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POLICY PAPER

Poland and Supplements:

Opportunities for European leadership

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Contents

Key Figures

4.4 bn PLN	the Polish dietary supplement market value in 2017
72%	of Poles admit to taking dietary supplements, while almost half declare that they take them regularly (48%)
27%	of Poles can properly define what dietary supplements are
37%	of Poles believe that dietary supplements are tested for efficacy
50%	of Poles believe that dietary supplements are subject to the same surveillance standards as drugs
4.2 bn PLN	was spent by the pharmaceutical industry on dietary supplement and over-the-counter medication advertising in 2018
6.24%	of dietary supplement control checks performed by GIS in 2018 had a negative, disqualifying result
2 years	is the average time it takes to make the first verification of a dietary supplement by GIS, during which time the product can be available for retail sale

Key Findings

The Polish (and any other) dietary supplement market suffers from two main imperfections:

- Consumers are not aware of the regulations governing the sale of dietary supplements, often mistake them with over-the-counter (OTC) medications, and lack knowledge on the effects of using supplements. This is the result of misleading advertising, misleading packaging, misleading pharmacy practices, insufficient access to information, and a low propensity to consult with physicians on taking these products,
- Dietary supplements are of questionable safety, which is the result of insufficient market surveillance, low barriers to entry for new products, and the lack of minimum safety requirements.

At the same time, the Polish dietary supplement market value continues to increase. Between 2008 and 2017 it has more than tripled (from 1.7 bn PLN to 4.4 bn PLN). The number of dietary supplement registrations with the Chief Sanitary Inspectorate (Główny Inspektorat Sanitarny, GIS) increased from around a thousand in 2008 to almost 13 thousand in 2018. More than 70% of Poles declare that they take dietary supplements. The quick growth rate is reflective of global trends and stems from the propensity of Poles to self-medicate, cost considerations, omnipresent advertising, and supplier-induced demand.

Independently, the abovementioned imperfections and the rapid growth would not necessarily be of concern. Rapid growth built on increasing demand from educated consumers purchasing safe products might otherwise be described as strong sector-specific growth. Imperfections alone, if they were present in a niche market, would have little capacity to do considerable harm. However, together they pose a potential threat to public health in Poland which highlights the need for a thorough assessment of policy solutions to these market problems.

Key Policy Proposals

Main proposals:

1. Introducing a fee on the registration of new supplements with the Chief Sanitary Inspectorate (Główny Inspektorat Sanitarny, GIS).
2. Increasing the capabilities of GIS in the area of market surveillance (especially with respect to tests of supplement samples taken from the market, for example tests of the composition or microbiological purity) by increasing its budget for such operations.
3. Improving the informative capabilities of the dietary supplement register maintained by GIS.
4. Amending advertising and packaging rules:
    a. Requiring that all laws on the advertisement of OTCs apply equally to dietary supplements,
    b. Increasing the fines which can be levied on advertisements that do not comply with requirements,
    c. Introducing the requirement that all packages of dietary supplements should have a legible, clearly visible, and large information that the product is a dietary supplement,
    d. Requiring language attesting to the fact that dietary supplements are not required to undergo testing for efficacy, that they are food products and not pharmaceuticals, and that they do not confer health benefits apart from those that can be achieved by a healthy and balanced diet (in a leaflet attached to packages),
    e. Banning advertising with implied claims of clinical efficacy,
    f. An inclusion of the following (or similar) warning message in all advertisements: “Dietary supplements are foodstuffs whose purpose is to supplement a normal diet”.
5. Introducing a consultation system between General Practitioners and patients.
6. Clear labelling of dietary supplements as such in pharmacy expositions, banning expositions implying clinical effectiveness of supplements.

Additional proposals (with somewhat ambiguous effects):

1. Increasing the VAT rate for all dietary supplements to the standard rate.
2. Requirement for e-commerce sales of dietary supplements to be linked to brick-and-mortar locations.
3. Co-localisation of pharmacies and small clinics / including pharmacists in the treatment process.

Introduction

The dietary supplement market is on the rise. It is estimated that the global market value exceeded 100 bn USD in 2018 and is expected to rise by around 7% per annum through 2025 (Grand View Research, 2019; Research and Markets, 2019). The Polish dietary supplement market has experienced dynamic growth, mirroring European and global trends. Over the last decade its nominal value has more than tripled, from 1.7 bn PLN (0.4 bn EUR) in 2008 (PMR, 2010) to 4.4 bn PLN (1.05 bn EUR) in 2017 (Śnieżek, 2019). Moreover, it is forecasted that the market will increase 5% per year in the immediate future.

The value of 4.4 bn PLN translates to per capita spending of 113 PLN in 2017. Almost three-quarters of the Polish population reports taking dietary supplements (72%), while almost half declare that they take them regularly (48%) (SW Research, 2017).

Though per capita spending on dietary supplements continues to increase, the salient public policy question is not whether Poles take "too many" dietary supplements, but whether there are sufficient safeguards against market failures arising from information asymmetry between producers and consumers. Many consumers believe supplements confer health benefits, when in reality, supplements are not subject to testing for efficacy and may in some cases be associated with medical harm. The results of the 2014 survey on the dietary supplements accurately represent this problem of information asymmetry. Only 27% of Poles could properly define what dietary supplements actually are, as many as 41% attributed medicinal properties to those products, 37% were convinced that dietary supplements are tested for efficacy, and 50% that they are subject to the same surveillance standards as drugs (Markiewicz, 2014; Najwyższa Izba Kontroli, 2017).

Polish lawmakers have sought to balance free consumer access to products with proper protections to public health. However, the ever-increasing use of dietary supplements in Poland, together with insufficient consumer knowledge on such products and their questionable safety suggest that a thorough assessment of the current policy solutions regarding the dietary supplements might be needed.

