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From:	Presidency
To:	Permanent Representatives Committee/Council
Subject:	COVID-19 vaccine procurement *- Exchange of views*

COVID-19 vaccine procurement

In response to the COVID-19 pandemic, the European Commission enacted a single central purchasing procedure, negotiating with vaccine manufacturers together with and on behalf of all the Member States. EU Advance Purchase Agreements (APAs) included up-front EU financing from the Emergency Support Instrument to de-risk essential investments in order to increase the speed and scale of the manufacture of successful vaccines. As stated in the Annex to Commission Decision C(2020) 4192, participating Member States agreed not to launch parallel procurement procedures with vaccine manufacturers with whom negotiations had started, unless they opted out of the Agreement. APAs enabled Member States to swiftly secure and ensure equitable access to COVID-19 vaccines for European citizens and to make a significant contribution to global vaccine-sharing efforts, essential for combating the pandemic.

Prior to the EPSCO meeting in June 2022, ten Member States addressed a letter to the European Commission raising concerns about the significant surplus of COVID-19 vaccines and the obligation to purchase even more under the existing APAs. Though the Member States expressed their appreciation for the Commission's work in ensuring the needed amounts of COVID-19 vaccines in due time – a significant step which proved that EU Member States are stronger when they act together – they also pointed to an oversupply of vaccines that significantly exceeded Member States' needs and their capacity to absorb them.

While acknowledging that the agreements negotiated by the Commission and Member States' representatives on the Joint Negotiation Team are firm purchase contracts and that it was impossible to predict how the pandemic would develop over time, many Member States found themselves facing an excessive burden on state budgets, caused by the delivery of unnecessary amounts of vaccines. The French Presidency of the Council of the EU addressed the topic at the **ministerial lunch during the June EPSCO meeting.** Member States proposed that the APA with BioNTech/Pfizer be amended not only to postpone deliveries – something which already happened in spring 2022, in a welcome sign of goodwill on the part of the producers – but also to allow for deliveries to be cancelled and/or made subject to the availability of adapted vaccines.

The Czech Presidency of the Council of the EU (CZ PRES), realising the need to resolve the issue, has been constantly working with the European Commission (HERA) on addressing Member States' key concerns when it comes to existing agreements with COVID-19 vaccine producers.

Regular meetings involving the Joint Negotiation Team, HERA and the CZ PRES took place with the two biggest producers of COVID-19 vaccines on the EU market throughout the summer of 2022. Preliminary conclusions were presented at the **HERA Board meeting at ministerial level**, which took place as part of the **Informal Meeting of the Ministers of Health on 7 September in Prague**.

During that meeting, producers were asked to present the following scenarios and conditions for:

1) lowering the number of incoming doses in autumn months/postponing them (to 2023)
2) altering deliveries according to expected pandemic waves and/or so that the newest available vaccine is always delivered
3) spreading deliveries over time to 2024 and beyond
4) cancelling ordered doses (partially or totally)
5) establishing stockpile management services for doses already expired in Member States
6) cancelling the APAs themselves

During the HERA Board meeting at ministerial level, Member States emphasised the need for more flexibility in current and future contracts, considering the evolution of the epidemiological and political situation. Ministers raised concerns over the short shelf-life of vaccines, the shortage of storage capacity, the handling of expired doses and the inability to donate rephased doses through COVAX. Several Ministers welcomed the proposal to create a Central Warehouse at EU level to free up some storage capacity in the Member States, while additional operational flexibilities needed to be agreed upon to allow donations from the warehouse and the extension of the maximum storage period.

A number of Member States expressed an interest in extending the duration of the BioNTech/Pfizer contract over two years and in rephasing the deliveries of doses expected in 2023 with a schedule that better matches Member States' needs. Several Ministers also mentioned the need to reflect on new procurement instruments and contract models adapted to pandemic preparedness and response needs.

Overall, Ministers pointed to the need to find common solutions and remain united when renegotiating with companies.

