# Parvoduk

## Procedural steps taken and scientific information after the authorisation



| Application number | Scope | Opinion / Notification [1] issued on | Commission Decision Issued [2] / amended on | Product Information affected [3] | Summary |
|---|---|---|---|---|---|
| R/0006 | Renewal of the marketing authorisation. | 08/11/2018 | 09/01/2019 | SPC, Annex II, Labelling and PL | The European Commission renewed the marketing authorisation for Parvoduk. |
| WS/1366 | This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.<br><br>B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method | 19/04/2018 | n/a | | The Agency accepted the variation to register a new site responsible for sterility testing of the finished product. |
| WS/1195 | This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.<br><br>B.II.d.2.c - Change in test procedure for the finished | 15/02/2018 | n/a | | The Agency accepted the variation to add a new test method for the finished product. |

[1] Notifications are issued for type I variations (unless part of a group including a type II variation or higher procedure or a worksharing application). Opinions are issued for all other procedures.
[2] A CD is issued for procedures that affect the terms of the marketing authorisation (e.g. SPC, Annex II, Labelling, PL). The CD is issued within 2 months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within 1 year for other procedures.
[3] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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| | product - Substantial change to or replacement of a biol/immunol/immunochemical test method or a method using a biol. reagent or replacement of a biol. reference preparation not covered by an approved protocol | | | | |
| WS/1151 | This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.<br><br>B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS | 07/09/2017 | n/a | | The Agency accepted the variation to change a test method for reagents. |
| IB/0002 | C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation | 04/12/2015 | 13/12/2016 | SPC, Labelling and PL | The Agency accepted the variation to amend the product information following assessment of a post-authorisation safety study. |
| IG/0592 | C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure | 04/09/2015 | n/a | | The Agency accepted the variation to change the QPPV. |