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company	PHARMENA

PHARMENA SA Evaluation concerning the application for authorisation of 1-MNA dietary supplement

With reference to the Company's Strategy for 2012-2015 (published in current report No. 16/2012 of 13.04.2012) and the information on completing the application for authorisation of 1-MNA as a new food ingredient (published in curent report No. 55/2014 of 06.11.2014), the information on scheduling the date of assessment concerning the completion of application for authorisation of 1-MNA dietary supplement for 12th February 2015 (current report No. 7/2015 of 09.02.2015) the Management Board of PHARMENA S.A. informs that on 10th March the Company obtained an information following the session of the Advisory Committee on Novel Foods and Processes (ACNFP) during which the committee discussed the application of the Company concerning the authorisation of 1-MNA as a new food ingredient pursuant to Art. 4 of the Regulation (EC) No. 258/97 of the European Parliament and of the Council of 27th January 1997.

The Committee highly evaluated the quality concerning the results of sub-chronic (90 days) toxicity tests performed on animal models submitted by the Company. After the review of submitted results of toxicology tests, the Committee requested the Company to perform additional risk evaluation by estimating Margins of Exposure. Margins of Exposure are calculated basing on obtained toxicology data (NOAEL) and on the estimated dose of exposure. The Committee also recommended that the future dietary supplement containing 1-MNA should not be used by pregnant women and children under 18 years of age.

What is more, the Committee also requested the Company to submit additional information concerning the influence posed by 1-MNA supplementation on niacin metabolism. The Company informs that the above information has already been twice submitted to the Committee - on 18th December 2013 and on 6th November 2014 together with results of toxicology tests. Simultaneously, the Company informs that today it submitted an inquiry to the FSA Agency demanding explanations, why additional information submitted by the Company concerning the influence posed by 1-MNA supplementation on niacin metabolism have not been discussed during the session of the Advisory Committee on Novel Foods and Processes (ACNFP) on 12th February this year.

The Company shall perform the additional risk evaluation by estimating margins of exposure without any delay and shall submit the required information to the Committee. Further evaluation covering the application of the Company concerning the authorisation of 1-MNA as a new food ingredient shall be conducted pursuant to Art. 4 of the Regulation (EC) No. 258/97.The Company shall promptly inform about any further information on the evaluation relating the application concerning the authorisation of 1-MNA as a new food ingredient in a current report.

The procedure stipulated in 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, basing on research and scientific publications that are available for PHARMENA S.A., the safety of the ingredient's use within the proposed area. Within this procedure, the entity responsible for placing the new food ingredient on the Community market submits appropriate application to the 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 (EFSA). Following full assessment, the European Commission grants permission for placing the new foodstuff on the market.

Successful authorisation will open EU markets for the dietary supplement.

The 1-MNA dietary supplement will be an innovative product with a capacity to influence 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 developing atherosclerosis.

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