Since the meeting in Prague, the Commission has reached several important agreements with the producers. Most importantly, negotiations were concluded on the Central Warehouse for Comirnaty vaccines[1]. In addition, both companies successfully registered their innovative bivalent vaccines. Booster vaccines for children, as well as primary series doses for very young children, have also been successfully registered[2].

Furthermore, three COVID-19 vaccines were given a 'standard' marketing authorisation in October: Spikevax on 3 October, Comirnaty on 10 October, and Vaxzevria on 31 October.

Nevertheless, the major outstanding issue of oversupply remains unaddressed. Despite the commitment to work on adding more flexibility into the contracts, no agreement has been formalised on postponing vaccine deliveries due in December to 2023. No agreement on a possible splitting of deliveries between 2023 and 2024 has been reached, and so the original schedule based on deliveries from January to June 2023 remains valid. Similarly, no agreement has been reached on spreading the vaccines from 2023 to at least 2024.

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1 On 8 November, the first Member States interested in using the Central Warehouse services were able to sign the Agreement.

2 1 September 2022: Comirnaty Original/Omicron BA.1; 1 September 2022: Spikevax bivalent Original/Omicron BA.1; 12 September 2022: Comirnaty Original/Omicron BA.4-5; 20 October 2022: Spikevax bivalent Original/Omicron BA.4-5; 6 September 2022: Nuvaxovid registered as booster for 18+; 16 September 2022: Comirnaty as booster for 5-11 years; 20 October 2022: Comirnaty as primary dose for children 6 months+; 20 October 2022: Spikevax as primary dose for children 6 months+.

Moreover, we are missing clarity on the future availability of Spikevax vaccines, since the APA with Moderna comes to an end on 1 March 2023.

CZ PRES has been regularly meeting with the HERA team, sharing information as needed. And while the Commission is certainly engaged in intensive negotiations with the producers, trying to advance the interests of Member States, progress has unfortunately been slow despite the Commission's clear efforts to pursue the matter.

The Member States that addressed the abovementioned letter to the Commission in June have thus once again raised their concerns. The CZ PRES feels obliged to address these, since we do believe that they express (at least partially) the opinions of a majority of Member States. Moreover, Russia's unprovoked and unjustified military aggression is also putting a burden on Member States, including in the form of the energy and economic crisis. This burden needs to be considered, especially as Member States are under pressure to spend public finances much more efficiently.

The signatories call upon the Commission to speed up negotiations with producers, due to the constraints on the economies of all EU Member States caused by the war in Ukraine. The letter emphasises that these Member States continue to struggle with an excess of Comirnaty and Spikevax vaccines. Although proposals to postpone deliveries and extend expiry dates may be assessed positively, in reality this does not solve the current problem, it merely postpones the inevitable, i.e. the problem of disposing of vaccines.

They state that an urgent revision of the provisions of the contracts for the purchase of vaccines is essential. The current inflexibility of contracts has created a situation where public funds are allocated to a large quantity of vaccines which may not be used in Member States or donated to third countries, and is thus destined to be destroyed. We must ensure that the vaccines that are currently being produced for delivery under the EU PAs will not meet the same fate.

The signatories emphasise that any further delay in taking action with the manufacturers will undermine the trust of society in vaccination and vaccines. They call on the Commission to coordinate and act with and on behalf of Member States, in accordance with the positions agreed on at the Vaccines Steering Board.

The CZ PRES sees a need to put the topic up for debate by the Ministers at the upcoming EPSCO meeting. We believe it is important to hear the opinions of all Member States when it comes to the steps they expect the Commission to take. It is also important to remind ourselves that solidarity and a united approach are the strongest tools that Member States have at their disposal when it comes to negotiating with vaccine producers. It is also important to remind the Member States that in order to ensure the smooth progress of the negotiations and formalisation of amendments to the contracts, close cooperation with the European Commission is necessary and reactivity of the Member States is key.

Ministers are encouraged to address the following questions during the debate:

1) **What are your expectations when it comes to the future steps that the Commission should take on behalf of the Member States in relation to existing APAs?**
2) **At this stage of the pandemic, should a return to standard national procurement procedures be considered/preferred as an alternative to the current common approach?**