Financial Supervision Authority

Current report No. 56/2018

Date prepared: 2018-08-06

Abbreviated name of the issuer:

Mabion S.A.

Subject:

Granting of approval from The European Medicines Agency for submitting the second registration application (‘Duplicate application) for the drug under the working name MabionCD20.

Legal basis

Art. 17 section 1 MAR – confidential information

Content of the report:

With reference to Current Report No. 36/2018 of 1st June 2018 concerning the submission of the application to The European Medicines Agency (‘EMA’) for granting an approval for a marketing authorization of a drug under the working name MabionCD20 and the Current Report No. 46/2018 of 21st June 2018 concerning the acceptance by EMA of this application for evaluation, the Mabion S.A. Management Board (‘the Company’) hereby informs that on 6th August 2018 was granted from the EMA approval for submitting the second registration application (‘Duplicate application) for the drug under the working name MabionCD20.

The assumption of the second application is to obtain by the Company additional trade name for which the list of indications for the product will be limited and will not involve the Rheumatoid Arthritis (RA).

This operation may accelerate the commercialisation of the drug under the working name MabionCD20 on the market, where RA is still the subject of the patent protection for Mabthera.

In addition the Company informs that the approval granted from the EMA is only the initial confirmation of the possibility of drug registration and does not guarantee the success in the this proces. The Company also reserves the possibility to withdraw from submitting the second registration application depending on the final evaluation of the potential business benefits for the Company.