EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Gripovac 3

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/0005	Renewal of the marketing authorisation.	09/10/2014	04/12/2014	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Gripovac 3.
II/0002	B.II.e.1.a.3 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/immunological medicinal products	12/09/2013	n/a		The Agency accepted the variation to register a new, second material for the PET bottles, "Eastar MN021".
II/0003	B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [] substance in the manufacture of a biological/immunological medicinal product and is not related to a protocol	16/05/2013	n/a		The Agency accepted a variation to change pore size of preliminary filter for the media used for the preparation of the active substance.
IB/0004	B.II.b.3.z - Change in the manufacturing process of the finished product - Other variation	17/04/2013	n/a		The Agency accepted a variation to change the manufacturing process of the finished product.

[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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II/0001/G	This was an application for a group of variations. B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological medicinal product and is not related to a protocol B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	14/06/2012	n/a		The European Medicines Agency accepted a group of type II and type IA variations to increase the size of containers for the virus harvest and for the reduction of the shelf life for solutions prepared in-house.