POLISH FINANCIAL SUPERVISION AUTHORITY

Current report no. 22 / 2019

Date of preparation: 2019-07-25

Abbreviated name of the issuer:
MABION S.A.

Subject:
Information from the European Medicines Agency on the assessment of the results of GMP inspection related to MabionCD20 production in the Complex in Konstantynów Łódzki.

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

Report content:
The Management Board of Mabion S.A. ("Company") hereby informs that on 25 July 2019, it received a letter from the European Medicines Agency ("EMA"), ("Agency") informing that on the basis of the inspection carried out by the Chief Pharmaceutical Inspectorate on behalf of the EMA, classified as a pre-authorisation inspection concerning a medicine with the working name "MabionCD20", the Agency considers that the manufacturing processes run in the Company comply with the principles and guidelines of Good Manufacturing Practice (GMP) set forth in Directive 2003/94/EC. The findings of the inspection enable the inspectors to recommend to the EMA the establishment of the Mabion S.A. Scientific and Industrial Complex for Medical Biotechnology in Konstantynów Łódzki as a manufacturing site for the medicine with the working name "MabionCD20".

The Company informs that the above forms one of the milestones necessary to obtain the marketing authorisation for MabionCD20, however, it does not guarantee the registration.