07/11/2023
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EMADOC-360526170-1613300

Committees and Quality Assurance Department

Deolinda Silva
Agon Pharma Lda.
Lugar De Crasto Zona Industrial II Lote 1
4560-657 Penafiel
Portugal

Initial Notice of Parallel Distribution

Notification of 18/10/2023 for:

Product Name	RotaTeq
Product Strength	--[1] One dose (2 ml) contains: Rotavirus type* G1 not less than 2.2 x 10E6 IU[1], [2] Rotavirus type* G2 not less than 2.8 x 10E6 IU[1], [2] Rotavirus type* G3 not less than 2.2 x 10E6 IU[1], [2] Rotavirus type* G4 not less than 2.0 x 10E6 IU[1], [2] Rotavirus type* P1A[8] not less than 2.3 x 10E6 IU[1], [2] * Human-bovine rotavirus reassortants (live), produced in Vero cells. [1] Infectious Units [2] As lower confidence limit (p = 0.95)
Product Dosage Form	Oral solution
Product Pack Size	1 tube
EU number	EU/1/06/348/001
Member State(s) of origin[1],[2]	Austria, Belgium, Denmark, Finland, France, Germany, Greece, Italy, Norway, Spain, Sweden, Netherlands, Ireland
Member State(s) of destination[1],[2]	Portugal
Repackager(s)	Kohlpharma GmbH
Repackaging method	Relabelling

[1] For the UK, as from 1.1.2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on Ireland/NI.
[2] Where United Kingdom (Northern Ireland) "UK(NI)" is a member state of origin, it should also be noted that medicinal products placed on the UK market by 31 December 2020 may still be subject to parallel distribution into EU/EEA and Northern Ireland based on the provisions foreseen in the Withdrawal Agreement.

Dear Deolinda Silva,

Further to your submission of a notification for parallel distribution of the above-mentioned Centrally Authorised Medicinal Product, we hereby notify you that the regulatory check by the European Medicines Agency has now been completed.

As the above-mentioned Centrally Authorised Medicinal Product is a **biological medicinal product** (e.g. a vaccine, monoclonal antibody or blood product), the parallel distributor should inform, if applicable, the Official Medicines Control Laboratory (OMCL) of the Member State of destination on the parallel distribution of the product and to provide the OMCL with the following information for each batch: name of the medicinal product, strength, pharmaceutical dosage form, pack size, EU number, name and address of the marketing authorisation holder, manufacturer and parallel distributor, Member State of origin, batch number, expiry date, batch size (number of packages to be parallel distributed).

We take this opportunity to remind you that a Centrally Authorised Medicinal Product may be distributed in parallel only if it is in conformity with the latest annexes to the Community Marketing Authorisation for the product. For this purpose, the Agency will prospectively provide such annexes to all parallel distributors.

It is the parallel distributor's responsibility to verify that their supplier of the medicinal product complies with the principles and guidelines of good distribution practices and that they hold an authorisation. Due diligence checks should be carried out in order to assess the suitability, competence and reliability of the other party.

Once a year you must send a completed annual update form and supporting documentation to the Agency for review, provided that the information supplied previously to the Agency has changed (e.g. change in repackager, package leaflet, labelling, etc.). The annual update notification should be completed per product, pharmaceutical form and Member State of Destination. In addition, you must submit safety updates relating to amendments to the Marketing Authorisation as communicated by the Agency.

We would also like to remind you that, according to the current case-law of the Court of Justice of the European Communities, the trademark owner must be given advance notice by the parallel distributor that the repackaged product is to be put on sale. We should highlight that this regulatory check is without prejudice to the rights of the trademark owner.

Further information is available in the Post-Authorisation Guidance on Parallel Distribution on the Agency's website http://www.ema.europa.eu.

The authenticity of this notice may be verified in the public register of parallel distribution notices on the IRIS website: https://iris.ema.europa.eu/registerpd/. If it does not appear, please contact the European Medicines Agency via our online form: Send a question to the European Medicines Agency