EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Coliprotec F4

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 [4]
R/0005	Renewal of the marketing authorisation.	07/11/2019	15/01/2020	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Coliprotec F4.
IB/0002	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	22/12/2015	28/09/2016	SPC	The Agency accepted the variation to increase the shelf-life of the finished product from 15 months to 18 months.
IB/0001	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	23/09/2015	28/09/2016	SPC	The Agency accepted the variation to extend the shelf-life of the finished product from 1 year to 15 months.

[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).
[4] Since October 2019 summary information is no longer published for quality variations that do not impact upon the product information

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