

type of report	Current report
number	64/2013
company	PHARMENA

Acceptance of application for authorisation of 1-MNA as new food ingredient

With reference to the Company's Strategy for 2012-2015 (published in current report no. 16/2012 of 13th April 2012) and communication on establishing date of assessment/consideration of application for the authorisation of 1-MNA dietary supplement (published in current report no. 40/2013 of 26th June 2013), the Management Board of Pharmena S.A. informs, that on 18th September 2013, the Company received information that Food Standards Agency in London (FSA) formally accepted the application for authorisation of 1-MNA as new food ingredient by its regulation no. 258/97, on 31st August 2013.

Also, the Company informs that the application for authorisation of 1-MNA was accessed during the meeting of the Advisory Committee on Novel Foods and Processes (ACNFP) on 26th June 2013. The ACNFP Committee, which together with Food Standards Agency (FSA) performs the assessments of applications for authorisation of new food ingredients, requested the Company to submit additional information on the application. The Company forwarded additional clarification to the ACNFP Committee. Further assessment of application for authorisation of 1-MNA as new food ingredient will be held by circulation.

The Food Standards Agency conducts 21-day public consultation, as part of the assessment of applications. Also the application for authorisation of 1-MNA as new food ingredient will undergo such consultation, which will be held simultaneously with substantive evaluation.

The assessment of application for authorisation of 1-MNA will be prepared by Food Standards Agency until 30th November 2013.

Successful authorisation will open EU markets for the dietary supplement.

The 1-MNA dietary supplement will be an innovative product with capacity to influence the risk biomarkers of cardiovascular diseases and to stimulate the endogenous (natural) production of prostacyclin. Low levels of prostacyclin in human organism increase the risk of atherosclerosis. Studies have shown that the concentration of endogenous 1-MNA in human organism decreases with age. 1-MNA dietary supplement can complement 1-MNA deficiency in the organism and therefore stimulate the production of prostacyclin which reduces the risk of atherosclerosis development.

The procedure stipulated in the provisions of Art. 4 of Regulation (EC) no. 258/97 of the European Parliament and of the Council of 27th January 1997, concerns foods and food ingredients that have no record of safe consumption in the Community, which means they were not used in foods before 15th May 1997 in any EU Member State.

The goal of subjecting 1-MNA to this procedure is to prove, by the use of available for PHARMENA S.A. research and scientific publications, the safety of the ingredient's use within the proposed area. Within this procedure, the entity responsible for placing on the Community market submits appropriate application to EU Member State, where the new foodstuff is to be first placed on the market. An additional scientific assessment at European level may appear necessary. In such case, it will be performed by European Food Safety Authority. Following full assessment, the European Commission grants permission for placing the new foodstuff on the market.

The information is made public due to the fact that introduction of innovative dietary supplement containing 1-MNA on the market may have a significant influence on the Company's revenue in the next few years.

Legal basis: Alternative Trading System Rules – Exhibit 3 "Current and Periodical Information in the Alternative Trading System on the NewConnect Market", Article 3 (1).

Representatives of the company:

- Konrad Palka - President of the Board
- Marzena Wiczorkowska – Vice President of the Board