



Post Authorisation Assessments

Prid Delta 1.55 g Vaginal Delivery System for Cattle Vm 15052/4047

14 December 2024	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. (NI)
12 December 2024	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible. (GB).
23 August 2024	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV). (GB)
18 May 2024	Minor change in the manufacturing process in the manufacture of the finished product. Change in the specification parameters of an active substance/intermediate used in the manufacturing process of the active substance.
21 March 2023	Change in the specification parameters and/or limits of an excipient: - Other changes.
10 October 2022	Change in the address of the MAH from Unit 3 Anglo Office Park, White Lion Road, Amersham, Buckinghamshire, HP7 9FB to Explorer House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom.
17 March 2022	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
06 July 2020	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
02 April 2020	Addition of a new therapeutic indication.
16 July 2019	Submission of a new Ph. Eur. certificate of suitability for an active substance from a new manufacturer.
19 September 2017	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change of the back-up procedure of the QPPV of an existing pharmacovigilance system as described in the DDPS.
18 May 2017	Replacement of administration device with CE markings which is not an integrated part of the primary packaging.
15 February 2017	Change in immediate packaging of the finished product. Change in immediate packaging of the finished product. Deletion of a non-significant in-process test. Change in shape or dimensions of the container or closure (immediate packaging). Change in the specification parameters and/or limits of the finished

	<p>product.</p> <p>Change in the specification parameters and/or limits of the immediate packaging of the finished product.</p> <p>Change to in-process test or limits applied during the manufacture of the finished product.</p> <p>Change to in-process test or limits applied during the manufacture of the finished product.</p> <p>Change to in-process test or limits applied during the manufacture of the finished product.</p> <p>Change to in-process test or limits applied during the manufacture of the finished product.</p> <p>Change to in-process test or limits applied during the manufacture of the finished product.</p> <p>Replacement of an excipient with a comparable excipient.</p>
31 March 2016	Submission of an updated certificate of suitability.
06 January 2016	Submission of an updated DDPS.
13 October 2015	Change in pack size of the finished product.
30 April 2015	Renewal application.
28 April 2015	<p>Replacement of a manufacturing site for parts of the manufacturing process of the finished product.</p> <p>Addition of a manufacturing site for secondary packaging.</p>
13 February 2015	Change to the MAH address in Slovakia and Czech Republic only.
11 October 2013	Changes to an existing pharmacovigilance system as described in the DDPS.
03 July 2013	Repeat use Procedure.
24 August 2012	Change in specification limits of the finished product.
13 February 2012	To change the UK Marketing Authorisation Holder address.
06 January 2012	To change the name and address of the Marketing Authorisation Holder in Italy only.
13 October 2015	To add a new pack size