This report outlines the reasons the dietary supplement market deserves the attention of Polish regulatory bodies. Two fundamental imperfections of the market are identified: (1) insufficient knowledge of consumers on the benefits of supplements and regulations governing their market authorisation process as well as (2) questionable safety of dietary supplements, which stems from inadequate safeguards to protect customers from unscrupulous producers and unsafe products. Considering those imperfections, as well as the skyrocketing sales of supplements, this report raises policy proposals for protecting public health. Its construction is as follows. First, we demonstrate the legislation on the dietary supplements currently in force, present the evidence for the two abovementioned imperfections, discuss the current state of the Polish supplement market, and acknowledge the previous calls for legislative changes. Second, we debate the possible reasons for the information asymmetry, safety concerns, and high levels of use of dietary supplements in Poland. Finally, we propose policy solutions that could improve consumer

safety and awareness. Recommended policy solutions include: (a) advertising restrictions, (b) greater costs for introducing new products to the market, (c) tighter and well-funded market surveillance, (d) investment in the electronic communication systems, and (e) limiting the exposition of dietary supplements in pharmacies.

Defining the scope of the problem

Defining supplements

The European Union defines food supplements as "concentrated sources of nutrients (or other substances) with a nutritional or physiological effect. Such food supplements can be marketed in dose form, such as pills, tablets, capsules, liquids in measured doses, etc." The rules and regulations governing these products were harmonised in EU Directive 2002/46/EC with annexes listing vitamins and minerals permitted in food supplements and approved manufacturer sources (European Commission, 2019a).

In Poland, the 2006 Act on Food Safety and Nutrition (Dz.U. 2006 nr 171 poz. 1225) and a 2007 decree of the Minister of Health on the composition and labelling of dietary supplements (Dz.U. 2007 nr 196 poz. 1425) govern the regulation of these products. The law defines "dietary supplements" with virtually the same language as the EU directive, adding that they "exclude products possessing the characteristics of medicines within the meaning of pharmaceutical law."

In the United States, the primary law regulating these products is the Dietary Supplement Health and Education Act of 1994 (DSHEA), which defines a dietary supplement as "a product, other than tobacco, intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract or combination of any of the aforementioned ingredients."

CATEGORISING SUPPLEMENTS

One consequence of the broad and sometimes opaque definition of a supplement is that simply knowing that something is a supplement does not indicate anything about its efficacy or the safety profile for any given individual product. They operate in a grey area between medication and food products. There are several ways to categorise supplement products including:

- *Type of compound:* vitamins (such as D for bone health), minerals (calcium), herbal extracts (echinacea), specialty compounds (fish oils, glucosamine, probiotics, caffeine),
- *Stand-alone products versus mixtures,*
- *Manufacturer size:* Does the manufacturer of a supplement product also produce OTC medication or prescribed medications?
- *Intended use:* bodybuilding, beauty, energy, weight loss, etc.,
- *Target age group:* marketed towards the 65+ population, towards young men, pregnant women.
- *Country of origin*: Products sold in Poland may have origins in the EU, North America or Asia.

Even these minor differences in definitions, and the choice of the US and Poland to use "dietary supplement" rather than "food supplement" (Polish translations of the EU law use a separate term for "food supplement") (Zboralska, 2012), denote the lack of global consensus in terminology with regard to these products. Furthermore, the taxonomy of related terms without clear distinctions, such as "nutritional and herbal supplements (VHMS)" (Wilson et al., 2006), "functional foods" (Donato-Capel et al., 2014), and "sports supplements" (Martin, 2018) further public confusion about their distinguishing properties.

How much do people know about dietary supplements?

One central problem with the pharmaceutical market is that consumers are often unaware of the difference between over-the-counter medications (OTCs) and dietary supplements as well as the differences in regulations that govern their sale. The difference is that supplements are regulated for safety while OTCs are assessed for efficacy and safety. Another problem is that most consumers do not realise that supplements are not required to be subject to any safety testing prior to commercialisation.

Dietary supplements, also called food supplements, are exactly what the latter term implies – food. They are intended to correct malnutrition and nutritional deficits. Studies have shown that, if properly administered, supplementation achieves these purposes (Baldwin, Parsons, 2004; Hickman, Tapsell, 2009; Milne et al., 2009). Unlike drugs however, the vast majority of dietary supplements confer little to no health benefits, while a portion of marketed supplements can be considered harmful (Marik, Flemmer, 2012). Therefore, in most jurisdictions, food supplements cannot, through their labelling, claim to alleviate or prevent disease. Dietary supplements are consumed by as much as half of the population in developed countries (e.g., Kantor et al., 2016; Sirico et al., 2018), even though the knowledge on their efficacy, safety, and intended use remains obscure (Dodge, Kaufman 2007; Mozzafarin, Rosenberg, Uauy, 2018; Sirico et al. 2018).

Consumption of these products has increased in Poland. According to the Central Statistical Office, close to 50% of the population reported taking dietary supplements in 2016, a 10pp increase from 2010 (Główny Urząd Statystyczny, 2018). Knowledge on the supplement regulatory framework and their properties is also poor. As mentioned in the introduction, in 2014, 41% of Poles attributed medicinal properties to dietary supplements, 37% were convinced that dietary supplements are tested for efficacy, and 50% that they are subject to the same surveillance standards as drugs (Markiewicz, 2014; Najwyższa Izba Kontroli, 2017).

In a more recent study (though with a small, non-representative sample) published in 2019, knowledge about dietary supplements among Poles was also investigated (Karbownik et al., 2019). In one part of the study, authors compared knowledge about dietary supplements between people with medical and non-medical education based on a specially designed 17-part questionnaire.

