



Post Authorisation Assessments

Pyceze 500 mg/ml Concentrate for Solution for Fish Treatment Vm 30824/4004

17 December 2025	Addition of a site of secondary packaging. (NI).
01 December 2025	Change in distributor details from: CZ Vaccines S.A.U., La Relva -Torneiros s/n, 36410 O Porriño, Pontevedra, Spain to: Seacure Scotland Ltd, C/O Cloch Solicitors, 94 Hope Street, Glasgow, Lanarkshire, G2 6PH.
31 October 2025	To add two additional sites for secondary packaging (Zinereo Pharma and Laboratorios Ovejero). (GB).
29 October 2025	Change of Distributor from: Elanco Europe Ltd, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL to: CZ Vaccines S.A.U., A Relva s/n - Torneiros, 36410 O Porriño, Pontevedra, Spain.
04 March 2025	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex. (NI)
11 December 2024	Change in the manufacturer of the active substance: - Introduction of a manufacturer of the active substance supported by an ASMF. (GB & NI).
11 May 2024	Addition of a 1 litre bottle.
23 May 2023	Change in the name or address or contact details of a manufacturer or importer of the finished product. Change in the name and address of the Marketing Authorisation Holder from: CZ Veterinaria, S.A., La Relva s/n- Torneiros, 36410 Porriño, Spain to CZ Vaccines S.A.U., La Relva s/n – Torneiros, 36410 O Porriño, Pontevedra, Spain.
29 April 2022	Deletion of local representative information from the package leaflet.
29 December 2021	Replacement of a manufacturing site of the finished product. Decrease in batch size range of the finished product. Replacement of a manufacturer responsible for batch release including batch control/testing. Replacement of a secondary packaging site of the finished product. Replacement of a primary packaging site of the finished product.
04 February 2020	Change of MAH from Elanco Europe Limited, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL to CZ Veterinaria, S.A., La Relva s/n – Torneiros, Porriño, 36410 Spain.
01 May 2018	Change in RMS from UK to FR.
21 July 2017	Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
07 March 2017	Introduction of a new pharmacovigilance system.
18 January 2017	Increase in batch size of the finished product.

30 September 2016	Change in the name and address of the Marketing Authorisation Holder. Change of distributor details.
01 October 2014	Renewal procedure.
10 April 2014	Change to the MAH address.
27 March 2014	Change to the QPPV contact details and updates to the DDPS that do not affect the pharmacovigilance system.
04 April 2013	Grouped variation to update the manufacturing procedure: change to the in-process controls, and a change to the manufacturing processes.
21 March 2013	Variation to change the finished product specification
21 March 2013	Grouped variation to change the shape or dimensions of the container or closure, to change the specification parameters of the immediate packaging, and to change the test procedures for the immediate packaging.
16 August 2012	Variation to update the DDPS.
09 February 2012	Grouped variation to make minor changes to the composition, shape, and dimensions of the current packaging.
11 November 2011	Variation to delete a safety warning on the SPC and Package Leaflet.
04 November 2011	Submission of an additional finished product batch size.
14 April 2011	Variation to change the QP for Pharmacovigilance.
05 March 2009	MRP – UK as RMS.
06 June 2007	Variation to bring the SPC/Labelling in line with the Veterinary Regulations, 2005. Transfer of the legal category from POM to POM-V.
03 May 2006	Change to the active substance manufacturer.
05 April 2006	Change of a packaging component.
22 June 2005	Corrections to the SPC.
03 November 2003	Addition of a pack size.