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Introduction of a food supplement into the Polish market

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1.- Introduction

According to the EU law food supplements are foods, regulated by the provisions of food law. They are concentrated sources of nutrients or other substances with a nutritional or physiological effect, designed to be taken measured small quantities in forms such as capsules, pastilles, tablets, pills, sachets of powder, ampoules of liquids, etc. [1]

Despite the categorisation of food supplements as foods with a view to their composition, effect, or even the form of consumption, they bear some similarity to medicinal products, which leads to a number of problems hampering the proper application of legal regulations on food supplements. It is extremely difficult to draw an unquestionable line between food supplements (foodstuffs) and medicinal products. However, categorising a specific product as either a food supplement or a medicinal product entails grave consequences. Introduction of medicinal products into the market of a Member State is subject to an extremely restrictive and time-consuming procedure for obtaining a market authorisation. On the other hand, the introduction of food supplements (foodstuffs) into the market is not subject to such restrictions.

Introduction of food supplements into the Polish market encounters difficulties resulting not only from the inability to distinguish them from medicinal products but also from the lack of adequate legal provisions regarding procedures that would stipulate unequivocal and clear rules for the marketing food supplements.

This article presents Polish legal regulations on the introduction of food supplements into the Polish market.

([1]) According to directive 2002/46/EC food supplements are *foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities*.

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2.- Scope of Polish legal provisions on food supplements

In the Polish legislation the introduction of food supplements into the Polish market is regulated by the Act of 25 August 2006 on Food and Nutrition Safety (Dz. U. of 2006, no. 171, item 1225, with further amendments) [2], hereinafter referred to as "the AFNS".
This Act is the main act of law regulating food law in Poland. It governs the implementation and execution of most EU regulations on food law[3]. As for food supplements it implements the provisions of directive 2002/46/WE *on the approximation of the laws of the Member States relating to food supplements*[4].

3.- Definition of a food supplement

Article 3 point 39 of the AFNS contains a definition of a food supplement (it should be pointed out that provisions of the Polish law use a term "dietary supplement" (*suplement diety*) rather than "food supplement" (*suplement żywności*), which is used in the Polish language version of directive 2002/46/EC). By virtue of this provision "*dietary supplements means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in*

([2]) The current Polish constitution contains a closed and hierarchical system of the sources of universally binding law of the Republic of Poland (applicable to all persons). The sources of universally binding law of the Republic of Poland shall be (according to their rank): the Constitution (as a document of the highest rank), ratified international agreements, acts, and regulations. Moreover, in the area of operation of local bodies and local public administration enactments issued by these bodies shall be a source of universally binding law of the Republic of Poland. An act is a basic act of law. An act is issued by the Sejm of the republic of Poland (however, also the higher chamber of the Parliament, i.e. the Senate, as well as the President are involved in the legislative procedure). An act is adopted independently, which means it does not require any specific authorisation.

([3]) This Act executes 53 regulations of the European Parliament, Council of the EU and the Commission, and implements 43 directives.

([4]) OJ L183, 12.07.2002, p. 51.

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measured small unit quantities, excluding products with features of a medicinal product in the meaning stipulated by the provisions of the pharmaceutical law";
The definition included in the AFNS is a word-for-word reflection of the definition contained in directive 2002/46/EC except from the additional wording including a reference to medicinal products. The aim of the additional provision stipulating that a product with properties of a medicinal product is not a food supplement was to draw a clear distinction between a food supplement and a diet supplement. Such a legislative measure seems unjustified. Firstly, if a food supplement is considered a foodstuff than by virtue of Article 2 (d) of regulation 178/2002/EC defining "foodstuff", a medicinal product cannot be considered food. Secondly, as a result of the introduction of directive 2004/27/EC of 31 March 2004 *amending Directive 2001/83/EC on the Community code relating to medicinal products for human use*, a provision was introduced into the Polish Act of 6 September 2001 on Pharmaceutical Law (Dz. U. of 2008, no. 45, item 271, with further amendments), hereinafter referred to as "the APL", stipulating that the provisions of the Act on Pharmaceutical Law are applicable to products that meet both the criteria of a medicinal product and a different category of products, especially a food supplement or a cosmetic (Article 3a of the APL).
It should be pointed out that even though these two provisions were introduced, the problem of distinguishing between food supplements and medicinal products still arises on the basis of the binding Polish legislation.