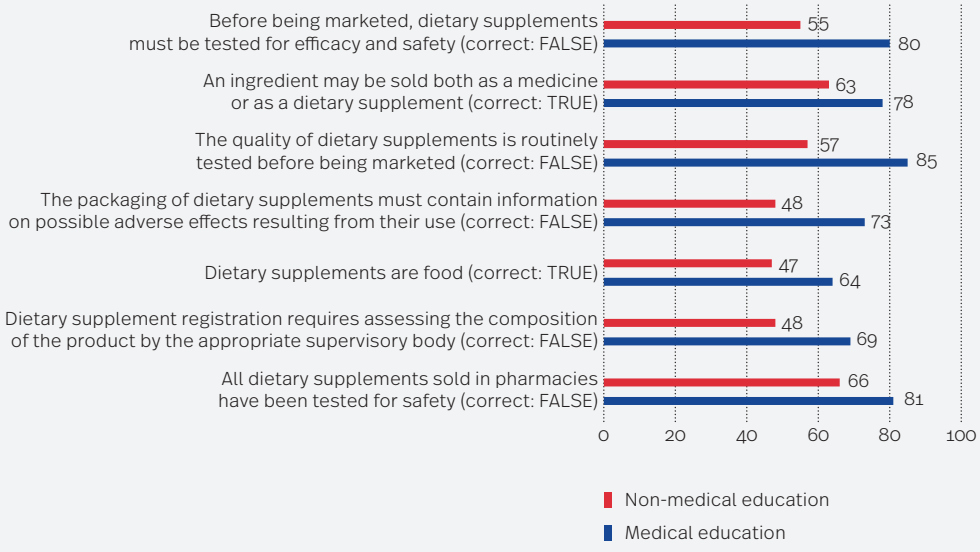
The first seven questions of the survey encompassed the legal framework for dietary supplements. The results (Figure 1) show that the non-medically educated respondents had little familiarity with those regulations. For example, only 55% of respondents correctly answered that dietary supplements do not have to be tested for efficacy and safety, 57% knew that the quality of those products is not routinely checked, and only

48% were able to correctly classify dietary supplements as food. These results are even more alarming given that the expected rate of correct answers for a survey with binary questions filled in at random is 50%. Respondents with a medical educational background performed more strongly. Still, their scores were far from perfect and reflective of a global trend of poor knowledge on dietary supplements even among medical professionals (Cellini et al., 2013; Ashar et al., 2007; Waddington et al., 2015). For example, around 19% were not aware that dietary supplements sold in pharmacies are not tested for safety, while 22% were unfamiliar with the fact that an ingredient may be sold both as a medicine or as a dietary supplement.

Subsequent questions probed common misconceptions about supplements (Figure 2). Scores in this category were even worse. Moreover, some misconceptions were shown to be even more pervasive among those with a medical education than the general public (though it has to be noted that some questions in this part are formulated in a rather confusing way)..

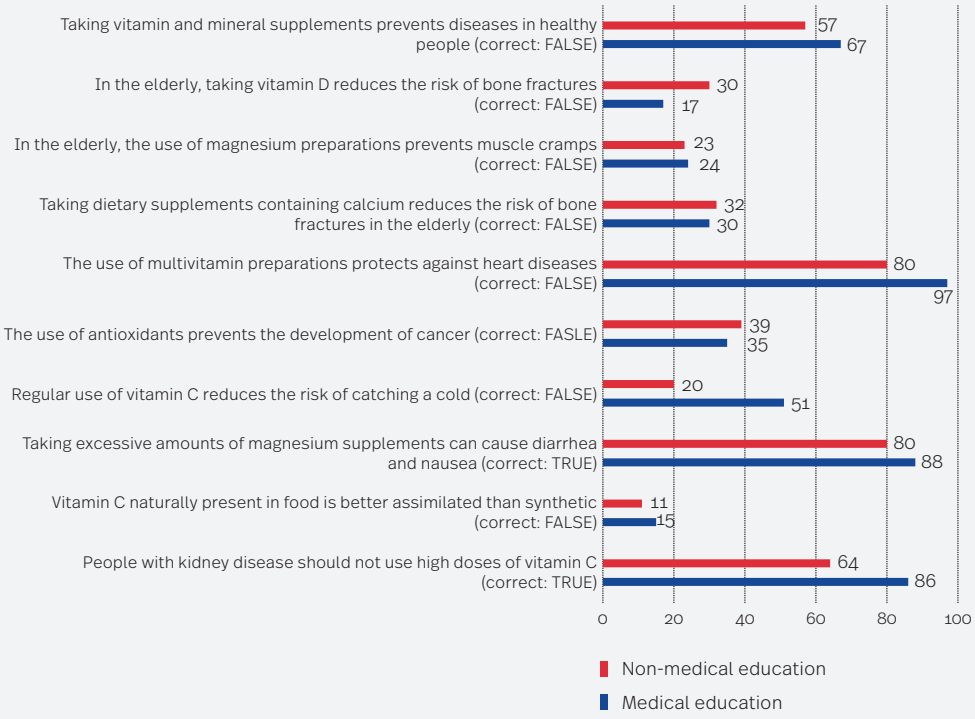
These results highlight the importance of educating people about food supplementation and seem to indicate that if the decision makers wish to make the food supplement market safer and more transparent, they cannot focus solely on supply-side measures, but also on the demand side.

↘ Figure 1. **Results of the survey on the knowledge about dietary supplements among non-medically educated and medically educated Poles – questions about regulations (percentage of correct answers)**



Source: own work based on Karbownik et al. (2019).

↘ Figure 2. Results of the survey on the knowledge about dietary supplements among non-medically educated and medically educated Poles – questions about benefits of consuming dietary supplements (percentage of correct answers)



Source: own work based on Karbownik et al. (2019).

Safety profile of supplements

In some circumstances, dietary supplements might confer health benefits for some individuals. The reason these products raise regulatory concerns is due to the presence of undeclared substances (da Justa Neves, Caldas, 2017; Guadiano et al., 2016) batch variation in preparations (Gurley et al., 2000; Stickel et al., 2015), contamination (Booker et al., 2016; da Justa Neves, Caldas, 2017; Stickel et al., 2009; Matthews, 2018), purposeful adulteration of products (Booker et al., 2009; Maughan, 2005), (often undisclosed) drug-drug interactions (Asher, Corbett, Hawke, 2017; Guadiano et al., 2016, Raynor et al., 2011), side-effects (Pittler, Schmidt, Ernst, 2005), and the replacement of supplement use for traditional sources of healthcare. Given the rate of contaminants discovered in those supplement products that are tested and the relative ease with which products can enter the Polish market (even those which have

negative evaluations from the US Food and Drug Administration, FDA), regulatory bodies are revisiting the need for tighter controls. Concerns about laxity of regulation of this market periodically arise both in the EU and the US (Cohen, Sharfstein, 2019).

