30/04/2025
EMA/PD/0000262656
EMADOC-360526170-2318909

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 25/03/2025 for:

Product Name	Galvus
Product Strength	50 MG
Product Dosage Form	Tablet
Product Pack Size	56 tablets
EU number	EU/1/07/414/005
Member State(s) of origin	Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, Norway, Spain, Sweden, Netherlands, Ireland
Member State(s) of destination	Portugal
Repackager(s)	Kohlpharma GmbH
Repackaging method	Relabelling

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.

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 Send a question to the European Medicines Agency (EMA).