FINANCIAL SUPERVISION AUTHORITY

Current report No. 50 /2018

Date prepared: 28/06/2018

Abbreviated name of the issuer:

MABION S.A.

Subject

Information regarding a meeting with the US Food and Drug Administration _FDA_ concerning registration and marketing authorization for MabionCD20 drug on the territory of the USA.

Legal basis

Art. 17 item 1 of MAR – confidential information

Content of the report:

The Management Board of Mabion S.A. _"the Company" _ informs that on June 27, 2018 the Company received a summary from the US Food and Drug Administration _'' FDA", "Agency"_ after the BPD _Biosimilar Biological Product Development_ Type 2 meeting.

The aim of the meeting was to briefly present general information collected by the Company concerning MabionCD20 development in reference to MabThera referential drug and – on the basis of this data – to settle basic issues regarding possible cooperation with the FDA in order to register MabionCD20 in USA.

According to the content of the received summary the FDA provided for the possibility to use data collected by the Company as supportive for the application process. At the same time, it suggested a general strategy of connecting the product registered in the European Union_Mabthera_with the product authorized for marketing in the USA_Rituxan_. The FDA underlined the lack of necessity to set a completely separate process of development of MabionCD20 for the American market.

The Company was admitted to further stages of the advisory process, whose aim is to specify FDA's requirements.

The Company informs that the registration and marketing authorization of MabionCD20 drug on the territory of the USA is a multi-stage process and it is possible that additional requirements concerning FDA's approval of the product will appear in the future.