EXAMPLES OF DANGERS FROM SELECTED GROUPS OF SUPPLEMENTS

Weight loss and body-building supplements

The potential dangers of weight loss supplements are well documented (González-Stuart, Rivera, 2018; Inayat et al., 2018; Petroczi, Taylor, Naughton, 2011). Weight loss supplements can include intentionally added but non-reported synthetic thyroid hormone, or "designer stimulants" such as 1,3-dimethylamylamine or methylsynephrine, which in some cases are advertised as having natural origins from geranium oil and orange peel bitter. Many designer stimulants have been banned in some jurisdictions due to reports of cerebral hemorrhage and cardiac arrest. In many regulatory jurisdictions, manufacturers have entered an arms race with regulators by producing a succession of related compounds with related functions but similar side effect profiles. Ephedra body-building supplements can include steroids or aromatase inhibitors (Matthews, 2018).

Products claiming to boost immunity

Products advertising immunity and recovery benefits have also come under scrutiny. Blue green algae (BGA) supplements such "Spirulina" raised concerns over carcinogenicity and toxic components, and in some cases have been found to contain a dangerous neurotoxin, anatoxin-a (Rellán et al., 2009). A study from Poland in 2017 found that users of these products experience significant side effects which are more pronounced in individuals with pre-existing chronic diseases (Rzymski, Jaśkiewicz, 2017).

Probiotics

Probiotics can contain or be contaminated with undeclared microorganisms (bacteria/fungi) (Sanders et al., 2010). In 2015 the Polish Supreme Audit Office oversaw research on probiotic dietary supplements. Even though the sample size was limited, in four out of eleven tested products the presence of undeclared bacterial stains, including the pathogenic Enterococcus faecium, was detected. Moreover, the number of live active bacteria in products was greatly exaggerated in almost all cases (Najwyższa Izba Kontroli, 2017). The common use of probiotics also confers the risk of transferring antibiotic-resistant genes from probiotic bacteria to pathogens, and consequently lowering the efficacy of antibiotics in the general population (Zheng et al., 2017).

An example helps illustrate the problem: men who bypass the traditional healthcare system and purchase supplements for sexual enhancement, out of embarrassment or due to cost, may put themselves at risk of exposure to counterfeit PDE-5i inhibitors (the class of drugs

that include tadalafil and sildenafil), and will not receive information about potentially deadly interactions between these products and other drugs. Moreover, problems with sexual performance associate with vascular, endocrine and psychiatric comorbidities that warrant screening, and will go undetected when patients "self-medicate" with supplements (Chiang et al., 2017).

Not all supplement products are created equal in terms of their capacity to do harm. Data from the Food and Drug Agency (US) help illuminate the need to stratify types of supplement products while tightening or implementing regulatory standards. In the United States, between 2004 and 2012, more than half of all Class 1 recalls by the FDA were for dietary supplements. Since 2018 there have been 26 FDA recalls for dietary supplements in the United States with nearly all of those products falling into the categories of male enhancement, weight loss, or muscle building products. The reasons for recalls included undeclared anabolic steroids, undeclared inclusion of PDE-5i inhibitors, and detection of other contaminants (Food and Drug Administration, 2019). These higher rates of contamination translate into poor health outcomes. A retrospective study from Harvard's T.H. Chan School of Public Health found that among adolescents and youth, muscle building, energy, and weight loss products were almost three times as likely to produce adverse events as vitamins (Or et al., 2019).

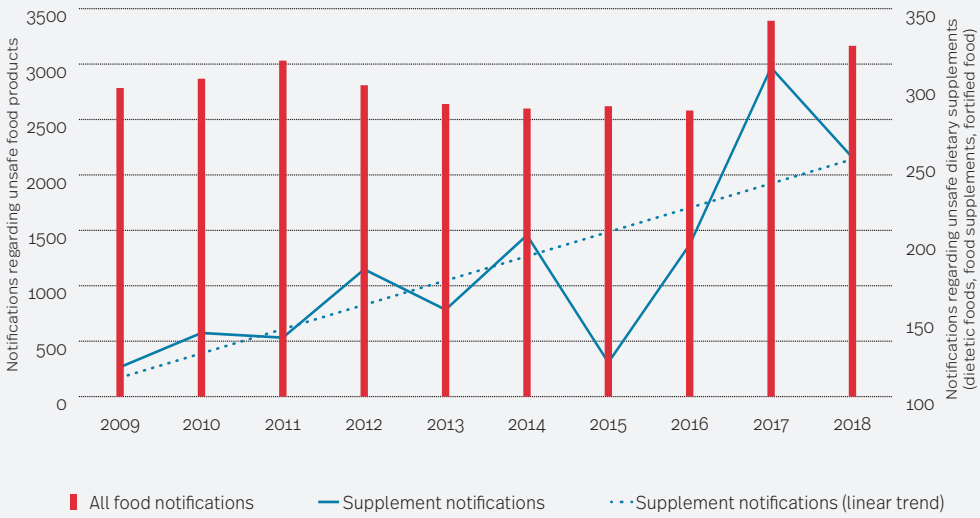
Analysis from the EU demonstrates a similar trend. The Rapid Alert System for Food and Feed (RASFF) collects information on adverse analytical results of food distributed within the EU. A study from 2011 found that the major categories of offending supplements included sexual performance enhancers, weight loss products and bodybuilding products. It should be noted that among these supplements which were notified for breach of safety standards, a majority were produced in non-EU countries (notably China and the United States) (Petroczi, Taylor, Naughton, 2011).

The data on market growth underscore the urgency to improve consumer safety: PMR data (Makowska, Jasiński, 2019) suggest that those types of supplements which are positioned for the highest growth are also those that have the most concerning safety profiles: supplements for athletes (including body-building), weight loss, libido, and products claiming to improve immunity.

The RASFF data also shows how, due to the increasing consumption of supplements, the safety of dietary supplements is becoming a pressing issue in the European Union. Analysis of the 2009-2018 RASFF data (European Commission, 2019b) shows that the number of notifications regarding dietary supplements has been on the rise this decade, while the overall number of notifications for all food products remained relatively stable (Figure 3). This phenomenon was present also in the first decade of the XXI century (Petroczi, Taylor, Naughton, 2011).

