For an EU initiative in favour of Covid-19 Vaccines donations

In line with the political steer of the Heads of State and Governments' visioconference of Thursday, 19 November, this paper sketches (i) the objectives, (ii) the principles and (iii) options for the concrete functioning of an EU-coordinated donation mechanism based on the EU Covid-19 vaccines' portfolio.

1. Objectives: securing access to the vaccine for the top priority group and the most vulnerable around the world

Access to a vaccine will be one of the keys to the resolution of the current pandemic. Since the COVID-19 outbreak, the EU – the world's leading donor of humanitarian aid – has been providing humanitarian health assistance in the form of medical supplies, medical staff and funding relief. The EU has also been at the forefront of the creation of the *Access to Covid-19 Tools Accelerator* (ACT-A) at the end of April, to ensure equitable access to tests, treatments and vaccines around the globe. The "vaccine pillar" of ACT-A, Covax, was set up following these principles. It has received substantial support from the "Team Europe", amounting in financial terms to close to 1 Bn €, i.e. half of the needed contribution to the procurement of the vaccine for the 92 lower and middle income eligible countries.

In parallel, the EU has supported the ramp up of the development and the production, and secured doses of several promising vaccine candidates. A total of six contracts have either been signed or are in the final round of negotiations and more may come. It is possible that some of these vaccines become available by the end of this year, after EMA approval and EU marketing authorisation. This means that European Member States will, by that time, have access to vaccines considered safe and efficient to start a vaccination campaign in their respective countries. Other countries around the world may also start vaccinating their people around the same date.

It is of utmost importance that the top priority groups around the world are vaccinated first, rebutting any sort of "vaccine nationalism"**.** The World Health Organisation has identified **health and social care professionals** among the first target group. In the 62 lowest income countries, they are estimated to represent **16 M persons**, reaching 51 M when adding the 54 lower middle income countries. Other vulnerable persons may not be able to secure a rapid access to the vaccine, such as the staff of **humanitarian organisations and those dependent on humanitarian aid** (refugees, asylum seekers and internally displaced, estimated at around 50 M persons by WHO).

Donating vaccines from our EU portfolio to reach these priority groups therefore appears to be, in the short term, the most efficient way of achieving the ambition of making the vaccine a Public Good, in line with our values.

2. Proposals: real time donations to ACT-A of doses secured by the EU

An EU-coordinated approach seems essential. If some Member States might conduct bilateral initiatives, these are technically and logistically complex to handle for individual Member States. On the other hand, deciding at the EU level allows setting up one efficient mechanism to channel donations and make sure they are allocated where they are most needed. This would of course not prevent the EU from providing specific support to neighbouring countries, under the form of resale or donation, for instance to Western Balkans countries, as already implemented with EEA countries.

To that effect, a commitment expressed in percentage of the total volumes secured by the EU would have the benefit of clarity. An aggregate commitment of 5 % of the total volumes would for instance, as a best case scenario, allow donating up to 65 M vaccines, which could in turn allow vaccinating up to 38 M individuals.

Table 1 : Sharing 5 % of the EU contracts (in millions)

	AZ	Janssen	Sanofi-GSK	BionNtech-Pfizer	CureVac	Moderna	Total
Volume of the EU contract (excl. options)	300	200	300	200	225	80	**1 305**
5% of the volume	15	10	15	10	11	4	**65**
Number of persons vaccinated	8	10	7,5	5	6	2	**38**

The EU should consider donating part of these vaccines as soon as they are made available. The EU's donation mechanism is not set up to cover "leftovers", even though it should also be able to cater for unused doses. Its objective is to contribute immediately to covering the most urgent needs around the world (top priority groups and most vulnerable populations, following WHO guidelines), possibly before the start of deliveries through Covax. Of course, timing is key and vaccines should theoretically become available for donation at the same time as they are made available to EU countries. However, it should be made clear that donations should occur only when the recipient is able to demonstrate its capacity to properly handle the vaccine, from storage to administration. Of course, any donation policy should be included in a broader initiative that would take into account technical assistance and support towards country readiness of the beneficiaries[1].

ACT-A and its equitable allocation mechanism should be the platform to manage these donations. EU countries would only donate through a safe and efficient mechanism, which can ensure that vaccines are properly allocated and that recipient countries or organisations have the capacity to administer them. WHO's equitable allocation mechanism, at the core of ACT-A, would come into play to make sure that European doses are sent to beneficiaries who need them most, consistently with Covax's allocation scheme. The EU should of course remain closely involved in the allocation mechanism, sharing the accountability of the proper use of the vaccine. Donations could therefore be labelled as donations from the "Team Europe" to ACT-A, channelled directly by the Commission to the equitable allocation scheme, with no country-to-country interaction. Access of the NGOs to the allocation scheme will be an essential criterion to the EU.

[1] "Team-Europe" could also mobilise technical assistant teams for the deployment of the vaccination campaign in the field, within the framework of the ACT-A initiative, created to receive all the necessary support for the ambitions.

