

**MEETING WITH EU COMM. KYRIAKIDES MEETING**  
**out of scope AND BUSINESS**  
**EUROPE**

**5 March 2021 – 12:00**


**Online**

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# **1. Main messages**

## **1. Export authorisation scheme**

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- Underline that the export authorisation system is necessary for transparency purposes and will not delay the distribution of vaccines.
  - Europe has invested massive amounts of public money and needs to have transparency on how its investments are protected.
  - We have not banned any exports – apart from one case you will be aware of, where we followed the opinion of the national authorities. This concerned one particular company with which we have particular challenges on the performance of our agreement.
  - So far there have been no other issues and the EU is supplying 80% of vaccine supply all over the globe. The system works and permits are issued in a number of hours, including on weekends.
  - What is essential is now for industry to ensure that the production capacity is in place and can guarantee delivery of vaccines to EU citizens according to our agreements.

## **2. Efforts to ramp up production capacity on variant vaccines/Hera incubator**

- The HERA Incubator is an unprecedented initiative to address a real and urgent threat - variants.
- We want to work hand in hand with industry, Member States, scientists to ensure we have guaranteed access to variant vaccines. We are ready to mobilise all instruments – scientific, regulatory and funding to ensure this project comes to fruition.
- We look forward to our closest possible collaboration in this endeavour.

## **3. Security of supply**

- We launched the structural dialogue on shortages of critical medicines. We count on your active participation and concrete contributions to diagnose and resolve the issues over the coming year.

#### **4. Latest development in the implementation of the Protocol on Ireland and Northern Ireland concerning the location of the Marketing Authorisation Holder**

- Call on industry to implement the necessary regulatory changes to avoid shortages of medicines in small markets such as Northern Ireland and Malta.
- Stress that our regulatory framework is stable and requirements are well-known. Preparedness should have been done by all industry players and now it is imperative that necessary adjustments are made.

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# 1. Export authorisation scheme

## Lines to take

- Recall that the EU has provided significant financial support for the rapid development and production of several vaccines. Express serious concern that until now one particular vaccine manufacturer is not in a position to supply the quantities of vaccines destined to the Union and explain that vaccines produced in the Union are exported, particularly to non-vulnerable countries.
- Explain that the system of export authorisation has been put into place to increase transparency and will not delay the shipments for the companies who deliver vaccines to the Union. [REDACTED] the significant amount of vaccines exported to third countries since the entry into force of the measure.
- Reassure that the system operates in a smooth manner and is temporary. We have received more than one hundred requests for export authorisations and they have been granted according to the timeline [REDACTED]  
[REDACTED] Inform that we have provided transparency to our trading partners concerning this measure.
- **(If raised)** Confirm that the samples and clinical trials are covered by the scope of the export authorisation. Unfortunately, experience shows that most of the export authorisations represent significant amounts of doses and it is not possible for the competent authorities in charge of customs or health, as well as the Commission, to check if the vials are sent for analytical testing, clinical trials or commercial use. Very few requests correspond to the amount necessary for analytical testing and clinical trials.

## State of play/background information

The EU has provided very significant financial support for the rapid development and production of several vaccines against COVID-19 amounting to a total of €2.7 billion.

In January it became clear that some vaccine manufacturers are not able to supply the quantities of vaccines destined to the Union. Therefore, from 30 January onwards, vaccine manufacturers with whom the EU has advance purchase agreements must seek an export authorisation to export vaccines. They must in parallel supply relevant data (EU and export sales) to the Member States and the Commission to ensure sufficient transparency on their exports to third countries.

The EU's export authorisation scheme is proportionate, transparent and temporary.

92 vulnerable countries, which do not have sufficient financial resources are exempted from the system. The authorisation is also not required for exports of goods through COVAX. So far, the Commission has been consulted on 190 requests [REDACTED]  
[REDACTED] and all except one have been granted.

In case of shortages or delays in the production of vaccines, the Commission will endeavour to ensure that exports are authorised in an equitable manner. It is precisely the monitoring mechanism that will allow to determine whether the export request

respects this principle, i.e. that production delays are shared in an equitable way between the Union and export destinations. Export authorisations should be granted whenever this principle is respected. This assessment will therefore be made on a case-by-case basis, and taking into account the specificities of each Advance Purchase Agreement.

Industry considers that samples for analytical testing and material for clinical trials should be exempted. They are covered by the Regulation to ensure transparency and avoid applicants to circumvent the rules by sending small shipments to third countries.

## 2. Security of supply, global supply chains, HERA incubator

- The HERA Incubator is an unprecedented initiative to address a real and urgent threat - variants.
- We want to work hand in hand with industry, Member States, scientists to ensure we have guaranteed access to variant vaccines. We are ready to mobilise all instruments – scientific, regulatory and funding to ensure this project comes to fruition.
- We look forward to our closest possible collaboration in this endeavour.

### Security of supplies

- Recall that the Commission launched on 26 February the Structured Dialogue that will focus on security of supply of critical medicines. The purpose of the initiative is to identify the EU vulnerabilities as regards the supply of medicines in order to propose concrete actions. The Commission counts on industry's active participation and concrete contributions to diagnosing and resolving the issues causing shortages of medicines.
- Clarify that the Structured Dialogue is complementary with other Commission initiatives targeting more specifically vaccines and the EU response to the pandemic.
- Encourage participation of associations and companies in the initiative.

