Mr. V. Dombrovskis, Executive Vice-President and Commissioner for Trade
Mrs. S. Kyriakides, Commissioner for Health and Food Safety
Mr. T. Breton, Commissioner for the Internal Market

Brussels, 12 February 2021

Dear Executive Vice President, Dear Commissioners,

We are writing to you on behalf of Business Europe, EFPIA, and Medicines for Europe to express our serious concern regarding Implementing Regulation 2021/111 announced on 29 January that has made the exportation of vaccines and certain ingredients thereof subject to an export authorisation. While we recognise the importance of transparency regarding vaccine production and supply in relation to the Advanced Purchase Agreement contracts, we believe this proposal is disproportionate and possibly counter-productive.

The proposed mechanism, which does not allow for automaticity in clearance of exports, goes well beyond the transmission of factual information on production and supplies, and legally enables Member States to restrict exports without clear cause. This could delay and undermine the supply of vaccines as well as medicines in Europe and around the world, and undermines the EU's clear policy objective to cooperate with international partners e.g. under COVAX and other initiatives. We fail to understand why such a broad and disruptive measure, affecting all COVID-19 vaccine production in the EU, is deemed necessary.

In line with the joint-association letter of 10 April 2020, we believe that globally integrated supply chains are vital to ensure quality, safety, innovation and distribution of medical and protective equipment and all medicines including in this case vaccines.[1] Imposing restrictions on exports poses the following important concerns:

- The export authorisation system runs counter to the EU's 8 April 2020 Communication and long-standing position of defending strong and resilient global supply chains and open trade[2]. It also risks undermining the EU's leadership at the WTO where it leads on the 'Trade in Healthcare Products' initiative, as well as at the WHO where it has made multiple commitments to partner for global vaccination. These initiatives look inconsistent with the measures taken last week.
- Notwithstanding the Commission's assessment that the measure is WTO compliant, should trade partners retaliate, there is a clear risk of a negative impact on the ability to produce vaccines or indeed other medicinal products given that imports of vital ingredients or components of vaccines that are sourced from outside the EU (e.g. viral vectors or lipids) could be delayed or stopped. Moreover, trade partners may also retaliate beyond COVID-19 related medicines and vaccines, broadening any impact of the measure to other industries and sectors. These reactions may not become apparent until a first negative export authorisation decision is taken. Also, trade partners that have adapted or think of adapting restrictive approaches to exports of COVID-19 vaccines and treatments, are now given a good argument why they should or could do this.

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1 https://www.efpia.eu/news-events/the-efpia-view/statements-press-releases/european-industry-trade-and-supply-chain-needs-to-respond-to-covid-19/ [accessed 30 January 2021]

2 https://ec.europa.eu/info/sites/info/files/communication-commission-guidelines-optimal-rational-supply-medicines-avoid.pdf [accessed 30 January 2021]

- Given the speed at which vaccine producers have built their global supply chains to ramp up vaccine production, it is vital to make sure all newly adopted policies are aimed at strengthening these global supply lines. This export authorisation scheme forces adjustments and adds red tape in the preparation for exports which could lead to additional delays and/or temporary reductions in supply capacities, aggravating the very situation the measure tries to solve.
- Since its effective implementation, it is now becoming apparent that the authorisation scheme not only applies to final COVID-19 vaccines, but that, for example, clinical trial materials and samples are in scope and require an export authorisation as well. Inclusion of these non-commercial products complicates and delays sharing of information, materials and knowledge to do global testing – for example on vaccine efficacy against new strains that are emerging.
- Finally, we believe that this measure sends a negative, long-term, signal about investment and manufacturing in Europe to global industries who want to manufacture final products in the region to meet global demand. This directly contravenes one of the flagship objectives of the pharmaceutical strategy: to increase Europe's attractiveness as a manufacturing base to increase EU resilience.

Earlier this year, Sanofi indicated it will start to produce 100 million doses of the Pfizer/BioNTech vaccine in 2021, while Novartis announced that the company has signed an initial agreement to support production of Pfizer/BioNTech vaccines. More recently Pfizer indicated to produce another 75 million doses for the EU in Q2 2021, and GSK indicated that they would support the manufacturing efforts by producing of up to 100 million doses of CureVac's first generation COVID-19 vaccine candidate in 2021. Also, Bayer is planning to manufacture an additional 160 million doses of CureVac's vaccine in 2022 to further expand their supply network and overall capacity and supply using Bayer's manufacturing network. These announcements, combined with cooperation and voluntary licensing agreements to increase contract manufacturing and to remove potential regulatory hurdles, are the best tried and tested solutions to ramp up production and supply of vaccines for EU Member States and their citizens as well as to support the EU's commitments to help other countries.

Because we understand the pressure to rapidly vaccinate the EU population, and want to do all we can to support that objective, we ask for the EU to support the industry in its unparalleled efforts to increase manufacturing capacity of COVID-19 vaccines. There are various ways in which this would be possible. Firstly, by ensuring open trade and global supply chains that are free to operate to maximise production of vaccines and flow of vaccines to patients. Secondly, we ask the EU to consider the removal of the export authorisation scheme as soon as possible, or – alternatively – discuss measures that could in practice reduce the negative effects by streamlining practical implementation of the scheme, while increasing transparency of production and exports of vaccines.

We believe that a constructive dialogue between the key actors is needed to achieve our joint goals. The COVID-19 fight is one only a united front can win.

Yours sincerely,

Business Europe

EFPIA

Medicines for Europe