FINANCIAL SUPERVISION AUTHORITY

Current report no. 38/2019
Date of report: 16 December 2019

Abbreviated name of the issuer
MABION S.A.

Subject
Receipt of the summary from the CHMP meeting regarding the registration procedure of the MabionCD20 drug

Legal basis
Art. 17 section 1 of MAR - confidential information.

Text of the report:
With reference to current report No. 37/2019 of 12 December 2019 and previous communication regarding the application of Mabion S.A. ("the Company") for the issue of a marketing authorization for the drug with the working name of MabionCD20 by the European Medicines Agency (EMA), the Management Board of the Company announces that in the evening of 13 December 2019 it received a summary of the meeting of the Committee for Medicinal Products for Human Use (CHMP) held on 9-12 December 2019, during which the Company's applications for registration of the drug were considered. The document was immediately analysed in order for the Company to assess the issues contained therein and to make the results of this assessment available publicly as soon as possible.

The summary of the CHMP meeting contains a list of issues referred by EMA and the Company is required to provide answers thereto in order to continue the registration procedure. The received comments of the regulator primarily concern the commercial production process of MabionCD20, as well as the similarity of the product covered by this process to MabionCD20 tested in a clinical trial and to the reference drug. The Company makes a reservation that the document has undergone preliminary evaluation and will be subject to further detailed discussion.

On the basis of the preliminary analysis of the document, the Management Board of the Company may conclude that its reservations as to the possibility of amending the information received by it on 29 November 2019 (current report No. 37/2019 of 12 December 2019) were justified and the final list of issues raised by EMA differs from the initial information received from the reporting entities, as mentioned in current report No. 37/2019. The scope of the received issues is narrower compared to the previously-obtained information.

The Company declares that it will closely cooperate with the regulator in resolving the presented issues. The preliminary assessment of the situation shows that the already-planned and implemented tasks are consistent with the scope of work required to address the latest inquiries of the regulator, and therefore the internal work schedules will not change.

At the same time, the Company makes a reservation that EMA may require further interactions with the Company.