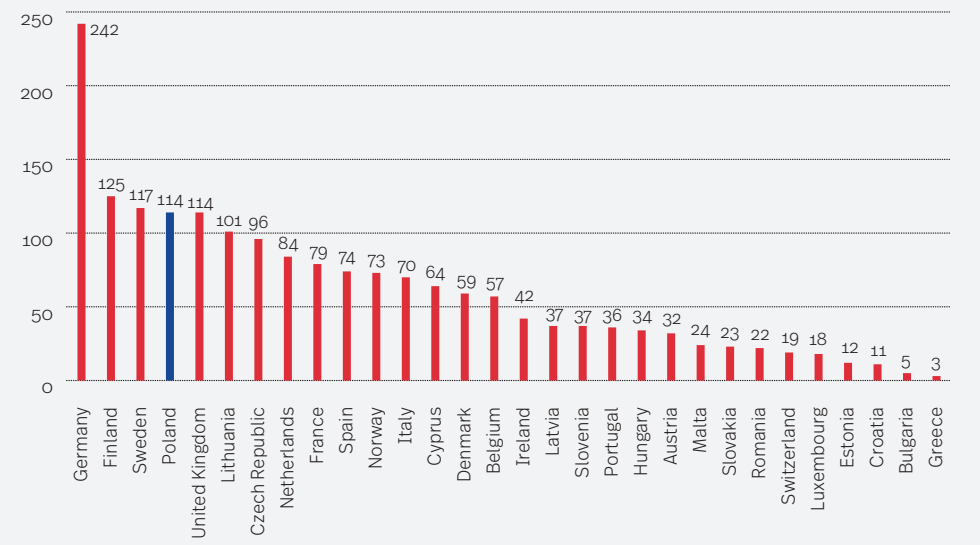
In 2011 products manufactured in Poland did not have an elevated rate of being detected for contaminants, nor did Polish regulators flag supplements for contaminants at a higher rate compared to EU averages (Petroczi, Taylor, and Naughton, 2011). This trend has since shifted. Poland seems to have improved its capabilities in detecting unsuitable supplements. Only three EU countries (Germany, Sweden, Finland) have flagged more products over the last decade (Figure 4). On the other hand, 39 products originating from Poland have been found to be unsafe and only products from United Kingdom, Netherlands, Germany, Sweden, France have been reported more often (Figure 5).

↘ Figure 3. Notifications regarding unsafe food products and unsafe dietary supplements (dietetic foods, food supplements, fortified foods) reported to RASFF between 2009 and 2018



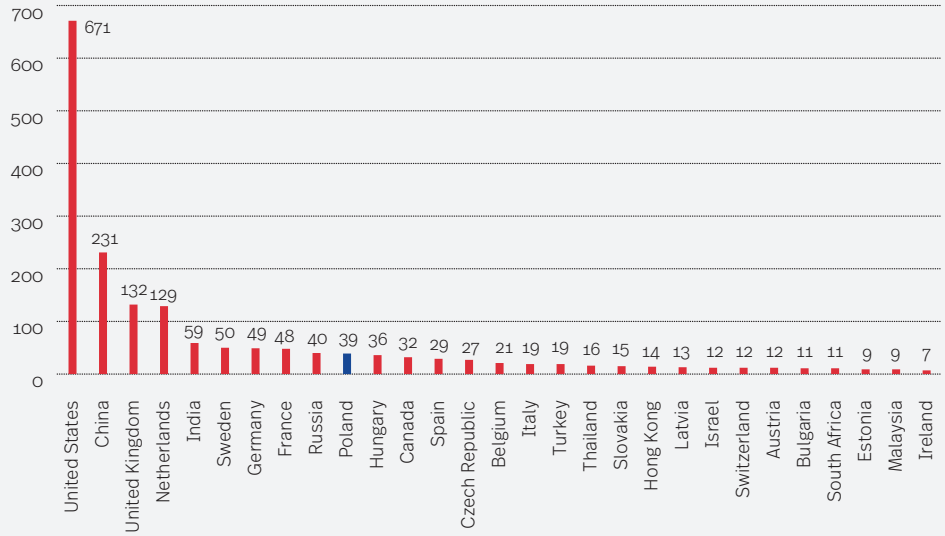
Source: own work based on RASFF Portal European Commission (2019b).

↘ Figure 4. Number of notifications sent to RASFF by reporting country (aggregate 2009-2018)



Source: own work based on RASFF Portal European Commission (2019b).

↘ Figure 5. Number of notifications sent to RASFF by the country of origin of the flagged product (aggregate 2009-2018)



Source: own work based on RASFF Portal European Commission (2019b).

HOSPITAL VISITS DUE TO SUPPLEMENTS

A 2015 study from the New England Journal of Medicine estimated that in the United States 23,000 emergency department (ED) visits are attributed to adverse events from supplement use yearly. In younger individuals, weight loss and energy products caused more than half of visits, frequently for cardiac symptoms. In the elderly, swallowing problems caused nearly 40% of ED visits due to many micronutrient products sold in oral tablet formulations approaching or exceeding 22mm in the United States (Geller et al., 2015). This study most probably underreported the ED usage caused by supplements as not all of these events are accurately categorised or reported. In the United States, about half of the population uses some form of supplement. No similar studies have been conducted in Poland as of 2019, however, since the utilisation rate in Poland is similar (Główny Urząd Statystyczny, 2018) it can be roughly estimated (assuming the same hospitalisation rate and accounting for population) that at least 2900 ED visits yearly can be attributed to adverse events related to dietary supplements.

Growth in the Polish Market

The imperfections of the Polish dietary supplement market described above would be less concerning if not for year-on-year increases in the size of the supplement market in Poland.

