30/07/2024
EMA/PD/0000221034
EMADOC-360526170-1940468

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 02/07/2024 for:

Product Name	Bonviva
Product Strength	150 mg
Product Dosage Form	Film-coated tablet
Product Pack Size	1 tablet
EU number	EU/1/03/265/003
Member State(s) of origin[1]	Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, Norway, Spain, Sweden, Netherlands, Ireland
Member State(s) of destination[1]	Portugal
Repackager(s)	Kohlpharma GmbH
Repackaging method	Reboxing

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.

Please be aware that during the assessment of the above-mentioned medicinal product it has been decided that an **educational programme** will be put in place. The Marketing Authorisation Holder (MAH) has the legal responsibility to produce and distribute this educational material (e.g. physician's pack, patient alert card, etc) to the concerned parties. Therefore, we strongly recommend that you liaise with the MAH for the distribution of the educational material to patients and contact the National

[1] As of 1.2.2020, the UK is no longer an EU Member State. However, EU law still applies to the UK during the transition period.

Competent Authorities in the Member State of Destination, as there might be some additional responsibilities for parallel distributors under the national legislation.

On the basis of the assessment of your application we accept the **cutting of blisters** as proposed by your company. However, please note that cutting of blisters affects the inner packaging and has therefore a potential to adversely affect the original condition of the product. According to the case law of the Court of the EU the repackaging should not have an adverse effect on the original condition of the product. Taking this into account the EMA is currently reviewing its policy on conditions to allow repackaging that has an effect on inner packaging of a product.

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 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.

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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 ParallelDistribution@ema.europa.eu