

## Novaquin

### 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>
IG/1436	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	27/01/2022		PL	The Agency accepted the variation to delete all the local representatives from the package leaflet.
R/0005	Renewal of the marketing authorisation.	23/04/2020	24/06/2020	SPC, Labelling and PL	The European Commission renewed the marketing authorisation for Novaquin.
IG/1170	B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)	19/12/2019	n/a		n/a
IG/1168	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	12/11/2019	24/06/2020	PL	The Agency accepted the variation to update the list of local representatives in the package leaflet.
WS/1666	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.  C.II.7.b - Introduction of a new Pharmacovigilance system - Which has been assessed by the relevant national competent authority/EMA for another product	10/10/2019	n/a		The Agency accepted the variation to update the current detailed description of the pharmacovigilance system (DDPS).

<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

	of the same MAH				
IAIN/0001	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	22/01/2016	09/01/2017	Labelling and PL	The Agency accepted the variation to update the list of local representatives in the package leaflet.