Coliprotec F4/F18

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/0009	Renewal of the marketing authorisation.	09/09/2021	11/11/2021	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Colilprotec F4/F18.
T/0008	Transfer of Marketing Authorisation	26/03/2021	26/04/2021	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from 'Prevtec Microbia GmbH', Germany to 'Elanco GmbH', Germany.
IAIN/0007	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	25/02/2021	26/04/2021	Annex II and PL	The Agency accepted the variation to add an alternative site responsible for batch release of the finished product (not including batch control/testing).
IB/0006	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	20/05/2020	n/a		n/a
IB/0004	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	12/10/2018	04/10/2019	SPC	The Agency accepted the variation to extend the shelf-life of the finished product from 15 months to 2 years.

[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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IAIN/0003	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	03/05/2017	09/07/2018	SPC, Annex II and PL	The Agency accepted the variation to change the manufacturer responsible for batch release of the finished product.