The donation mechanism should provide sufficient guarantees in terms of liability. Our contracts provide companies coverage in terms of liability related to losses due to defects in the product which are not imputable to the manufacturer. But in no cases should EU Member States remain liable for the doses which have been donated. If these contracts allow us donating doses, they impose that beneficiaries of these donations agree to the same liability clauses as the original parties to the contract. By default, it should be envisaged that recipient countries sign an agreement to this effect[2]. If for some reason, this was not a workable solution – for instance when recipient are NGOs and not countries, alternative solutions can be envisaged, either through WHO, Covax, financial guarantee by a public institution (e.g. EIB) or *via* private insurance coverage[3].

To avoid logistical hurdles and save costs, the donation mechanism should envisage the direct sending of the doses to the recipient. Unless already taken care of by ACT-A processes, a specific contractual arrangement might be needed with the vaccine suppliers, so that they stand ready to deliver the doses to an identified beneficiary (third country, NGO or international body). To this effect and confirm the volumes, the recipient could use an order form similar to the one already in place between the EU and suppliers. The system would avoid any stockpile and additional storage costs. This would also be the safest option for donating countries, who would avoid taking the responsibility for the physical handling of the product.

Finally, an agreement will have to be found on the transaction costs: who should pay for the additional delivery cost due to shipping to other parts of the world? There is no straightforward answer: it could be imputed to donating Member States, to the EU Budget (humanitarian aid), to ACT-A relying for instance on Covax budget or, alternatively, a discussion could be engaged with companies for them to contribute to the donation mechanism. In all cases, companies should be free to organise production and delivery. In some cases companies may wish to produce, fill & finish near the delivery hub through outsourcing or licencing with a local producer. Promoting local manufacturing and fill & finish should be encouraged.

[2] Following the model of H1N1 donations organised by WHO (recipient countries needed to sign a letter of agreement).

[3] Companies may also be reluctant to accept indemnification commitments by countries with low financial rating. A financial guarantee or backstopping could then complement the liability and indemnification commitments by recipient countries. Indemnification requires further reflection and discussion with companies.

3. How this would work in practice for our contracts

First of all, all our contracts contain donation clauses. As it is already the case in signed contracts, all new Advanced Purchase Agreements (APAs) should include the principle of the donations and organise the transfer of responsibilities. New contracts should of course include the principle of donations and already foresee technical mechanisms to ease the process, such as the principle of an order form directly placed between the recipient and the company from the Member State to the beneficiary (country/international organisation/NGO).

3.1. Sharing the volume of the donations

Contracts for which the allocation has yet to be decided (Sanofi-GSK, Moderna and new contracts). This concerns contracts for which the allocation has not been decided yet; as a contract with no obligation to buy, the Sanofi-GSK contract also falls in that category. As the sharing of the doses among Member States has not been decided, the doses to be donated could constitute **a separate "allocation pot"**, as a 28th country, to which a certain percentage of the total volume would be assigned (5 % for instance). Then, at the time of the Bazaar, countries will share the 95 % remaining doses, while covering their share of the cost for 100 % of the doses.

Contracts for which the allocation has been decided or is soon finalised (Janssen, CureVac). In both cases, a Bazaar has been circulated and Governments have in most cases already given their position on a given number of doses they are interested in purchasing. To gather the 5 % of doses to donate, it would be necessary to have Governments approve a **new table where 5 % would have been deducted** from all national allocations.

Contracts for which orders have been confirmed (AstraZeneca, BioNTech). For these two contracts, the order form has already been signed and sent to the company. In each Member State, a budgetary line (from the Health budget in general) has most likely been assigned to this purpose. Implementing an automatic 5 % rule would be technically more complex. For these two cases, several solutions could be envisaged:

- the donations mechanism would most likely have to rely on **voluntary contributions** by individual Member States on the quantities they have already ordered – where the global goal of reaching 5 % of the total could remain as an objective, and donations would remain « Team Europe »;
- the central objective here being to **release volumes** in order to allow for other countries to access the vaccine, a simple agreement twisting the delivery calendar (with fewer doses in Q1 and more, later in 2021) could improve access of the priority groups through Covax;
- as an alternative (which could work for any contract), the Commission could activate the options included in our contracts to order **new volumes** for donations, to be financed through ODA funds, either from EU budget, COVAX or Member States contributions, without any guarantee though on the timing of these deliveries.

3.2. Sharing the cost of the donations

The ESI contributes to the purchase of vaccines for EU Member States with upfront payments covering between 10-40% of the full price. **Conditional on an agreement by all 27 EU Member States to donate a share of their own vaccines, a non-recovery decision by the European Commission could be made on the ESI-funded part of the price of the dose**.

Member States financial contribution to the donations mechanisms would then be limited to the delivery price under the APAs. To finance the donation mechanism, Member States could contribute to a **common trust fund in proportion to their GNI[4].**

[4] With possible co-funding from the Union Civil Protection Mechanism.