Pexion

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
II/0011/G	This was an application for a group of variations. B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	25/05/2018	05/07/2018	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new therapeutic indication - 'For the reduction of anxiety and fear associated with noise phobia in dogs'. The grouped variation was also to add a new pack-size of 30 tablets for Pexion 100 mg tablets and for Pexion 400 mg tablets and to additionally introduce changes in the specification parameters of the immediate packaging. In the framework of this variation, product information was aligned with QRD template v. 8.1 and changes were implemented following the renewal procedure (R/0010), a type IB variation (IB/0012) and the assessment of the 7th PSUR.
IB/0012	B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	13/03/2018	05/07/2018	SPC and PL	The Agency accepted the variation to delete the in-use shelf life for the finished product from the SPC and the PL.

[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).

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R/0010	Renewal of the marketing authorisation.	05/10/2017	21/11/2017	SPC, Labelling and PL	The European Commission renewed the marketing authorisation for Pexion.
II/0009	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	15/06/2017	31/10/2017	SPC and PL	The Agency accepted the variation to amend the SPC and package leaflet following assessment of a PSUR. The product information was simultaneously aligned with the latest QRD template and the list of local representatives was deleted from the package leaflet.
IG/0722	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	27/09/2016	31/10/2017	PL	The Agency accepted the variation to update the list of local representatives in the package leaflet.
IB/0007	C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR	09/12/2015	18/04/2016	SPC and PL	The Agency accepted the variation to make amendments to the SPC section 4.6 and the corresponding section of the package leaflet, as recommended by the CVMP.
IB/0006	B.II.e.1.z - Change in immediate packaging of the finished product - Other variation	06/08/2015	18/04/2016	SPC	The Agency accepted the variation to remove the desiccant canister from all bottle sizes.
IB/0005	C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR	10/04/2015	18/04/2016	SPC, Labelling and PL	The Agency accepted the variation to amend the SPC and the package leaflet following the outcome of the CVMP discussions on the second and third PSURs.
IB/0003	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	03/01/2014	16/12/2014	SPC, Labelling and PL	The Agency accepted the variation to extend the shelf life of the finished product as packed for sale from the current 30 months to proposed 3 years.
IG/0380	C.I.9.d - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH	05/12/2013	n/a		The Agency accepted the variation to harmonise the Detailed Description of the Pharmacovigilance System (DDPS).
IA/0002	B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits	12/06/2013	n/a		The Agency accepted the variation on the change of the testing specification.
IA/0001	B.II.b.3.a - Change in the manufacturing process of the finished product - Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions	12/06/2013	n/a		The Agency accepted the variation on a minor change in the manufacturing process.