Applicant: Baxter AG, Industriestrasse 67, 1220 Vienna, Austria

Submission number: KA600552-65

ECHA contact: OTTATI Maria

1. Summary

The applicants Baxter AG and Baxalta Belgium Manufacturing SA request ECHA consider the inclusion of the R&D product *CoVIg-19 hyperimmune*, developed in response to the COVID-19 pandemic, in the ongoing assessment of its application for an Authorisation for Continued use of 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated (as a detergent) for virus inactivation via S/D (Solvent/Detergent) treatment in plasma-derived and recombinant medicinal products, reference number KA600552-65.

2. Background

In response to the global COVID-19 pandemic, the company has entered an Alliance to address the medical need for a treatment. Initiated in early 2020, an existing small-scale R&D platform sited in the Baxter AG facility at [redacted], 1220 Vienna, one of the facilities included in the Baxter AG manufacturing complex, was determined suitable for the development of a new potential treatment, *CoVIg-19 hyperimmune*, and is being used for product development and clinical trial material. 4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated (referred as OPnEO) is used in the solvent/detergent viral inactivation step of this development product under strict R&D guidelines (OPnEO amount < 1 tpa, controlled conditions). In keeping with the REACH guidelines, all waste from the R&D line is collected for off-site incineration, effectively achieving zero emissions to the environment.

Global Health Authorities have offered accelerated clinical trial and eventual product registration pathways for COVID-19 treatments. At the current rate of development, the company anticipates entering clinical trials in 2020 and the treatment to be available early 2021.

3. Commercial Production

3.1 Lessines

Consistent with the products listed in the Application for Authorisation, commercial production occurs in the EU for EU and global patient populations. To enable timely access to the new product, the applicant intends for commercial production to occur at Lessines using one of the production lines cited in the submitted Application for Authorisation referenced above.

Based on the same production method, including production line equipment, OPnEO handling and treatment, the production runs of *CoVIg-19 hyperimmune* would replace production runs of one of the medicines currently cited in the application. As a result, the production of *CoVIg-19 hyperimmune* at Lessines will not alter the annual use or the annual emissions of OPnEO as stated in the current application.

The applicant requests ECHA consider the product listing for Lessines is indicative of products manufactured at the site, and the inclusion of *CoVIg-19 hyperimmune* **as a new product in the site's production portfolio does not constitute a change requiring a review report considering the use is consistent with the current applied for use, that production is to occur on the same production lines and there is no increase in annual use or emissions of OPnEO.**

3.2 Vienna

In the course of developing *CoVIg-19 hyperimmune*, the company has engaged with global health authorities to determine registration requirements for the medicine and understand the appropriate product sourcing strategies required to effectively meet projected market demands. Whilst a reliable assessment of demand is not possible at this stage, sourcing commercial product from Vienna is a potential requirement. In the event output from production steps occurring outside the EU is barred from export, the company would need the ability to manufacture the product at different scales in the EU. The R&D line in Vienna therefore requires authorisation in order to effectively produce smaller quantities required to satisfy smaller markets.

Assuming the line is run at maximum capacity for *CoVIg-19 hyperimmune*, the additional annual volume of OPnEO required for Vienna is [redacted] kg; emissions from the line will remain zero, consistent with the current R&D waste management requirements.

The applicants request ECHA consider the addition of *CoVIg-19 hyperimmune* **to the site's production portfolio does not constitute a change requiring a review report considering the use is unaltered from the application, the additional increase of OPnEO for eventual commercial production is limited (< [redacted]% change to the annual total requested) and emissions from this additional volume are zero.**

4. Analysis of Alternates

For *CoVIg-19 hyperimmune* the same production method is used as for the other medicinal products described in the pending application and the same criteria for a possible alternative apply. Therefore, the current state of assessment of the alternates is unaltered from our last response to the query raised by the SEAC in Mar-2020.

5. Socio-Economic assessment

Considering the early stage of product development and the urgency with which the pharmaceutical industry is responding to the treatment demands caused by the COVID-19 pandemic, an assessment of a change to the socio-economic evaluation stated in the ongoing application is not possible. Determining the level of change is contingent on the product meeting its clinical trial endpoints, obtaining marketing authorization approval, the number of alternate treatments available at the time the approval is issued and the demand for *CoVIg-19 hyperimmune* at the time it becomes available to patients.

An impact is assumed; however, the scale of this impact cannot be predicted at this time.