

Steps taken after granting the Marketing Authorisation

- An Opinion on a Type II variation to increase the batch size of the freeze-dried component of the vaccine from 80,000 vials to 170,000 vials was adopted by the CVMP on 13 July 2005. Amendments have been incorporated into the relevant sections of the Commission Decision and of this EPAR.
- On 22 January 2008 the Commission approved a Type II variation concerning a change in manufacturer of active substance. The Commission Decision was based on a positive opinion as adopted by the CVMP on 12 December 2007.
- On 22 January 2008 the Commission approved a Type II variation concerning a change in the product literature to shorten the onset of immunity of the R, C and Ch components of the vaccine. The Commission Decision was based on a positive opinion as adopted by the CVMP on 12 December 2007.
- On 22 January 2008 the Commission approved a Type II variation concerning an update of the product literature to indicate compatibility of the vaccine with Rabisin. The Commission Decision was based on a positive opinion as adopted by the CVMP on 12 December 2007.
- On 22 September 2008 the Commission approved a Type II variation concerning an increase of the target formulation titre for the R component and tightening of release specifications for the R and Ch components. This Type II variation did not require any amendment to the Community marketing authorisation and was based on a positive opinion as adopted by the CVMP on 17 September 2008.
- On 12 February 2009 the Commission approved a Type II variation concerning the addition of an alternative manufacturing site for the production of inactivated feline calicivirus antigens (G1 and 431 strains) and update of the product information to include a warning in section 4.6 of the Summary of Product Characteristics (SPC) and section 6 of the package leaflet. The Commission Decision was based on a positive opinion as adopted by the CVMP on 14 January 2009.
- On 15 January 2010, the European Commission renewed the marketing authorisation for Purevax RCCh. This decision was based on the favourable opinion and an assessment report adopted by the CVMP on 11 November 2009.