

**COMMISSION IMPLEMENTING REGULATION (EU) 2021/2071****of 25 November 2021****subjecting certain vaccines and active substances used for the manufacture of such vaccines to export surveillance**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2015/479 of the European Parliament and of the Council of 11 March 2015 on common rules for exports <sup>(1)</sup>, and in particular Article 4 thereof,

Whereas:

- (1) On 30 January 2021, the Commission adopted Implementing Regulation (EU) 2021/111 <sup>(2)</sup> making the exportation of COVID-19 vaccines as well as active substances, including master and working cell banks, used to manufacture these vaccines, subject to the production of an export authorisation, pursuant to Article 5 of Regulation (EU) 2015/479, for a period of six weeks. Hereafter, on 12 March 2021, the Commission adopted Implementing Regulation (EU) 2021/442 <sup>(3)</sup> making the exportation of the same products subject to an export authorisation until 30 June 2021, pursuant to Article 6 of Regulation (EU) 2015/479.
- (2) On 24 March 2021, the Commission adopted Implementing Regulation (EU) 2021/521 <sup>(4)</sup> introducing as an additional factor when considering granting an export authorisation, the need to assess whether such authorisation does not pose a threat to the security of supply within the Union of the goods covered by Regulation (EU) 2021/442. By the same Regulation, the Commission decided on a temporary suspension of the exemption of certain destination countries from the scope of Regulation (EU) 2021/442.
- (3) Commission Implementing Regulation (EU) 2021/521 was adopted pursuant to Article 5 of Regulation (EU) 2015/479 and applied for a period of six weeks. The measures introduced by that Regulation were subsequently extended until 30 June 2021 by Commission Implementing Regulation (EU) 2021/734 <sup>(5)</sup>.
- (4) Both Regulation (EU) 2021/442 and Regulation (EU) 2021/521 were further extended, first until 30 September 2021 by Commission Implementing Regulation (EU) 2021/1071 <sup>(6)</sup>, and then until 31 December 2021 by Commission Implementing Regulation (EU) 2021/1728 <sup>(7)</sup>.
- (5) The production and deliveries of COVID-19 vaccine doses in the Union have been accelerated and the risk that exports would threaten the execution of the Advance Purchase Agreements between the Union and the vaccine manufacturers or the security of Union supplies of COVID-19 vaccines and their active substances have currently reduced.
- (6) Under the current circumstances and situation of supply, the Commission considered the application of the requirement to produce an export authorisation for the exports of vaccines against SARS-related coronaviruses (SARS-CoV species) and active substances, including master and working cell banks used for the manufacture of such vaccines, after 31 December 2021, not required.

---

<sup>(1)</sup> OJ L 83, 27.3.2015, p. 34.

<sup>(2)</sup> OJ L 31 I, 30.1.2021, p. 1.

<sup>(3)</sup> OJ L 85, 12.3.2021, p. 190.

<sup>(4)</sup> OJ L 104, 25.3.2021, p. 52.

<sup>(5)</sup> OJ L 158, 6.5.2021, p. 13.

<sup>(6)</sup> OJ L 230, 30.6.2021, p. 28.

<sup>(7)</sup> OJ L 345, 30.9.2021, p. 34.

- (7) However, it remains necessary to subject to surveillance using the procedure based on Article 56(5) of Regulation (EU) No 952/2013 of the European Parliament and of the Council <sup>(8)</sup>, and to require that the export or re-export declaration includes the TARIC additional codes, provided in the Annex, as well as the numbers of doses (in case of multi-dose containers, dose for adults) for a period of 24 months as from 1 January 2022.
- (8) This surveillance should allow the Commission to collect supplementary statistical export data at the level of each manufacturer with a view to detecting in a timely manner (i) any indication of lack of compliance with the Advance Purchase Agreement concluded by the Commission (ii) any other circumstance that could threaten the Union's security of supply, and (iii) the Union's capacity to pledge, and deliver, further donations. This should enable the Commission, where warranted, to take further action in order to prevent a critical situation from arising on account of a shortage of these products in accordance with the requirements of Regulation (EU) 2015/479,

HAS ADOPTED THIS REGULATION:

#### *Article 1*

1. The following goods shall be subject to export surveillance for a period of 24 months from the date of entry into force of this Regulation:

- (a) vaccines against SARS-related coronaviruses (SARS-CoV species) currently falling under CN code 3002 20 10, irrespective of their packaging;
- (b) active substances, including master and working cell banks used for the manufacture of such vaccines, currently falling under CN codes ex 2933 99 80, ex 2934 99 90, ex 3002 90 90 and ex 3504 00 90.

2. For the purposes of this Regulation, 'export' means:

- (a) an export of Union goods under the export procedure within the meaning of Article 269(1) of Regulation (EU) No 952/2013;
- (b) a re-export of non-Union goods within the meaning of Article 270(1) of that Regulation after such goods have been subject to manufacturing operations including filling and packaging within the customs territory of the Union.

#### *Article 2*

The export or re-export declaration of the goods mentioned in Article 1 shall, during the time referred to therein, include the TARIC additional codes mentioned in the Annex, or any corresponding future codes, and shall indicate the number of doses (in case of multi-dose containers, the number of doses for adults).

#### *Article 3*

The Commission shall make the information on the exports publicly available, due account being taken of the confidentiality of the data.

#### *Article 4*

This Regulation shall enter into force on 1 January 2022.

<sup>(8)</sup> Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 November 2021.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

---

## ANNEX

## TARIC ADDITIONAL CODES

| Manufacturer                                     | Taric additional code for vaccines against SARS-related coronaviruses (SARS-CoV species) | Taric additional code for active substances (*) |
|--|--|---|
| AstraZeneca AB                                   | 4500   | 4520  |
| Pfizer / BioNTech                                | 4501   | 4521  |
| Moderna Switzerland / Moderna Inc                | 4502   | 4522  |
| Janssen Pharmaceutica NV                         | 4503   | 4523  |
| CureVac AG                                       | 4504   | 4524  |
| Sanofi Pasteur / GlaxoSmithKline Biologicals S.A | 4505   | 4525  |
| Novavax  | 4506   | 4526  |
| Valneva  | 4507   | 4527  |
| Gedeon Richter                                   | 4508   | 4528  |
| Arcturus   | 4509   | 4529  |
| PCI Pharma                                       | 4510   | 4530  |
| Other manufacturers                              | 4999   | 4999  |

(\*) active substances including master and working cell banks used for the manufacture of vaccines against SARS-related coronaviruses (SARS-CoV species).

| Company           | TARIC additional code for other substances (*) |
|-------------------|--|
| All manufacturers | 4599   |

(\*) 'Other substances' are products or substances that are not going to be used to manufacture vaccines against SARS-related coronaviruses (SARS-CoV species), but that are classified under the same CN codes as the active substances.