

## Gumbohatch

### Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification <sup>1</sup> issued on	Commission Decision Issued / amended on	Product Information affected <sup>2</sup>	Summary <sup>3</sup>
II/0004	B.II.d.1.f - Change in the specification parameters and/or limits of the finished product - Deletion of a specification parameter which may have a significant effect on the overall quality of the finished product	20/01/2021	n/a		The Agency accepted the variation to waive the extraneous agents testing for the routine batch release of finished product.
IB/0003	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	11/09/2020	n/a		n/a
IB/0002	B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	04/09/2020	n/a		n/a
IB/0001	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	26/06/2020		SPC	The Agency accepted the variation to extend the shelf-life of the finished product from 21 months to 24 months.

<sup>1</sup> Notifications are issued for type I variations (unless part of a group including a type II variation or higher procedure or a worksharing application). Opinions are issued for all other procedures.

<sup>2</sup> SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

<sup>3</sup> Since October 2019 summary information is no longer published for variations that do not impact upon the product information