4.- Labelling food supplements

Food supplements introduced into the market have to be displayed and advertised under the term "dietary supplements", which cannot be replaced by any other (invented) trademark of a foodstuff. If a food supplement is labelled with an additional (invented) trademark, the term "dietary supplement" has to be placed in its direct vicinity[5].

5.- Procedure for marketing a food supplement

According to the provisions of the AFNS, the entity introducing a food supplement into the Polish market for the first time is obliged to inform the Chief Sanitary Inspector about this fact.

([5]) Compare Article 27 par. 4 of the AFNS.

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Competent authority

The Chief Sanitary Inspector (*Główny Inspektor Sanitary, GIS*) is a central government administration body in Poland subject to the minister responsible for health. The Chief Sanitary Inspector supervises the National Sanitary Inspectorate, as well as coordinates and controls the statutory activities of public sanitary inspectors. The National Sanitary Inspectorate is one of five inspectorates that create an official control structure in Poland[6]. The National Sanitary Inspectorate comprises of three levels. The central level includes the GIS, the voivodship level includes 16 voivodship sanitary inspectors who are the bodies of the National Sanitary Inspectorate, whereas the lowest level includes 318 poviat sanitary inspectors.

Information to be provided in the notification

The provisions of the AFNS specify a range of data and information that the notification has to contain, among other things, name of a product and its manufacturer, the form of the product, which is introduced into the market, model of the label in Polish, the qualification/type of a food stuff chosen by the notifying entity, qualitative composition including the specification of the ingredients of the product, including active agents, and quantitative composition of the ingredients. Moreover, if the food supplement is marketed in another EU Member State, the notification has to include the name of the competent body of that Member State that had been notified of the introduction of the foodstuff into the market or permitted the introduction of the foodstuff into the market, with a copy of that notification or permit enclosed.
The requirement to provide so much information seems to exceed the scope of information mentioned in Article 10 of directive 2002/46/EC, which stipulates that a Member States may require the manufacturer or the person placing the product on the market in their territory to notify the competent authority of that placing on the

(6) Apart from the sanitary inspection official public structure of food control in Poland includes: Veterinary Inspectorate, Agricultural and Foods Quality Inspection, Trade Inspection, Main Inspectorate of Plant Health and Seed Inspection. According to the Polish law the inspections form a group of institutions operating with a specified degree of self-dependency and organisational independency. The group does not create any single institution but is treated collectively as a general organisation (inspectorate in general) appointed to carry out certain activities mainly in the area of control. The (usually impersonal) general inspection is an organisational structure that provides a substance and concrete character of inspection.

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market by forwarding it a model of the label used for the product. Therefore, there is doubt as to whether the requirement to provide a range of additional information is not a violation of a measure having equivalent effect as quantitative restrictions on imports, which is prohibited on the basis of Article 34 of the Treaty on the functioning of the European Union (before the Treaty establishing the European Union) [7].

Initiation of investigation procedure

According to the provisions of the AFNS, after the receipt of the notification the GIS "can" carry out an investigation procedure to determine whether the food supplements named in the notification comply with the requirements specified in applicable provisions of law and whether the product, as a foodstuff, does not have properties of a medicinal product specified by the provisions of the pharmaceutical law.
At the same time the AFNS specifies no premises or circumstances, neither general nor specific, which would justify carrying out of such a procedure. It means that in practice the GIS can launch an investigation procedure anytime they receive a notification.
Such a solution is inappropriate as it gives too much freedom to the authority which is not obliged to provide grounds for the initiation of the investigation procedure. The practice in the last few years has shown an increase in investigation procedures launched by the GIS.

Deadlines

On the basis of the provisions of the AFNS an investigation procedure cannot exceed 60 working days, excluding the time necessary to document the compliance with the requirements[8]. According to the wording of the provisions the 60-day period begins on the day of the initiation of the procedure, which should be notified to the entrepreneur.[9]
However, there is no provision specifying the deadline for the initiation of the investigation procedure after the notification is received. Such freedom for the GIS is unjustified, especially since an investigation procedure does not result in drafting

([7]) Compare M. Korzycka –Iwanow, M. Zboralska, *Never-ending debate on food supplements: harmonization or disharmonization of the law?*, EFFLR, 2010/3.

