POLISH FINANCIAL SUPERVISION AUTHORITY

Current Report no. 7 / 2020

Date of preparation: 2020-01-28

Abbreviated name of the issuer:
MABION S.A.

Subject matter: Submitting answers to the questions as part of the registration procedure for MabionCD20 with the European Medicines Agency

Legal basis: Article 17(1) MAR – confidential information.

Content of the report:
In reference to Current Report no. 2/2020 of January 13th, 2020 and earlier communication within the scope of application by Mabion S.A. ("Company") for the marketing authorization of a drug under the working name of MabionCD20 by the European Medicines Agency (EMA), the Management Board of the Company hereby informs that on January 28th, 2020 it received from a company contracted to deposit the answers, a confirmation of effective receipt of the Company's answers to the list of questions received from the EMA, referred to in Current Report no. 38/2019 of December 16th, 2019.

The answers submitted concern both registration applications – the basic application and the application in which the list of indications for the product does not include rheumatoid arthritis ("Duplicate application"). The submission of the answers allows the EMA to continue the evaluation of the applications, but does not guarantee the approval of the product.

The company stresses that the EMA regulator has a number of tools at its disposal to ensure its discretion and the possibility of individual adaptation of the solution to the needs of a given registration procedure. The Company has no influence on the assessment of the EMA, there are a number of possible events – issuing a positive or negative decision, obtaining a list of additional questions (once or more than once), an invitation to the round of oral answers (once or more than once), withdrawal of the application by the Company and its resubmission after additions, or other events not expected at this stage by the Company.

The Company will keep you informed of further formally binding and significant events within the EMA registration procedure for MabionCD20.