type of report	**Current report**
Number	16/2015

PHARMENA SA Submitting additional information supplementing the application for authorisation of 1-MNA as a new food ingredient

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 evaluating the application for authorisation of 1-MNA as a new food ingredient (published in curent report No. 9/2015 of 10.03.2015) the Management Board of PHARMENA S.A. informs that on 9th April 2015, pursuant to Art. 4 of the Regulation (EC) No. 258/97, the Company submitted additional information, completing the application for authorisation of 1-MNA as a new food ingredient to Food Standards Agency (FSA) and Advisory Committee on Novel Foods and Processes (ACNFP).

The Company performed risk evaluation by estimating margins of exposure (MoE), based on calculated basing on obtained toxicology data (NOAEL) and on the estimated dose of exposure. Calculated values of MoEs for the daily dose equalling 250 mg MNA reached 70, 140 and 280 for NOAEL doses of 250, 500 and 1000 mg/kg of body mass respectively (indicated by the ACNFP Committee). The NOAEL value obtained as a result of the toxicology study performed by an independent research laboratory and recommended for 1-MNA equals 1000 mg/kg of body mass. As far as this NOAEL value is concerned, the value of MoE margins equals 280.

In case when it is impossible to reach data concerning long-term exposure of people to the evaluated substance, the recommended value of the margin of exposure equals at least 100. The final risk analysis for the specific dose shall be performed individually, based on the obtained value of the margin of exposure for the given dose, as well as in the context of the character attributed to the given substance.

Data concerning long-term exposure of people to 1-MNA are available based on published data resulting from administrating niacin (Niaspan drug) during a period of nearly 20 years. For niacin transforms in about 60% to 1-MNA. Data related with administrating niacin confirm that long-lasting exposure to the dose of 1-MNA that is more than 5-times higher than the dose requested by the Company is perfectly safe for people. What is more, 1-MNA is a physiological substance. In relation with the above, as far as the Company is concerned, basing on the obtained data, as well as data resulted from obtaining niacin, the dose of 1-MNA requested by the Company, equalling 250 mg/day, is appropriate.

Moreover, the Company submitted additional information concerning the influence posed by the 1-MNA supplementation on niacin metabolism, based on expanded literature data, as well as obtained toxicokinetic information.

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 further evaluation relating the application 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 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 1-MNA 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.