([8]) Article 30 par. 3 of the Act.

([9]) Article 30 par. 2 of the Act.

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and administrative act. It is poviat sanitary inspectorate bodies that can prohibit marketing of the product or order its withdrawal from the market as a result of an entirely separate procedure.

Opinion of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

The provisions of the Act on Food and Nutrition Safety stipulates that during the investigation procedure the Chief Sanitary Inspector is require to impose an obligation on the entity that intends to market a product to submit an opinion from the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (hereinafter referred to as *Office for Registration*) [10]. This means that the opinion of the office for registration is an inherent element of the investigation procedure. Moreover, the provisions stipulate clearly that the GIS considers the opinion of the Office binding for the investigation procedure.[11]
Unfortunately, the provisions of the Act on Food and Nutrition Safety do not specify any form or deadline for issuing such an opinion. Also there are no grounds for issuing such an opinion by the Office for registration or documents on the basis of which it should be issued were specified.
Such a solution raises serious reservations. Firstly, the opinion is not issued in the form of an administrative act, so the stakeholder is not entitled to lodge an appeal against it, even though the GIS considers it binding. Even if the entity disagrees with the opinion, they have no legal instruments at their disposal that would allow them to challenge the opinion in any way. Taking into consideration the fact that such an opinion is binding for the decision-making authority, i.e. the GIS, such a solution seems unacceptable, since the stakeholder has no legal instrument to voice their arguments.
Secondly, no specific deadline for issuing the opinion also raises serious reservations. The stakeholder disposes of no legal instrument to demand that the opinion be issued at a specific time.
Thirdly, it should be pointed out that the entity that intends to market a food supplement for the first time in the territory of Poland, is not obliged to submit a

([10]) Office for Registration was appointed on the basis of the Act of 27 July 2001 on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Dz.U. No. 126 item 1379 with further amendments). The Office is supervised directly by the Minister of Health of the Republic of Poland who issues decisions regarding medicinal products and biocidal products on the basis of documentation drafted by the President of the Office. Decisions regarding medical devices are taken by the President of the Office.

([11]) Compare Article 31 par. 3 of the Act.

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range of documents required in the case of notification of a medicinal product (e.g. a number of results of studies, a detailed summary of product characteristics). Therefore, the Office for Registration receives much less information and data than in the case of the procedure for the registration of a medicinal product. There is serious doubt as to whether it is possible to submit a reliable and scientifically-grounded opinion. Practice shows that the Office for Registration verifies most of all if the composition of active agents includes agents that are contained in registered medicinal products. If it is the case, the opinion states that the product meets the criteria for a medicinal product, neglecting a significant factor, i.e. the concentration of the ingredient in the food supplement.
Fourthly, it should be noted that in the case of the marketing authorisation procedure for medicinal products, it is the President of the Office for Registration and not the Office that participates in the procedure which is finalized with an authorisation issued by the Minister of Health. It is the President of the Office who, among other things, verifies the application, who is entitled to require a responsible entity to supplement information or explain the documentation, draw up an evaluation report containing a scientific opinion on the medicinal product). It should be underlined that in this procedure the application is submitted to the Health Minister through the President of the Office for Registration[12]. On the other hand, in the case of the investigation procedure the opinion is issued not by the President of the Office for Registration but by the office itself, which raises doubt as to who is personally responsible for the opinion issued.

Opinions of other entities

Independently from the requirement to provide the opinion of the Office for Registrations, the GIS may require the entrepreneur to submit an opinion of a scientific institution and an opinion of the Team for Dietary Supplements (hereinafter referred to as „Team")[13]. The Team is a consultative and opinion-drafting of the GIS. Its activities include provision of scientific and expert knowledge to the Inspectorate during investigation procedures in order to examine the characteristics of particular products by issuing opinions in a form of decisions taken by a majority vote of the members of the Team.

[12] Compare Article 7 par. 1 of the APL.

