Fungitraxx

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
R/0004	Renewal of the marketing authorisation.	24/01/2019	14/03/2019	SPC, Labelling and PL	The European Commission renewed the marketing authorisation for Fungitraxx.
IA/0007	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	22/01/2019	n/a		The Agency accepted the variation to update a CEP for the active substance.
IA/0006	B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter	22/01/2019	n/a		The Agency accepted the variation to delete a non-significant specification parameter.
IA/0005	A.7 - Administrative change - Deletion of manufacturing sites	22/01/2019	n/a		The Agency accepted the variation to delete a manufacturer of the active substance.
IAIN/0003	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	07/10/2016	n/a		The Agency accepted the variation to add a new Ph. Eur. Certificate of Suitability.
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	26/05/2016	03/11/2016	PL	The Agency accepted the variation to add the local representatives in Germany, Austria, Cyprus, United Kingdom and The Netherlands on the package leaflet.

[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).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000
An agency of the European Union

© European Medicines Agency, 2019. Reproduction is authorised provided the source is acknowledged.

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	15/10/2015	03/11/2016	PL	The Agency accepted the variation to add the local representatives in Denmark and Sweden on the package leaflet.