



Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021,
please refer to the [EMA](#) website.

Profender 50 mg/10 mg Modified-Release Tablets for Medium Dogs Vm 06462/5008

12 February 2026	Addition of a new specification parameter with test method for an active substance. Addition of a new specification parameter with test method for a starting material. Change in the address name for an active substance manufacturer.
12 January 2026	Alignment of the product information with version 3.0* of the QRD templates. Additional subscripts and addition to adverse events approved.
10 December 2025	Submission of a Ph. Eur. CEP for an active substance.
27 November 2025	Introduction of a second manufacturing and testing site to manufacture Emodepside active substance.
25 November 2025	Minor changes to an approved test procedure for the finished product.
20 July 2024	Change in the batch size. Change in the manufacturing process of the finished product. Addition of a manufacturing site for the manufacturing process of the finished product.
06 July 2024	Change in test procedure for the immediate packaging of the finished product. Change in the specification parameters or limits of the immediate packaging of the finished product. Deletion of a non-significant specification parameter in the specification parameters of the immediate packaging of the finished product. Deletion of a Ph. Eur. CEP for an active substance. Minor changes: – to an approved test procedure for active substance. Addition of a manufacturer responsible for batch release including batch control or testing of a non-sterile finished product. Addition of a primary packaging site of a non-sterile finished product. Addition of a secondary packaging site of a finished product. Submission of an updated Ph. Eur. CEP from an already approved manufacturer.
09 August 2021	Introduction of a new pharmacovigilance system.