[13] The Team for Dietary Supplements was appointed on the basis of the Act of 8 January 2010 amending the act on food and nutrition safety and a few other acts (Dz.U. No. 21, item.105 of 2010).

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Providing the GIS with a possibility of consulting the Team raises doubt since the role of the Team in the investigation procedure is not entirely clear. As it was noted before, the Inspectorate is obliged to respect the opinion of the Office for Registration. Moreover, each investigation procedure requires an opinion of the Office for Registration. Therefore, it poses a question about the purpose of obtaining another opinion, especially since the provisions do not specify its character or whether it should be based on scientific sources, and if so, what sources (should it take into consideration the social and economic context)[14].

Completion of an investigation procedure

The provisions of the Act on Food and Nutrition Safety do not contain any specification of the manner or form of the completion of an investigation procedure. The only reference to the completion of an investigation procedure is included in the *Ordinance of the Minister of Health of 20 June 2007 on registration of products marketed in the Republic of Poland for the first time as foodstuffs, form of notification and methods for calculating costs of issuing an opinion on these products*[15], including an appendix titled "Form of the Registration of the products subject to notification of their first marketing as foodstuffs" that contains a footnote to a table saying: "*the Chief Sanitary Inspector notifies the notifying entity of the reception of notification of the product in the case when in terms of its composition and properties the product meets the qualification requirements adopted by the manufacturer or importer of the product at the date of the notification or other requirements, e.g. a medicinal product on the basis of the documentation supplied*".

([14]) It is also worth mentioning that not only the reasons for the establishment of the Team, as mentioned above, raise doubt but also the range of its activities, including drafting a list of plant ingredients with the indication of their maximum dosage in dietary supplements, which, when exceeded, has a therapeutical effect. This means that if a product contains a dosage higher than the maximum level it will be considered a medicinal product. Such an approach is based on a simplified guidelines and is inappropriate, since a decision to determine whether a product is a medicinal product should be based on an individual analysis of the product.

([15]) In the binding sources of the Polish legal system ordinances have a regulatory power under the authority of legal acts. They may be issued only by the bodies authorised by virtue of the Constitution (including the ministers as in this case) on the basis of a detailed authorisation specified in an act. The authorisation contained in the act should specify the body authorised to issue an ordinance and the scope of the issues it should regulate, as well as guidelines regarding its content.

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The above facts lead to a conclusion that an investigation procedure is not completed at the moment of issuing an administrative act, irrespective of whether the results of the examination carried out by GIS were positive or negative.
The entity that intends to market a food supplement in the territory of the Republic of Poland has no legal or official instruments to present their arguments in the procedure. In the case when such an entity receives information that the GIS considers the product it intends to market as a medicinal product, it has no possibility of questioning such an opinion issued by the GIS.
The grounds behind this solution are that an investigation procedure is not a procedure to grant marketing authorisation like in the case of medicinal products. The entity intending to introduce a food supplement into the territory of Poland may launch the product after submitting notification or simultaneously while submitting notification.
However, it should be noted that due to no possibility for the entrepreneur to voice their argument in the investigation procedure, this procedure is incredibly defective and insufficient. It cannot be taken for granted that the bodies participating in the procedure will have the full picture of the marketed product.
The fact that the bodies participating in the procedure are aware that their opinions are not verified by any higher instance, particularly by a court, has a negative effect on the result of the procedure, rendering the performance of the procedure unprofessional.
Such an outcome of the procedure is unfavourable for the entity aiming at marketing a product. A positive opinion could not be used in the future as an argument that the product was marketed in Poland on the basis of an authorisation granted by the GIS. On the other hand, in the case of a negative opinion (e.g. qualifying the product as a medicinal product) the marketing entity is able to present its opinion not sooner than at the stage of the procedure to withdraw the product from the market. Unfortunately, this leads to an increase in costs of product marketing, with an uncertain result of the administrative procedure. Moreover, due to the two-instance nature of the procedure and the court supervision such a procedure takes a long time.

