VALSTYBINĖ VAISTŲ KONTROLĖS TARNYBA
PRIE LIETUVOS RESPUBLIKOS
SVEIKATOS APSAUGOS MINISTERIJOS

STATE MEDICINES CONTROL AGENCY
UNDER THE MINISTRY OF HEALTH OF THE REPUBLIC OF LITHUANIA

28 November 2016

ACKNOWLEDGEMENT OF APPROVAL

Procedure No: **LT/H/0105/001-002/IA/012**
Product name in RMS: **Pantobax 20 mg or 40 mg gastro-resistant tablets**
Approval date: **28.11.2016**

The State Medicines Control Agency of Lithuania agrees to the request to vary the Marketing Authorisation detailed in the application. The proposed change is:

Variation type IA_{IN}/C.I (z)
Change in the Summary of Product Characteristics (SPC) and Package Leaflet (PL) including additional safety information with regards to elevated circulating levels of Chromogranin A (CgA) using Proton pump inhibitors. This "PRAC recommendations on signals" has been adopted by PRAC at the 4-8 July 2016. EMA/PRAC/452713/2016.
The PRAC has agreed that the MAH(s) of rabeprazole, lansoprazole, dexlansoprazole, pantoprazole, esomeprazole and omeprazole containing products should submit a variation to amend the product information in line with EMA/PRAC/452713/2016.

No new additional data is submitted by the Applicant.

The application is approved on the basis that the application has been submitted simultaneously to all Concerned Member States and the relevant fees have been paid as required by national competent authorities. Failure to comply with this provision may subsequently deem the application invalid.

Kind Regards,

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