POLISH FINANCIAL SUPERVISION AUTHORITY

Current report no. 30 / 2019

Drawn up on: 2019-11-11

Abbreviated name of the issuer:

MABION S.A.

Subject

Submission of answers to the Company's Duplicate application for registration of MabionCD20 with the European Medicines Agency

Legal basis

Art. 17(1) MAR – confidential information.

Content of the report:

Further to current report no. 29/2019 of 10 November 2019 on confirmation of receipt of the answers to the second round of questions by the European Medicines Agency (EMA) under the registration procedure for a medicine under the working name MabionCD20 (Day 180), the Management Board of Mabion S.A. ("Company") hereby informs that on 11 November 2019, it received confirmation from the company contracted to deposit answers that answers as part of the registration procedure for the Duplicate application ("Duplicate application") for medicine MabionCD20 were effectively received by the EMA electronic system. Rheumatoid arthritis (RA) will not be included in the list of indications for this product.

As from Day 181 of the procedure, the two applications will be processed in parallel.

The submission of the answers referred to in this report allows the Agency to continue its evaluation of the Duplicate application. The Company will now await the opinion of the Committee for Medicinal Products for Human Use (CHMP).

The Company informs that the submission of the answers referred to in this report does not guarantee the approval of the product by the European Medicines Agency.