

Stelfonta

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification ¹ issued on	Commission Decision Issued / amended on	Product Information affected ²	Summary ³
IB/0002	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	30/04/2020		SPC, Annex II, Labelling and PL	The Agency accepted the variation to extend the shelf life of the finished product from 42 to 48 months.
IAIN/0001/G	This was an application for a group of variations. B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	24/02/2020	n/a		n/a

¹ 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.

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

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