS DE CONSOMMATEURS AISBL | DER EUROPÄISCHE VERBRAUCHERVERBAND
Rue d'Arlon 80, B-1040 Brussels • Tel. +32 (0)2 743 15 90 • www.twitter.com/beuc • www.beuc.eu
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Why it matters to consumers

When consumers fall sick during a pandemic, it is crucial they get timely and affordable access to life-saving medicines. Advance purchases of pharmaceuticals by the European Union can play an important role in keeping people alive. But the EU must make sure these agreements have conditions attached, are transparent, and are clear about what pharmaceutical companies must do.

Summary

When governments team up to negotiate medicine prices and carry out joint procurement, they increase their bargaining power and the chance to secure a good deal. From this perspective, the EU's centralised procurement of COVID-19 vaccines has been a much-welcomed initiative. Thanks to the joint advance purchases, all Member States were able to secure vaccine supplies in a timely manner, regardless of their purchasing power. This has contributed to vaccine equity in the EU.

At the same time, a close look at the Advance Purchase Agreements (APA) signed by the European Commission with pharmaceutical companies reveals some shortcomings and areas for improvement. To make the most of similar initiatives in the future, BEUC has a set of recommendations:

1. Contracts must describe in detail the actions that companies must take to reach at-scale production capacity. There should be strong contractual clauses to ensure compliance with delivery schedules.
2. As a general rule, advance payments to support R&D and to ramp-up production capacity should be made conditional on sharing intellectual property rights and know-how. This is essential to ensure that there is enough production to meet global demand during a public health crisis.
3. Pharma companies should be responsible for covering indemnification costs related to injuries caused by their products to consumers, and not Member States.
4. Transparency should be the rule in APA negotiation frameworks. Any proposed exception should be well-justified and assessed by an independent committee.
5. Contracts must ensure that if companies fail to bring the product to the market, the EU gets back a fair share of the advance payment.

BEUC calls on the European Commission and Member States to ensure that, in the future, advance purchase agreements with pharmaceutical companies are more aligned with the public interest and involve far more the European Parliament and civil society.

1. Introduction

To speed up the development and production of much-needed COVID-19 vaccines, the European Commission and Member States agreed to provide EU financing to vaccine developers through Advance Purchase Agreements in June 2020. In return, Member States would be able to secure a specific number of vaccine doses within a given timeframe and price.[1] The deal was that part of the vaccine's price would be paid through the advance payment, and the rest directly by Member States after the vaccine got approved.

From August 2020 to November 2021, the Commission signed eight APA with companies on behalf of Member States. The advance payments were funded through the Emergency Support Instrument (ESI), a €2.7 billion EU financing scheme made available to tackle the COVID-19 pandemic.[2] So far, four vaccines have been approved by the European Medicines Agency.[3] Through these four APAs, the EU secured the right to 780 million first doses and the option to purchase millions of additional ones.[4]

However, negotiations with pharmaceutical companies were opaque. The pharma industry pushed for liability exemptions in case of safety incidents, and Member States faced vaccine supply disruptions.

A key question that arises is whether the negotiated APAs have maximised public return on public investment. Addressing this question is important for accountability purposes, and to learn lessons for the future.

To that end, BEUC assessed the first six APAs on COVID-19 vaccines published by the European Commission. All the contracts contained redactions that made it harder to assess them. However, our analysis includes the unredacted versions of three of these contracts, which are available online following a leak. These are the contracts with AstraZeneca, Pfizer and Moderna. In addition, we checked the redacted versions of the CureVac, Janssen and Sanofi-GSK APAs and used as additional sources of information other independent assessments.[5] [6]

Based on the information at hand, we have identified major shortcomings and formulated some recommendations for improvement. Whilst the scope of this paper is limited to pharmaceuticals, our recommendations can be transposed, mutatis mutandis, to advance purchases of medical devices or other health technologies.

A detailed description of problems and solutions can be found below.

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1 European Commission. 'Annex to the Commission decision on approving the agreement with Member States on procuring COVID-19 vaccines on behalf of the Member States and related procedures', 18 June 2020.

2 The redactions in the APA contracts published by the Commission do not allow to calculate how much has been disbursed in advance payments. However, the leaked (unredacted) contracts show that Pfizer got €700 million, AstraZeneca €336 million and Moderna €318 million. ESI's budget allocation for vaccines was topped up with at least €750 from Member States' contributions to be able to make all the advance payments.

