Veterinary Medicines Directorate
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Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the EMA website.

Syvazul BTV Suspension for Injection for Sheep and Cattle

Vm 31592/5000

12 May 2025	To replace the method for the detection of saponin.
08 May 2025	Submission of a new Ph. Eur. CEP from a new manufacturer for a non-sterile reagent used in the manufacturing process of the active substance.
11 February 2025	Optimisation of the manufacturing process of the active substances, without modification the process itself.
25 April 2024	Change of manufacturer for an excipient used during manufacture.
21 November 2023	Elimination of the viral inoculum, addition of a washing step and elimination of the lyophilisation step. Modification in the storage condition of the working seed virus (section 2C2 of the dossier): frozen.
11 October 2023	Unlimited renewal.
04 August 2023	Change in the address of a manufacturer of the finished product. Change in the address of a manufacturer of the active substance. Change of MAH address from Avda. Parroco Pablo Diez, 49, 24010 Leon, Spain to C/Marques de la Ensenada, 16, 28004 Madrid, Spain. Change of local representative address from Avda. Parroco Pablo Diez, 49, 24010 Leon, Spain to C/Marques de la Ensenada, 16, 28004 Madrid, Spain.
25 January 2023	Change in test procedure for the finished product.
25 January 2023	New certificate from an already-approved manufacturer using materials of human or animal origin for which an assessment of the risk with respect to potential contamination with adventitious agent is required. New certificate from an already-approved manufacturer using materials of human or animal origin for which an assessment of the risk with respect to potential contamination with adventitious agent is required. Updated certificate from an already-approved manufacturer using materials of human or animal origin for which an assessment of the risk with respect to potential contamination with adventitious agent is required. Updated certificate from an already-approved manufacturer using materials of human or animal origin for which an assessment of the risk with respect to potential contamination with adventitious agent is required. New certificate from an already-approved manufacturer using materials of human or animal origin for which an assessment of the risk with respect to potential contamination with adventitious agent is required. New certificate from an already-approved manufacturer using materials of human or animal origin for which an assessment of the risk with respect to potential contamination with adventitious agent is required.

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12 April 2022	Addition of a site where batch control/testing takes place.