

Baycox Iron

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
IG/1213	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	31/03/2020		PL	The Agency accepted the group of variations to delete the list of local representatives from the package leaflet.
IA/0001	A.7 - Administrative change - Deletion of manufacturing sites	06/12/2019	n/a		

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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