22 September 2017.

PASMI's position regarding the draft amendment to the Act of August 25, 2006 on food and nutrition safety (Polish J. L. of 2017 No. 149)

PASMI Polish Association of Self Medication Industry as one of the four initiators of the industry's self-regulation regarding advertising of food supplements, bearing in mind the draft prepared by the Ministry of Health, understands the necessity of adopting legislative measures that will affect the whole food supplement market. This goal, however, should be achieved by means of statutory measures, duly substantiated, legally correct and balanced in terms of achieving certain effects, as well as complying with applicable Community law.

PASMI is of the opinion that well-conducted self-regulation of the industry is an effective tool in the area of eliminating misleading content from advertising. The Code of Good Practices for Advertising Food Supplements, which has been developed and adopted by member companies of the 4 largest organisations of entities operating on the food supplement market, contains comprehensive regulations aimed at achieving the same effect as the Draft presented for the sector consultations.

In place of the solutions adopted in the Code, the Draft act offers proposals for extremely repressive solutions, dubious from the point of view of EU legislation, including the order to put a blue bar on the packaging of food supplements, regardless of the colour in which the packaging itself is used or a ban on the use of the so-called "umbrella names" in relation to food supplements and other product groups.

PASMI is therefore in the position of transferring the provisions from the Code to the amended Act, bearing in mind the changes already introduced from the level of 30 signatories of the Code, constituting 80% of the food supplement advertising market. In the case of umbrella brands, PASMI recommends setting up an advisory team by the minister competent for health matters, who assesses, first of all, the risk of consumers being misled as to the properties of a food supplement when a common stem for different categories has been used.

PASMI strongly supports the introduction of notification fees as well as simplification of the notification procedure and the transfer of full liability to the

entity marketing the food supplement. The verticalisation of the Sanitary Inspection becomes of key importance.

PASMI is also open to the development of a regulation regarding plant substances that can be used in the production of food supplements, following the existing lists in force in Belgium, Romania or Italy. We emphasise, however, that the list should take into account the local specificity in the scope of the use of certain substances in manufacturing processes and current scientific reports regarding the use of the above mentioned substances in food supplements.

According to PASMI, the pursuit of consumer protection by the regulator should not have the effect of intimidation and creating the impression that the consumer is dealing with extremely dangerous products, and only indicate that food supplements are legal products that have a nutritional or other physiological effect, aimed at supplementing the diet.

PASMI Polish Association of Self Medication Industry promotes the responsible selfmedication among the society through a conscious and safe use of products classified as drugs sold without Prescription. It pursues to establish relevant legal and systematic solutions for the development of the responsible use of OTC drugs as one of the elements of the healthcare system.

PASMI cooperates actively with European organisations whose goals and operations are in line with the statutory activity of PASMI. PASMI is a member of AESGP – Association of the European Self-Medication Industry. Currently, the Association has 18 members: Aboca, Adamed Consumer Healthcare, A&D Pharma, Bayer, GSK, Johnson&Johnson, Klosterfrau, Omega Pharma Poland, Pfizer, Pierre-Fabre, Polpharma, Reckitt Benckiser, Sanofi, Takeda, Teva, USP Zdrowie, Verco, Walmark.