

## Sedadex

### 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.	17/06/2021	18/08/2021	SPC, Annex II and Labelling	The European Commission renewed the marketing authorisation for Sedadex.
IAIN/0004	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	22/10/2020	18/08/2021	SPC, Labelling and PL	The Agency accepted the variation to change the local representatives for some of the Member States.
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 of the same MAH	10/10/2019	n/a		The Agency accepted the variation to update the current detailed description of the pharmacovigilance system (DDPS).
IAIN/0002	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	19/10/2017	18/12/2017	PL	The Agency accepted the variation to update the list of local representatives in the package leaflet.

<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

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	22/12/2016	18/12/2017	SPC, Annex II, Labelling and PL	The Agency accepted the variation to add the distributors and introduce minor linguistic amendments to the product information.
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