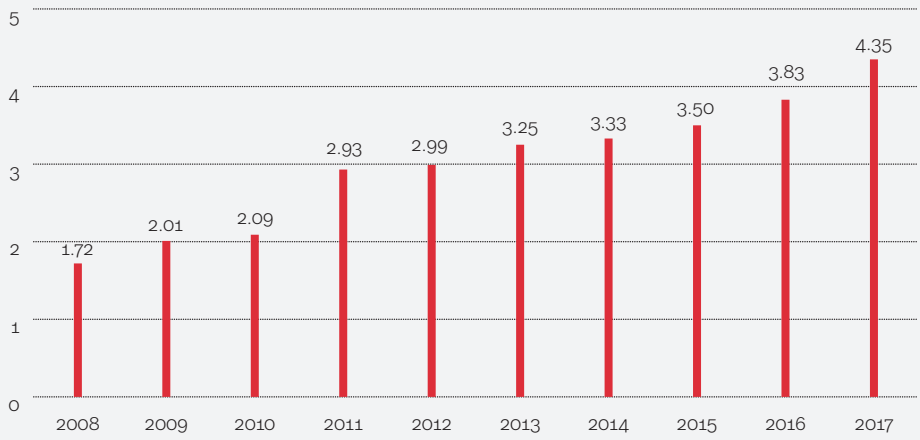
Increasing numbers of consumers (who are unaware of the intended use of supplements and regulations governing their sale) are purchasing more supplements (which are often unsafe or fraudulent).

A 2013 article from McKinsey described the global supplement market "as a robust growth sector" (Teichner, Lesko, 2013). It is estimated that the global market value well exceeded 100 bn USD in 2018 and is expected to rise by around 7% per annum through 2025 (Grand View Research, 2019; Research and Markets, 2019). The reasons for the fast rate of growth include (1) aging population demographics in major European and North American markets, (2) increased consumer awareness of preventative health in part thanks to "celebrity doctors," (3) the rise of self-medication, (4) large number of products, low barriers to market entry, and (5) increasing online sales (Dickinson et al., 2014).

Over the last decade, the Polish dietary supplement market increased more than two and a half times, from 1.72 bn PLN in 2008 to 4.35 bn PLN in 2017 (Figure 6). Growth to values well exceeding 5 bn is expected in the near future (Śnieżek, 2019). The most commonly used supplements include: magnesium, immunostimulants, probiotics, adult vitamins and minerals, muscle-building products, beauty products and weight loss products. The growth of the food supplement market in Poland is also notable for the recent spike in the number of new products registered with GIS. In 2008 there were 1,116 newly registered products while in 2018 this number has risen to 12,718 (Figure 7).

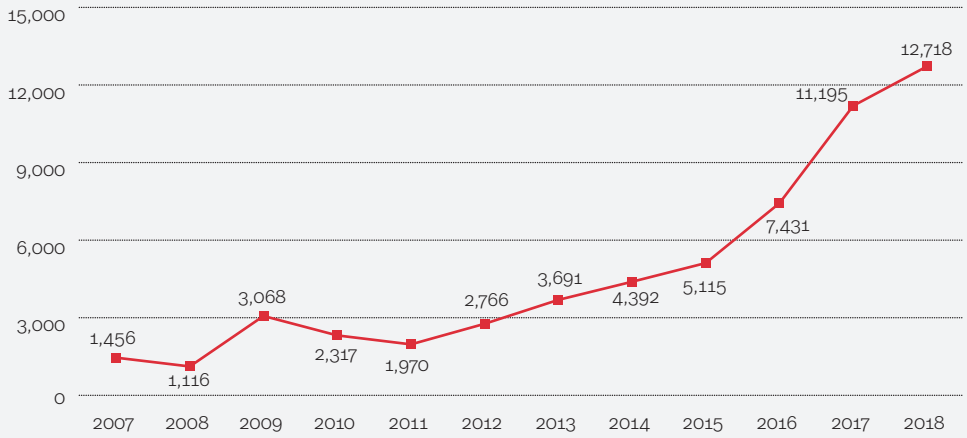
Growth in advertising for these products has also accelerated. According to a report from the Polish Ministry of Health, advertising expenditures on non-prescription items sold in pharmacies (including supplements, but also over-the-counter products and dermatologic-cosmetic products) between March 2017 and February 2018 was 1.961 million PLN representing a 15.8% increase from the previous year (Ministerstwo Zdrowia, 2018).

↘ Figure 6. **Polish dietary supplement market value 2008-2017 (bn PLN)**



Source: own work based on Instytut Ochrony Zdrowia (2017), Najwyższa Izba Kontroli (2017), Śnieżek (2019).

↘ Figure 7. Number of dietary supplements registered with the Chief Sanitary Inspectorate (2008-2018)



Source: Own work based on Główny Inspektorat Sanitarny (2019).

A 2017 report for SW Research found that about three quarters of Poles take dietary supplements, with about half of those taking them regularly (SW Research, 2017). Those study participants (N=584) who reported taking dietary supplements were asked to list their reasons for doing so: 55.4% cited a desire to strengthen the body, 44.3% sought immunity to infections, 40.7% wanted to supplement their normal diet, 35.8% aimed at having more energy, 31.7% cited beauty/aesthetic reasons (hair and nails), 23.8% wanted to treat a specific symptom, and 17.5% to have a slim figure. Ingredients, price, personal experience and the recommendation of a doctor or a pharmacist were the most important influences on the choice of supplement product. Of those polled, 65.0% purchased supplements in the pharmacy, while 10.4% purchased them online. While most Poles feel a positive effect from supplements, some 74.7% either believe that the components of supplements "certainly can be harmful" or "may be harmful" for the human body.

Calls for change

Calls for change in the regulations on dietary supplements are frequent in both academic and popular press. The most forceful document has been a 2017 report by the Supreme Audit Office (Najwyższa Izba Kontroli, NIK). The report indicated the presence of harmful substances in some dietary supplement products and called on the Prime Minister to consider supporting two sets of interventions: the first related to the regulation of dietary supplement products, and the second to advertising (Najwyższa Izba Kontroli, 2017). In terms of market authorisation, the document advocated for:

1. The introduction of a fee system for the notification of new dietary supplements.
2. The introduction of a warning system to notify consumers of supplements on the market for which proper notification has not been submitted to the government.
3. Removing from the Supreme Audit Office registry any dietary supplements which have been put under scrutiny for quality (especially relating to safety).
4. Regulating procedures for the withdrawal of dietary supplement products from the market, and ceasing production and marketing activities.
5. Instituting "zero tolerance" levels for specific compounds used in dietary supplements that are determined to be unsafe for human consumption.