### State of play/background information:

The Structured Dialogue is one of the flagships of the Pharmaceutical Strategy. Its purpose is to strengthen the resilience of pharmaceutical supply chains and ensure the security of supply of medicines, without compromising their affordability. It will do so by bringing together and facilitating discussions with and between the actors of the pharmaceuticals manufacturing value chain, public authorities, research community, health professionals and patient organisations.

The Structured Dialogue is a **two-phase process** steered by the Commission.

The main objective of phase 1 is to close the knowledge gaps, by gaining a better understanding of the functioning of global pharmaceutical supply chains and identifying the precise causes and drivers of different potential vulnerabilities. Building on the evidence gathered in phase 1, phase 2 will lead to concrete measures that will address the identified issues.

The Structured Dialogue aims to deliver results by the end of 2021 and will cover all major steps of manufacturing of medicines in the EU and globally. Any potential measure will also comply with EU competition and World Trade Organization (WTO) rules.

out of scope



### 3. Implementation of the Ireland/Northern Ireland Protocol for medicines

- Recall that from January 2021 the EU-UK Withdrawal Agreement and the Ireland/Norther Ireland Protocol applies. This means for medicines that EU pharmaceutical legislation applies in Northern Ireland.
- The necessary BREXIT guidance was provided to stakeholders and Members States.
- We are aware of the potential concern on supplies in Northern Ireland, Ireland, Malta and possibly Cyprus, for which we allowed conditional derogations until December 2021.
- Citizens and patients in the smaller markets deserve the same level of access to medicines as the bigger markets of the European Union. Industry has an essential role in delivering medicines to those markets. After **many years** of BREXIT preparedness, it is essential that industry makes the necessary regulatory changes to solve the outstanding issues as soon as possible.

#### State of play/background information

Overall, Brexit preparedness as regards medicines was achieved. There are some outstanding issues around industry regulatory changes, in particular as regards smaller Member States that have historically been dependent on the Great Britain (Ireland, Cyprus, Malta) and for Northern Ireland. To address these, the Commission adopted a Brexit Notice to waive the obligation of manufacturing authorisation, batch testing and requirements under the falsified medicines Directive until the end of 2021.

With the recent letter of February 2021, industry representatives are further requesting derogations under the IE/NI Protocol as regards the establishment requirements to maintain their operations in GB. UK as well in separate discussions with the Commission also requests the same. The UK has also informed the Commission that there are challenges in addressing the outstanding issues, in particular for the Northern Ireland market. This has prompted the UK to ask the Commission to extend the deadline for the derogations of the notice until 2023, as well as to grant derogations under the IE/NI Protocol as regards the establishment requirements. As discussed with the Commission, such derogations are not possible.

As of January 2021, stakeholders and Member States should be ready to implement the IE/NI Protocol that is part of the Withdrawal Agreement. From that date, the EU pharmaceuticals acquis applies to and in the UK with respect to Northern Ireland. The Commission Notice on Brexit readiness of March 2020 provided guidance on what this means for the pharmaceuticals sector. Further practical guidance on implementing the IE/NI Protocol was given by the EMA.

While the situation for the centrally authorised products is under control and further monitored by the EMA, the situation for nationally authorised products, where there are some outstanding challenges, is more complex. These affect certain Member States (Ireland, Cyprus, Malta) and Northern Ireland, because of their smaller market size and

interlinked markets with the UK. It is essential that industry implements the necessary regulatory changes to avoid any market disruption for medicines across the EU, and especially in the Member States affected.

From the discussions with the UK and Malta, making the required changes for small markets is not an attractive proposition for companies, due to the further investments needed. The companies would like to maintain one marketing authorization in the UK for all English packs including Malta and NI and a European marketing authorization for the rest of the Union.

As regards a long-term solution, the pharmaceutical strategy should investigate and prepare solutions to the problem of access to medicines across the EU.

## **Defensives**

### **Why do we include samples in the scope of the export authorisation ?**

At customs, it is not possible to make a distinction between samples for analytical tests, clinical trials or commercial use. Moreover, very few requests received so far correspond to small amounts necessary for analytical tests. Therefore, the Commission is not considering an exemption but a solution allowing to group the authorisations per destination to alleviate the burden on industry.

Ultimately, we would like to avoid that applicants circumvent the rules by sending small shipments to third countries. We do not intend to block the export but to acquire more transparency of the volume of doses exported to third countries.

## **Question #2**

### **Don't you think that the export authorisation delays the conduct of clinical trials?**

So far, the Commission has examined more than 100 requests and expressed an opinion in one working day. We are also confident that national authorities are taking all necessary measures to respect the total deadline of three days. We had a few incidents that took more time when companies didn't submit all required information. Companies are sometimes reluctant to communicate the quantity exported expressed in volume of doses.

[Redacted]

### 3. Annexes

I [Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

I [Redacted]

[Redacted]

[Redacted]

[Redacted]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]