

Ingelvac PCV FLEX

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification ¹ issued on	Commission Decision Issued ² / amended on	Product Information affected ³	Summary
IG/0855/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	24/11/2017		Annex II and PL	The Agency accepted the group of variations to delete two manufacturing sites and to add a new secondary packaging site. In addition, the product information was aligned with the latest QRD template and a minor editorial change was made in the SPC.
IG/0831	C.II.6.a - Changes to the labelling or the PL which are not connected with the SPC - Administrative information concerning the holder's representative	01/09/2017		PL	The Agency accepted the variation to delete the list of local representatives from the package leaflet.

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 A CD is issued for procedures that affect the terms of the marketing authorisation (e.g. SPC, Annex II, Labelling, PL). The CD is issued within 2 months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within 1 year for other procedures.

³ SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).