3 Comirnaty (Pfizer), Spikevax (Moderna), Vaxzevria (AstraZeneca), COVID-19 Vaccine Janssen.

4 Between the APAs, subsequent vaccine purchase agreements and negotiated options to request additional doses in the future, the Commission has secured more than €3.6 billion doses of these four vaccines. https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans_en [accessed 15 November 2021].

5 European Commission. EU Vaccines Strategy, website https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-health/eu-vaccines-strategy_en [last accessed 15 November 2021].

6 Boulet, P. et.al, 'Advance Purchase Agreements for COVID-19 vaccines. Analysis and comments', Medicines Law and Policy, July 2021.

2. BEUC assessment of COVID-19 vaccine contracts and recommendations

2.1. Vaccine delivery schedules

2.1.1. Problem

Although the advance payments made by the EU were meant to help companies prepare for at-scale production capacity, there were delivery delays that impacted Member States' vaccination campaigns and citizens' timely access to vaccines.[7],[8],[9],[10]

Our assessment of the contracts shows that companies' compliance with delivery schedules revolved around the concept of 'best reasonable efforts'[11], and that in general this was not backed up by strong measures to reinforce observance with the timetable.

During an emergency injunction procedure initiated by the Commission against one company over delivery delays, the court found that the company didn't use all the manufacturing sites at its disposal to produce and deliver the vaccines to the Member States.[12] In the end, the two parties reached a settlement agreement that replaces the notion of 'best reasonable efforts' with a ''firm commitment'' by the company to deliver the pending number of doses. This is to be done according to a new timetable associated with rebates on the cost of each delayed dose. [13]

2.1.2. Way forward

For accountability purposes, all contracts should include a detailed annex describing the efforts that the company commits to undertake to boost production capacity, respect the delivery schedule and prevent shortages.[14] The Commission should publish these plans and closely monitor companies' compliance with them.

In addition, contracts should include a section laying down penalties in case delays are not promptly notified or for unjustified late deliveries throughout the schedule. Penalties could range from fines to rebates on the price of delayed supplies. We were unable to find such a section in the assessed contracts.[15] We also recommend that all contracts provide Member

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7 Politico. '6 EU countries blast delays to BioNTech/Pfizer vaccine deliveries', 15 January 2021

8 Reuters. 'Moderna COVID vaccines delayed in Europe and elsewhere, adding to shortfalls', 29 January 2021

9 Politico. 'People likely died due to vaccine delivery delays: Commission official', 27 May 2021

10 Following some companies' early announcements of delivery delays, in February 2021 the Commission set up a Task Force to act ''as a one-stop-shop for manufacturers in need of support, and to identify and address bottlenecks in production capacity and supply chains''.

11 There are some variations in the definition of 'best reasonable efforts' or 'reasonable best efforts' among the contracts, but broadly speaking it means that companies commit to do their best, as any other company of the same characteristics would be able to do, to meet the objectives.

12 European Commission. 'Belgian Court orders AstraZeneca to deliver vaccine doses to the EU – Questions and Answers', Press release, 19 June 2021

13 European Commission. 'Questions and Answers: The EU and AstraZeneca agree on COVID-19 vaccine supply and on ending litigation', Press release, 3 September 2021

14 We could only find in Moderna's leaked APA an annex with some information on the company's ''intended utilisation of the down payment'' to expand manufacturing capacity and start at-risk production. The APA with CureVac has an annex with the same title, but the content is redacted. The titles of the annexes in Sanofi's contract, as well as their content, are totally redacted.

15 What we found is that in some contracts, the section outlining the 'reasons for termination of the APA' establishes that companies could end up paying some money back if they fail to deliver the full amount of vaccines *well after* the deadline by which they had to supply the last tranche of doses. However, this measure does not ensure that companies will stick to the delivery schedule and the various milestones contained therein. On the other hand, laying down specific penalties for delays throughout the delivery schedule would promote better compliance with the terms of the contract.

States with the possibility to cancel orders in case of late delivery and get a refund of any payments already made.[16]

As a general principle, the Commission and Member States should ensure that, as companies increase and consolidate their production capacity, there is a transition from compliance based on 'best reasonable efforts' to *actual* compliance with a fixed and time-bound delivery schedule. If this is not feasible within the advance purchase agreement itself, subsequent agreements with the companies to buy additional product doses should consider including this point.