In terms of advertising, the Supreme Audit Office recommended:

1. Increasing maximum fines which can be levied by GIS placed on businesses failing to comply with the requirements for labelling, presentation, advertising and promotion of supplements.
2. Increasing monitoring of advertising by GIS and the President of the Office of Competition and Consumer Protection.
3. Prohibiting the promotion or advertising of supplements as having medicinal or therapeutic properties.
4. Banning the inclusion of images of individuals from medical or pharmaceutical environments (or those suggestive of individuals having some medical or pharmaceutical education) in advertisements.
5. Regulating the practice of "umbrella branding" (creating uncertainty about whether a product is a medicine or supplement because of similar packaging).

In other areas it was suggested that:

1. The Ministry of Health should expand its educational activities regarding the rational use of dietary supplements.
2. Improving the capabilities of GIS in the area of monitoring the dietary supplement market. According to the report, the budget and staff constraints of GIS make it impossible to properly conduct market monitoring.

Other policy proposals, recommended by important stakeholders of the Polish healthcare system included:

1. Prohibition of images of medical professionals in the advertisements of dietary supplements, obligatory inclusion of a warning on the legal status of supplements in all advertisements, and other advertising regulations (similar to the ones already in place for the OTC medications) (Ministerstwo Zdrowia, 2016).
2. Transfer of competencies for monitoring dietary supplement advertising from the Office of Competition and Consumer Protection to GIS (Ministerstwo Zdrowia, 2016).
3. Total ban on advertising of OTC medications and dietary supplements (Naczelna Izba Lekarska, 2016).

Apart from minor changes, virtually none of the abovementioned regulations have been implemented as of November 2019.

Insufficient knowledge, compromised safety, high level of use – major causes

Low barriers to entry for new products

Introduction of new products to market is much easier for dietary supplements than for drugs. No clinical trials are required, neither is the testing of interactions with other products. Furthermore, supplements do not undergo quality or side-effect control. New products can be brought to market through an electronic notification system. Decisions are made based on the following criteria:

- The name of the product and its producer.
- The form of the product in which it is placed on the market.
- The labelling in Polish.
- The qualification / type of foodstuff accepted by an entity operating on the food market.
- Qualitative composition including data on the ingredients contained in the product, including active substances.
- Quantitative composition of ingredients.
- Name and surname or name and address of the notifying entity and NIP number if that entity has one.

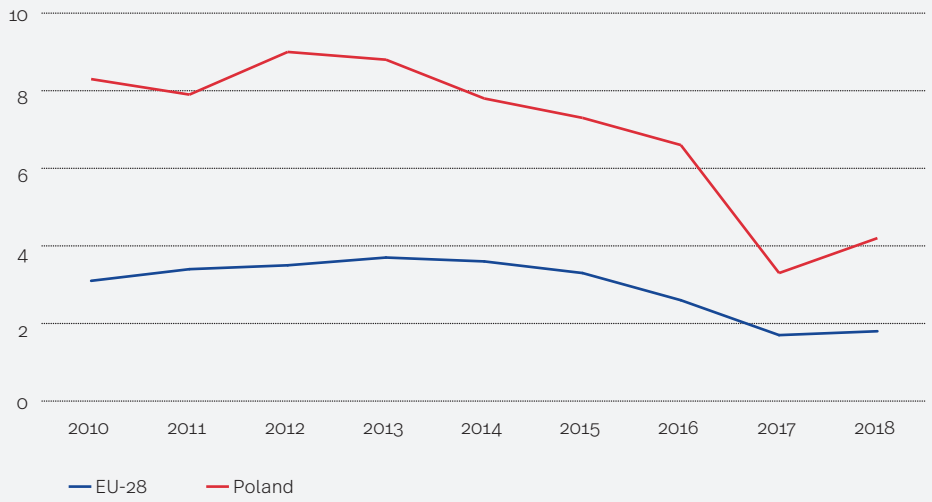
At present, there is no fee for submitting a notification to GIS of an intention to bring a new dietary supplement product to market. This has several unintended consequences, one of which is that some entities will submit applications for products with no intention of bringing those products to market, but as "trial balloons" to test how GIS will react (or not react) to the inclusion of particular substances (Najwyższa Izba Kontroli, 2017).

Structural problems in Polish healthcare: Access, Trust, Costs

One prominent hypothesis is that Poland's relatively high use of dietary supplements is a consequence of low investment in preventive healthcare services. While safe use of supplements may be increased with greater access to general practitioners, it is unlikely that improving access to primary doctors will decrease overall use of dietary supplements. One reason is that data suggests that healthcare access positively correlates with some kinds of supplementation (Shaikh, Byrd, Auinger, 2009; Vatanparast, Adolphe, Whiting, 2010). For example, in the paediatric population, the use of vitamin supplements is positively associated with healthcare access and economic status (Shaikh, Byrd, Auniger, 2009). Thus, while having access to reliable primary care may limit the use of some supplements, it may encourage the use of others for which observational studies have demonstrated some preliminary health benefits. Second, the number of Poles reporting financial or logistical barriers to getting healthcare has decreased during the same period that sales of dietary supplements have spiked (Figure 8). While access in an aggregate sense may have

improved during the last five years, the question of whether Poles feel barriers to professional consultation on questions of weight loss, erectile dysfunction, vitamin supplementation, which would be relevant to the use of dietary supplements, is unknown.