Supervision measures and sanctions

According to Article 32 of the AFNS if the product included in the notification is qualifies as a medicinal product or a medical device, a public poviat sanitary inspector (it should be underlined it is a body other than the GIS) decides to

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temporarily suspend marketing of such a food stuff or to withdraw it from the market until the investigation procedure is completed[16].
The supervision measures laid down in this provision is temporary and the deadline for its application is the completion of the investigation procedure. It should be noted that the provisions of Article 32 of the AFNS directly pertains to a situation when a product fulfils both the criteria of a medicinal product and a food supplement. There is no doubt whatsoever that in such a case a competent authority may undertake temporary measures, even when the product meets all the criteria to be qualified as a food supplement.
In practice in case regarding restrictions on marketing of products which are marketed as food supplements but at the same time fulfil the criteria for a medicinal product the provisions of Article 8 of the AFNS is applicable: "*public poviat sanitary inspector issues a decision to prohibit the products from marketing or orders withdrawal of the product from the market in the territory of the Republic of Poland as a food for particular nutritional use or a dietary supplement, which does not meet the criteria set for these foods in this Section*". The quoted provision is contained in Chapter II of the AFNS titled "*Health requirements and food labelling*" (Articles 5 to 52). The provisions on food supplements are contained in Section 7 Chapter II "*Dietary supplements and food fortification*" (Articles 27-29 of the AFNS). A sanitary inspectorate's body should apply the provisions of Chapter II of the AFNS that pertain to food supplements. The supervision measures provided for in the provision referred to should be undertaken only in the case when the product subject to the investigation procedure does not meet the requirements stipulated in the provision of Chapter II of the AFNS. These provisions do not state clearly that a product that meets the criteria for food supplements cannot meet the criteria for medicinal products at the same time. Unlike in Article 32 of the AFNS, in this case there is no direct reference to a situation when a product meets the criteria for a medicinal product and a food supplement simultaneously. This raises doubt as to whether it is possible to adduce this legal basis in a situation when a product fulfils the criteria for a food supplement stipulated in the AFNS, at the same time meeting the criteria for a medicinal product.
The sole fact that a product fulfils the criteria for a medicinal product, does not mean that it does not meet the requirements for a food supplement. On the other hand, it seems obvious that if a public poviat sanitary inspectorate is entitled to undertake temporary measures, it should be even more legitimate for it to undertake permanent measures. Therefore, it is justified to recommend an adequate change in the provisions in order to remove the ambiguity.

([16]) Compare Article 32 of the Act.

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Independently of the supervision measures stipulated in the AFNS, the provisions of the APL lay down specific measures regarding marketing of medicinal products. On the basis of the APL anyone who markets a medicinal product without a marketing authorisation is subject to a fine or a penalty of deprivation of liberty of up to 2 years[17].
Such a penalty is imposed following a court proceedings, so an entrepreneur has a possibility of defence. However, it should be pointed out that an opinion issued by the GIS on the basis of the opinion of the Office for Registration stating that the product meets the criteria of a medicinal product, will be taken into account in the decision whether or not to apply the pharmaceutical law provisions. Pharmaceutical law provisions are applied to products that fulfil both the criteria for medicinal products and food supplements (Article 3a of the APL).

6.- Conclusions

The solution stipulated in the Polish provisions of law regarding marketing of food supplements lacks transparency and does not guarantee proper protection of the rights of both entrepreneurs and consumers.
On the one hand, the situation where the GIS, as a body that carries out the investigation procedure cannot take any action that is legally binding in order to eliminated products that are unquestionably categorised as medicinal products but marketed as food supplements, poses a threat to consumers.
On the other hand, during an investigation procedure entrepreneurs cannot defend their rights. Decisions made during this procedure are not subject to any further verification by a second instance or court supervision, which is harmful for the interest of entrepreneurs. As a result of this legal solution, the outcome of an investigation procedure is decisive despite its non-binding character. The result of this procedure serves as a guideline for the poviat sanitary inspectorate bodies which have the power to make binding decisions (order to withdraw a product from the market, prohibition to market a product). Not until the procedure to prohibit product marketing or order its withdrawal has the entrepreneur an official possibility of expressing their view on the contents of the opinions issued by the GIS and the Office for Registration.
The legislative solution adopted by in Poland not only does not facilitate solving problems posed by the classification and qualification of borderline products, but

([17]) Article 124 of the APL.

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causes even more difficulties, which, unfortunately, hampers the free movement of goods on the European Union internal market.