



Federal Ministry
of Health

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Dear colleague,

I may contact you in your new role as acting Director General of HERA and look forward to a close and fruitful cooperation between EU Commission and Member States. In this sense we always agreed that ultimately, only global action against the pandemic can contain it. The international need for vaccines continues to be huge and it is essential to support countries that do not have sufficient vaccines to supply them in particular with vaccines with mRNA technology.

At the G 20 meeting on September 5, 2021, Germany announced to deliver 100 million doses of vaccine, thus supporting EU Commission's Team Europe approach. Swift implementation is key. Taking into account the donation agreements made available or announced by the EU Commission and pharmaceutical manufacturers, Germany intends to dispense vaccines mostly via COVAX, as we strongly support the multilateral COVAX mechanism to ensure fair and efficient worldwide distribution of vaccines.

Due to current delivery announcements by AstraZeneca and Johnson & Johnson, it seems likely that Germany will not be able to donate more than 50 million doses of vector-based vaccines before the end of 2021. We therefore rely on the possibility to give away mRNA vaccines from BioNTech/Pfizer and Moderna. We are prepared to donate about 10 million BioNTech doses in November 2021. Taking into account our ongoing national vaccination campaign it is obvious that a large portion of our donation volume with up to 40 million doses will have to be provided by Moderna.

However, in our endeavors to ensure that our donations to third countries as well as to COVAX are implemented quickly and efficiently, we are faced with ongoing bureaucratic, logistical and legal problems. Manufacturers tend to dictate conditions to Member States and recipient countries that make a quick response to international requests for help almost impossible. In addition, the fluctuations in the delivery quantities and the shelf life of the vaccines thwart reliable planning.

The terms and conditions of the purchase agreements negotiated by the EU Commission for donations and resale may turn out to be a substantial obstacle to a fair and needs-based worldwide redistribution of the vaccines. Manufacturers seem to take advantage of the Member States' contractual obligation to obtain their prior written consent to hamper vaccine transfers they deem potentially prejudicial to their commercial interests.

For example, I think it is unacceptable that manufacturers dictate minimum sales prices, impose exaggerated compensation schemes on recipients, reject swap procedures or prohibit distribution to International Organizations. With vaccine surpluses in many Member States increasing at present, we will soon be facing a situation of global allocation emergency, where some countries could be forced to waste large volumes of valuable vaccines urgently needed in other parts of the world.

Such an allocation emergency would be totally unacceptable and has to be avoided by any means. Since all donating Member States in the European Union are concerned in a similar manner we call upon the EU Commission to coordinate the further process and increase the pressure on the manufacturers to show more flexibility regarding donations and resale, including where necessary to attempt to renegotiate the terms of the purchase agreements that have proven too restrictive.

I may copy Alenka Forte for the Slovenian EU Presidency and Sandra Gallina for DG Health in and I stand ready for a high level video conference with you and colleagues at your earliest convenience. It is in the common interest of us all that no single dose is wasted.

Yours sincerely

A handwritten signature in blue ink, appearing to be 'L. Forte', is written below the text.