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European Commission

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Dear Ministers,

On the basis of the Agreement between the Commission and all Member States ("the Agreement"), the Commission was mandated to conclude, in the name and **on behalf of the Participating Member States**, Advance Purchase Agreements ("APA") with vaccine manufacturers with the objective to procure vaccines for the purposes of combatting the COVID 19 pandemic at Union level.

Our **collective effort** has major benefits for everyone. These benefits consist in particular of having the **availability** of a number of vaccines **as early as possible** and without the need of running a procurement procedure at national level, allowing to achieve **better conditions** than would otherwise be possible for any individual Member State.

However, it has been brought to my attention that some Member States may have had the intention to conclude separate contracts with companies within the EU portfolio of vaccines. In this light, I would like to recall that **Article 7(1)** of the Agreement foresees **an obligation not to negotiate separately.**

By concluding the Agreement, the Participating Member States **confirmed their participation** in the procedure under Article 4(5)(b) of the ESI regulation 2016/369 (as amended by regulation 2020/521) and thus made a binding commitment under Union law **not to launch their own procedures** for advance purchase of a given vaccine with the same manufacturer.

Allow me to remind you that according to the Agreement, there can be two types of contracts: (i) with a firm obligation to buy vaccine doses (possibly coupled with options) or (ii) contracts containing only an option to buy vaccine doses. With the exception of the APA with SANOFI/GSK, **all EU APAs contain a firm obligation to buy doses**.

EU Health Ministers

In this case, Member States have the right to **opt out** by explicit notification to the Commission **within 5 working days** after the Commission has communicated its intention to conclude the APA. In accordance with Article 4 of the Agreement, all Participating Member States not having opted out within the period of 5 working days are deemed to have authorised the Commission to conclude the APA with the vaccine manufacturer on their behalf.

In accordance with Article 5 of the Agreement, once concluded, the terms of the APA are **legally binding** on the Participating Member States.

However, Article 7(2) of the Agreement stipulates that in case an APA containing an obligation to acquire vaccine doses has been concluded with a specific manufacturer, the Member States having made use of the opt-out provided under the Agreement can enter into separate negotiations with the same manufacturer after the APA under the Agreement has been signed. Thus, under the explicit terms of the Agreement only in case a Member State has opted out – for instance because it is not satisfied with the conditions negotiated by the Commission – that it can launch its own procedures for negotiating with the same manufacturer.

So far no Member State has opted out from any of the APAs with one exception that was subsequently rectified in a manner that demonstrated the extent to which Member States have been loyal to each other in a spirit of true European solidarity.

However, as past days and weeks demonstrate the constantly evolving state of the pandemic and the speed and conditions in which vaccines obtain marketing authorisation may require the purchase of further vaccine doses for which Union law and the APAs concluded thereunder provide for the relevant legal framework. Thus, where a Member State that opted-in to an APA wishes to obtain additional vaccine doses to those contracted under the APA, it should express that wish to the Commission and the other participating Member States, and give the Commission the opportunity to negotiate an agreement regarding such additional doses for the benefit of all interested Participating Member States.

I would like to emphasise in particular that if an individual Member State were to conclude a bilateral agreement on the side of an APA for deliveries of the same vaccine, this might seriously affect the rights of other Participating Member States under the APA as the delivery schedules under competing contracts are likely to overlap. There is also a risk that the applicability of other provisions (such as liability clauses) becomes blurred as it may not always be clear whether a given administered vaccine was delivered under one or the other contract.

I want to remind you of the obligation of Member States to respect the principle of sincere cooperation as prescribed by Article 4(3) of the Treaty of the Union and in this regard I invite you to provide the Commission with a copy of any bilateral agreement or arrangement that might have been considered.

I count on the willingness of Member States to work in a spirit of European solidarity.

Yours sincerely,

S. Kyriakides