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From: [REDACTED]
Sent: Tue 3/2/2021 8:13:08 PM
Subject: NL questions and comments concerning the draft implementing regulation export authorisation COVID19 vaccines
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Dear Commission,

I herewith send you questions and comments concerning the draft Implementing Regulation making the exportation of certain products subject to the production of an export authorisation.

As noted in the Netherlands' declaration to the vote on the emergency implementing regulation regarding the export authorization regime, the Netherlands stresses the importance of the measures being temporary, targeted, proportional and transparent.

In this regard, the NL has the following questions on the regulation as such:

- 1) What are the experiences and benefits of this authorisation mechanism? Has it contributed to more supplies of vaccine?
- 2) Can the Commission list all the reasons (based on figures of supply / import/export) why she deems the extension necessary?
- 3) Is the Commission willing to conduct a survey / evaluation halfway through the extension period (by the end of April) so as to be able to assess the effectiveness of the measure?
- 4) What are the objective criteria on the basis of which an authorization request could be refused?
- 5) The regulation has been announced as primarily a transparency instrument. Is information on the requested export authorizations and decisions publicly available – as announced in the current regulation as well as in the present proposal? If not, when can we expect this?
- 6) Has there been any contact between the Commission and the US on the current measure as well as the proposed extension, and can the Commission elaborate on this contact when this is the case?

Furthermore, the Netherlands has a number of questions/concerns relating to the technical aspects, in particular the changes introduced compared to the previous regulation

The Dutch Healthcare and Youth Inspectorate (IGJ), as Netherlands export authorization authority under the regulation, observes that export of vaccines, and constituents thereof, is unnecessarily delayed due to the short allowed handling time and the amount of specific information, beyond the current wording of the regulation, as requested by the EC. Especially export of small amounts of vaccine or constituents thereof e.g., samples, required for the development of a global supply chain, is delayed.

1. **Relating to the widening of the scope.** Article 1, section 2, sub a, suggests a significant widening of the scope. The section suggests that all constituents of the COVID-19 vaccine manufacturing process imported into the Union and exported from the Union will require an export permit even when the products are not intended or will be registered for the Union. This would imply that e.g., a Dutch importer of a Russian drug substance would require an export permit when the product is exported to the USA. Even when the importer will not change anything to the imported product. By the current system of licenses (MIA and WDA) and API-registrations and EU pharmaceutical laws, this would place a huge administrative burden on both the IGJ and the applicable license holders.
2. **The EC is requested to conform the scope of the regulation with reference to registration dossiers and more specifically to the status of the starting materials for drug substance such as inoculum, mother virus seed (bank) and working seed (bank).** Inoculum, mother virus seed (bank) and working seed (bank) are not defined in the Regulation. The EC is requested to confirm the inclusion and exclusion criteria with regards to inoculum, mother virus seed (bank) and working seed (bank).
3. **Could the EC clarify and define the meaning of "any other relevant circumstances" in article 1, section 7.** In order to weigh a request the IGJ requires a definition and criteria in the Regulation.
4. **TARIC codes; The IGJ requests the EC to confirm that the TARIC system is fully operational with regards to the execution of products under the aforementioned TARIC codes at time of initiation of the Regulation. The IGJ wishes that the Regulation is adapted to prevent undesired delays in export of products that do not fall under the scope of the regulation.** The IGJ request the EC to confirm how it envisions the regular export of nucleic acids and their salts, whether or not chemically defined; heterocyclic compounds en Heterocyclic compounds with nitrogen hetero-atom[s] only under the mentioned TARIC codes whereby the IGJ stresses that more products than SARS-2 COVID vaccines and its constituents are covered under the TARIC codes which are not part of the Regulation. The IGJ hereby reiterates that nucleic acids and their salts could be part of the currently applied polymerase chain reactions analysis, better known as the PCR test to confirm

a.o., COVID-19 infections.

5. **In light of the EU system of MIA licenses and the GMP requirement, the IGJ is of the opinion that samples, especially samples for National Control Laboratories, should be excluded from the regulation.** In the EU, the MIA has to comply to the GMP (Eudralex Volume 4). In case a MIA holder defines a product as a sample, application for further human use is no longer possible. Samples are not only defined in registration dossiers, but the application of samples is defined in the GMP. In other words, samples cannot be applied as human end product. In this case other existing laws and supervision on companies by national authorities do prevent the use of samples in ways that are not allowed. There is no regulation required to prevent this.
6. **The IGJ proposes to exclude all export of MCB, WCB including samples up to 10 ml, from export authorization as defined under the regulation.** Article 1, section 5 defines the calculation of corresponding vaccine doses. The calculation of corresponding vaccine doses from starting materials or drug substance may be possible by use of theoretical or actual yields of the manufacturing process steps. If the inoculum, mother cell bank or working cell bank or virus seed are used to calculate the corresponding number of vaccine doses there may be an undesirable outcome. In case of optimal use of any of the aforementioned components an indefinite number of vaccine doses may be generated. This may cause some confusion and stress at the national authorities and EC once stated by companies.

Kind regards,

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