POLISH FINANCIAL SUPERVISION AUTHORITY

Current Report no. 11 / 2022

Date of preparation: 2022-04-19

Abbreviated name of the Issuer: MABION S.A.

Subject matter: Registration of the Company as the manufacturer of the SARS-CoV-2 rS active substance in the Register of the Chief Pharmaceutical Inspectorate

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

Content of the Report:

With reference to Current Report no. 52/2021 of 8 October 2021 on entering into a Manufacturing Agreement with Novavax, Inc. ("Novavax") for the years 2022-2025 concerning the COVID-19 vaccine antigen under the name of Nuvaxovid ("Manufacturing Agreement" and "Product", respectively), and Current Report no. 63/2021 of 19 November 2021 on the conclusion of a quality agreement and next steps in the implementation of the Manufacturing Agreement, the Management Board of Mabion S.A. ("Company") hereby informs that on 19 April 2022, it received information on registration of the Company's activity as a manufacturer of the Product, i.e. SARS-CoV-2 rS active substance, in the National Register of Manufacturers, Importers and Distributors of Active Substances kept by the Chief Pharmaceutical Inspectorate ("GIF").

From the operational side of the implementation of the agreement, obtaining the registration is a neutral event, i.e. it was not related to the tasks and settlements carried out to date, nor does it affect the tasks planned in subsequent periods, settlements between the parties, or the schedule for the production of the vaccine antigen. All these elements are governed by the agreement of 8 October 2021, which the Company implements as planned.

The event described here is significant for the Company in a regulatory context. It constitutes the last regulatory element for which the Company, as the entity conducting the manufacturing activities, is responsible as part of its cooperation with Novavax, i.e. having the appropriate, up-to-date GMP certificate and ensuring that the Company, as the manufacturer of the SARS-CoV-2 rS, active substance, is entered in the Register of the Chief Pharmaceutical Inspectorate as the competent authority for the Company. Other regulatory activities, those related to updating regulatory documentation on the product side, rest with Novavax.

Due to obtaining the registration, all batches of the Product manufactured by the Company in compliance with the GMP standard for Novavax, after completion of formalities by Novavax, will be available for sale by Novavax. The Company receives remuneration on an ongoing basis upon completion of manufacture and quality control of each specific batch.