2.2. IP sharing and vaccine prices

2.2.1 Problem

The assessed APAs do not require companies to share intellectual property (IP) rights and know-how on the vaccines with third parties to allow an expansion of production capacity. The only IP licensing provision that we found was limited to the scenario where the company would have abandoned its vaccine development efforts.[17]

Insufficient vaccine production is contributing to global inequity in terms of access in the current pandemic, and to the surge and rapid spread of COVID-19 variants.[18] This happens even though the EU and Member States have spent large sums of money to support the development and production of COVID-19 vaccines through various financial instruments. Globally, the public sector spent at least €88 billion on this endeavour.[19]

In addition, leaks about the prices of vaccines negotiated in the APAs show important variations with price tags ranging from €19 per dose to €2.90 per dose.[20] The prices of the most expensive vaccines went up in subsequent purchases, even though these companies are reported to be making billions in revenues.[21] This indicates that lower price tags should be possible.

2.2.2 Way forward

To maximise public return on public investment, advance payments made to companies to support R&D efforts and increase manufacturing capacity should in principle go hand in hand with requirements to share IP and know-how. This would allow other pharmaceutical companies to produce and market more vaccines and therapies, thus enhancing their availability and affordability globally through increased competition. APAs should favour

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16 As far as we can tell, only Moderna's contract includes such kind of clauses by offering countries the chance to: 1. cancel an order and get a refund if there is a 90-day difference between the initial delivery schedule (i.e., agreed before marketing authorisation) and the updated delivery schedule (reflecting any changes in the approval date); and 2. cancel orders that are delayed by more than 90 days. On the other hand, the APA with AstraZeneca allows countries to suspend payments if there are delays and resume them once the delivery has been completed.

17 AstraZenca's APA (Clause 11.2) states that the Commission, or any third party designed by it, shall have the right to obtain a license or sublicense for the vaccine IP rights to the extent reasonably necessary to continue the development efforts for the vaccine, if the compay abandons such efforts.

18 Georgieva, K., Adhanom Ghebreyesus, T., et al. 'A New Commitment for Vaccine Equity and Defeating the Pandemic', World Health Organization, 31 May 2021.

19 The figure includes advance purchase agreements. Businesswire. 'Governments Spent at Least €93bn on COVID-19 Vaccines and Therapeutics During the Last 11 Months', 11 January 2021

20 Leaked information in the media on vaccines' prices reveals that the most expensive was Moderna's and the cheapest AstraZeneca's. The negotiated price for one dose of the Pfizer vaccine was €15.50. According to the APA with AstraZeneca, the vaccine was to be sold at ''no profit or loss'' until July 2021, unless the company would determine that the COVID-19 pandemic had not ceased. In November 2021, AstraZeneca announced that it plans to make profits in 2022.

21 Euronews. 'Pfizer and Moderna raise COVID vaccine prices in Europe amid Delta variant fears', 2 August 2021

the use of initiatives set up at the regional/global level that offer a one-stop shop for vaccine developers to share IP with other manufacturers.[22]

In addition, there should be transparency on the product's price and how it was built. This will facilitate public accountability on whether prices are fair or excessive.

2.3. Liability in case of product related-harm to consumers

2.3.1. Problem

The assessment of the contracts reveals that the costs for damage compensation in case of a safety incident were largely passed onto Member States.[23] As such, there is no liability *in practice*' as the companies do not bear the full costs of liability.

The approach of passing on compensation matters to governments has implications on Member States' ability to donate or resell vaccine doses to third countries. Among the various APAs, we found clauses requiring that receiving countries accept similar conditions to those laid down in the agreement, or terms satisfactory to the company including on compensation. It appears that similar requirements were included in subsequent vaccine purchase agreements.[24]

2.3.2. Way forward

Pharmaceutical companies should be fully responsible for compensating injured consumers economically. Furthermore, to ensure easier access to compensation there should be a publicly managed compensation fund. Such compensation funds exist for example in Denmark and France and include COVID-19 vaccines. The financing of the mechanism should come from manufacturers.

The Commission and/or Member States should design a common EU framework for a compensation scheme of medicines acquired through advance purchases. The scheme could be implemented through Member States or directly at EU level. In fact, a similar initiative exists at the global level in relation to vaccines purchased through the COVAX facility.[25]

2.4. Transparency of the APA framework

2.4.1. Problem

There was little transparency on the negotiation process, including on the negotiating team composed by some Member State representatives and the Commission. The APA contracts were only made publicly available months after they were concluded, following pressure from civil society and only after companies gave their approval.

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22 Such as the Covid-19 Technology Access Pool (C-TAP), an initiative launched by the WHO and partners to facilitate equitable access to COVID-19 health products.

