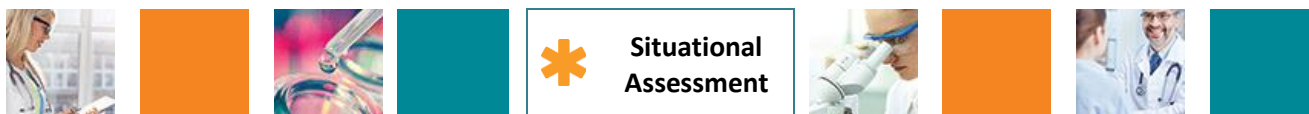


19 February 2021 – Final



## Impact of the COVID-19 outbreak on the supply of medicines in the Union/EEA

Additions to the 12 February 2021 report are written in red for ease of reference.

EFPIA and Vaccines Europe members currently report one shortage episode in the European Union (see below), due to an increase in demand.

The threats on the continuity of supply outlined in previous reports are being confirmed and keep putting the future continuity of supply of further products at risk. EFPIA and Vaccines Europe particularly highlight the concern over the provision of disposable materials, ingredients and raw materials required for the production of biotechnological products (including vaccines). If not remedied it may put at risk the manufacturing of biological products for a variety of health conditions, including life threatening ones (e.g. cancer) and vaccines in the medium term. We fear the situation will worsen with the scaling up of C-19 vaccines production. See details in this report.

### Increase of demand

Generally companies report an increase of demand for some products.

- There is currently a shortage of Valium (diazepam) in France, as a result of an increase in demand following stockouts of other suppliers. The company is exploring options to increase supply and cover the demand.
- For Enoxaparin, a company flagged the demand is 20% higher than ordinary levels, causing tension on the supply side. They do not anticipate shortages for the time being.

### Issues affecting supply

Without facing shortages for the time being, companies reported the following challenges:

- For Depo-Provera Vials, due to the prioritization of COVID-19 Vaccine production, one manufacturer site ceased production as of 01-Feb-2021. The impact is a projected shortage of 1ml and 3ml & 3.3ml vials presentations, spread across all regions. Further MAH actions regarding revised product allocations have largely mitigated any potential shortage of Depo-Provera Vials impacting EU markets. The potential impact across other regions later in 2021 is still under assessment. The Depo-Provera



syringe presentations are not impacted by this event. Notification to affected EU Member States will occur as required (the product is nationally registered).

- Supply tensions on the provision of materials and key components required for the production of biological products are more widely reported, and with a greater level of concern for the medium-term. Companies experience supply tensions with the following categories of products, used in the manufacturing of biological products: Filters (NFR Virus, XOSP, etc.), Single Use Technology Bags (Mobius bags), Peptone, TRIS HCL, Glass vials. We understand these difficulties result from an increase of demand triggered by the production of COVID19 vaccines. Manufacturers have enacted their contingency plans and are working closely with their suppliers, which are doing significant capacity expansions to be able to supply the global demand. Latest reports indicate however that the delivery timelines are lengthening (up to one year now for some products), causing worry that buffer stocks may not suffice over the coming months. This scarcity may affect the manufacturing of biotechnological medicines and vaccines in a variety of therapeutic areas, including life-saving medicines (e.g. cancer) or vaccines. We are concerned this situation will worsen as C-19 vaccine production increases, creating potential supply shortages in the future.
- We also observe supply tension on the provision of nitril single use gloves. We do not see any market impact for the time being considering the buffer stocks available.
- Transportation capacity remains limited, with the Global air cargo capacity down by 18% and a shortage of sea freight equipment limiting global sea freight capacity. Companies report a 2-3 weeks delay on-board some of the sea cargo, **as well as reduced reliability affecting their capacity.**



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