Sevohale

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]
R/0007	Renewal of the marketing authorisation.	17/02/2021	20/04/2021	SPC, Labelling and PL	The European Commission renewed the marketing authorisation for Sevohale.
II/0006/G	This was an application for a group of variations. B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.f.1.e - Stability of FP - Change to an approved stability protocol B.III.1.a.1 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer 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	05/11/2020	20/04/2021	PL	B.II.b.5.b - To add new in-process tests 'Visible Inspection of Bottles' and 'Vacuum Leakage Detection' during Packaging of the Finished Product. B.III.1.a.1 – To replace ASMF with CEP no. R0-CEP 2016-297-Rev 00 for the already approved manufacturer of sevoflurane active substance, Jiangsu Hengrui Medicine Co., Ltd. B.II.d.1.e – To widen the limits of 'water content' test procedure from 'NMT 0.013%' to 'NMT 0.05%'. B.II.f.1.e – To add the 'identification' test procedure to the long-term stability protocol. B.II.e.7.b – To add Shandong Pharmaceutical Glass Co., Ltd as an alternative supplier of glass bottles.

[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

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	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range				C.II.6.a - To update the list of local representatives in the Package Leaflet.
IAIN/0005	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	15/06/2018	04/10/2019	PL	The Agency accepted a variation to update details of the local representatives
IB/0003	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	28/03/2018	25/05/2018	SPC, Annex II, Labelling and PL	The European Commission amended the Decision granting the marketing authorisation to add a new non-food producing target species (cats), in line with the reference product SevoFlo. The applicant also took the opportunity to update the list of local representatives.
IA/0004/G	This was an application for a group of variations. B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits B.II.e.2.a - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	28/03/2018	n/a		The Agency accepted the group of variations to introduce changes in the manufacturing process and changes to the packaging.
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	15/12/2017	25/05/2018	PL	The Agency accepted the variation to update the list of local representatives in the package leaflet. The product information was simultaneously aligned with the latest QRD template.
IAIN/0001	A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	29/07/2016	21/09/2017	SPC, Labelling and PL	The European Medicines Agency accepted the variation to change the invented name of the product from Sevocalm to Sevohale.