23 According to the unredacted (leaked) version of the contract with AstraZeneca, exceptions to Member States' obligation to cover such costs include situations of wilful misconduct by the company, or defects in the vaccine that arise from its failure to comply with good manufacturing practices or EMA pharmacovigilance regulations (Clause 14.1). The unredacted Moderna contract also includes exceptions such as situations of wilful misconduct, gross negligence or failure to comply with good manufacturing practices by the company (Clause II.5.1). Similar provisions are included in the unredacted version of the contract with Pfizer (Clause I.12.1). As for the other contracts, the various redactions in the contracts do not allow to confirm that there are similar exceptions in place, but it is likely.

24 Politico. 'EU fears losing geopolitical clout as vaccine donations lag', 19 October 2021

25 Mechanism that facilitates pooled procurement of COVID-19 vaccines for low and middle income countries. The compensation programme allows individuals from these countries to apply if they suffered serious adverse events associated with distributed vaccines. It is funded via donor contributions.

All the contracts published by the Commission include important redactions, with some differences among them. In all, crucial information such as the amount of the advance payment, the vaccine price and details of the delivery schedule were blacked out, among others. The European Parliament has called upon the Commission to disclose this information without further delay.[26]

2.4.2. Way forward

The European Commission should develop a 'transparency policy for advance purchase agreements'' that informs these negotiation processes. As a general principle, information in the contracts should be considered of public interest and contracts be published soon after their conclusion.

Any proposed publication delays and/or redactions by the signatory parties should be well-justified and assessed by an independent committee for final decision. Such a committee should be composed of Members of the European Parliament and independent (non-industry) experts.

The committee should organise hearings to get the views of concerned stakeholders on publication/confidentiality clauses - it should invite the European Commission and Member States, the pharmaceutical company, and representatives of consumer, patient and healthcare professional groups. The committee should observe the overriding public interest principle in the sense of Regulation 1049/2001 regarding public access to European Parliament, Commission and Council documents.

2.5. Return of advance payments if vaccines do not make it to the market

2.5.1 Problem

Whilst it is positive to find clauses requiring companies to return the 'unspent amount' of the advance payment and even procured materials[27] if they fail to bring a vaccine to the market, some provisions caught our attention. These are:

1. In some of the contracts it appears that companies can include too many costs under their 'expenses' incurred in relation to the APA, for example, cost related to IP, litigation, penalties, and fines.[28] This reduces the amount of money that should be returned to the EU.
2. In one of the contracts, the advance payment includes costs incurred by the company ''for any trade-off resulting from the prioritization of the Adjuvanted Pandemic Vaccine production over the production of the existing vaccine portfolio'.[29]

2.5.2 Way forward

APA agreements must ensure that in case companies fail in their efforts to develop the product and get market authorisation, the EU gets back a fair share of the advance

[26] European Parliament. 'EU transparency in the development, purchase and distribution of COVID-19 vaccines', Resolution of 21 October 2021.

[27] The contract with AstraZeneca mentions the transfer of purchased vials and stoppers to the Commission or a named third party to be repurposed in case the company abandons development and manufacturing efforts (clause 12.2). The contract with Sanofi also foresees possibilities for 'getting back' unused raw materials and primary components (II.15.5) as well as the contract with CureVac (11.14.5).

[28] Contracts with Moderna (clause II.16.5) and CureVac (11.14.5). On the other hand, the Pfizer contract would have allowed the Commission to terminate the APA and require the company to return all the advance payment in case the vaccine had not obtained marketing authorisation by August 2021, among other circumstances (clause 1.8.1).

[29] Contract with Sanofi Pasteur and GSK, clause 1.6.1.1: ''Costs actually incurred by Sanofi Pasteur and GSK in relation to deferred commercial agreements, in particular for any trade-offs resulting from the prioritization of the Adjuvanted Pandemic Vaccine production over the production of the existing vaccine portfolio''.

payment. This means that companies should only be allowed to record as 'incurred expenses' those costs that are clearly connected with, and necessary for, the activity of drug development and/or production.

At the same time, where investments made by a company with the advance payment can be used for other of its activities, the agreement should contain provisions for a partial reimbursement of the funds.

Above all, APA contracts should uphold the principle that medicines are **global public goods**. Despite pledges by the EU and Member States in that direction, this has not become a reality so far during the COVID-19 pandemic.[30] This must be ensured for COVID-19 vaccines as stressed by the European Parliament[31], and in the future.

ENDS

[30] Whilst the Agreement between the Commission and Member States on procuring COVID-19 vaccines says that in the negotiations with pharmaceutical companies, the Commission would promote vaccines as global public goods and seek to promote questions such as IP sharing, especially when developed with public funding, it has failed to get there.

[31] See reference 26.

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