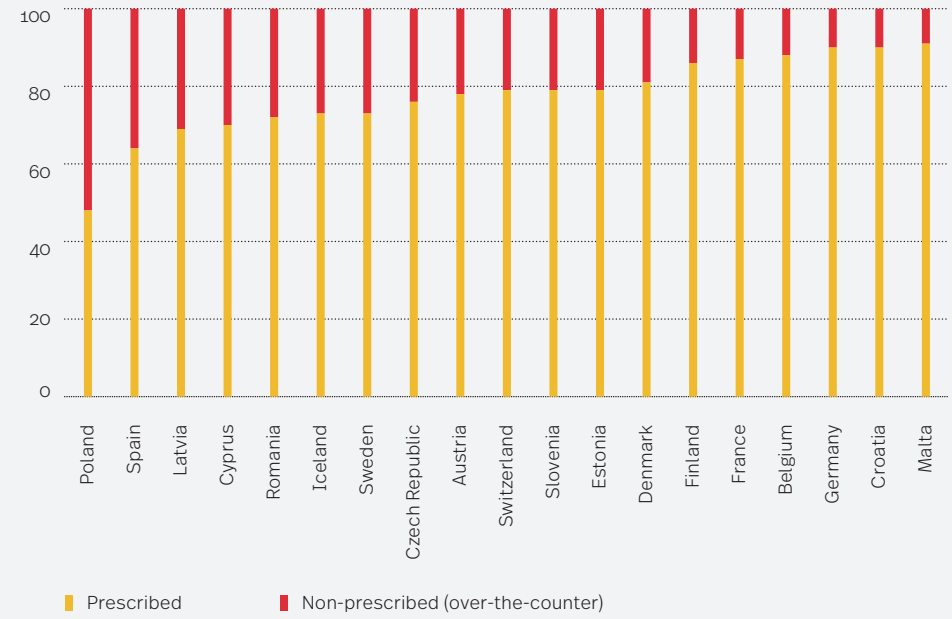
↘ Figure 8. **Proportion of people with self-declared unmet needs for health care services due to either financial barriers, waiting times, or travelling distances in Poland and in the EU (%)**



Source: Eurostat.

On the other hand, self-medication is highly prevalent in Poland. According to the OECD, Poland has the highest share of OTC medications as measured by total retail pharmaceutical sales (Figure 9) (OECD, 2018). Moreover, according to Eurostat, in 2014, 52% of Poles admitted to taking non-prescribed medicines, which, among the EU countries, placed Poland only behind Finland (70%), Lithuania (57%), Denmark (56%), and Latvia (54%). The causes of Poland's relatively high level of self-medication may include convenience and availability, omnipresent advertising, and healthcare access problems. Another factor that likely drives Poles towards self-medication is the low overall reimbursement level of prescribed drugs. In 2016 the per capita drug reimbursement via compulsory schemes was equal in Poland to 90 EUR, third lowest in the EU (Figure 10). Taking high levels of competition and consequent low prices in the OTC market into account, self-medication may simply be more affordable than treatment with prescription drugs, which are subject to high co-payment rates. Since, as previously mentioned, people often are not aware of the differences between OTC drugs and dietary supplements, it is possible that the same drivers are fuelling the recent surge in supplement consumption and high OTC consumption and purchases, namely, barriers to access and cost considerations.

↘ Figure 9. Share of prescribed and non-prescribed medications in total pharmaceutical retail expenditure in selected European countries (%, 2016)



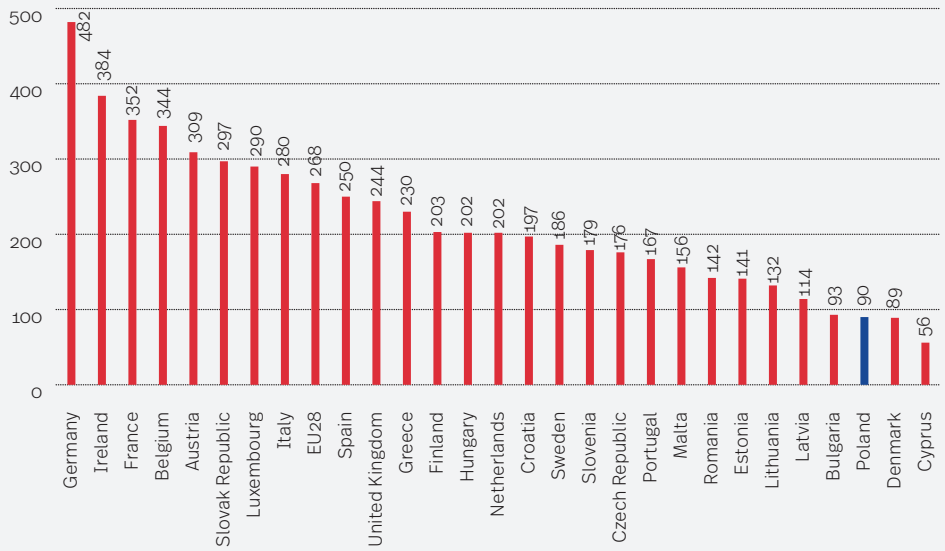
Source: OECD (2018).

Most Poles do not take supplements at the suggestion of their healthcare provider, but rather use them to self-treat, self-diagnosed health problems. However, trust in the healthcare system can cut both ways in terms of sales impacts. Often, medical recommendations fluctuate with the publication of observational and randomised studies on the effects of supplements. In Poland, the high rates of use of supplements for weight loss, building muscle, nail and hair health, erectile dysfunction and low energy may represent greater trust in these products than in the traditional healthcare system (or an acceptance of risks against the benefits of cost and expediency). However, the healthcare system and its associated research environment can also drive the use of supplements.

This is true in the United States where a study of the National Health and Nutrition Examination Survey (NHANES) found that while the use of supplements in the United States was stable between 1999 and 2012, the use of specific supplements changed after media reports of primary research on their health benefits (Kantor et al., 2016). In that study, the use of multivitamins and multimineral products decreased from 37% to 31% during that time frame. Notably, use of individual supplements fluctuated with media reports of evidence from major trials. The use of omega-3-fatty acids increased by 7-fold given preliminary reports of its salutary effects on cardiovascular health. It remains to be seen whether these increases will hold after the negative results of the VITAL trial (Manson et al., 2019).

Increases in Vitamin D consumption aligned with research on the beneficial role of Vitamin D with regard to bone health, cancer, cardiovascular diseases, and mental health. Increases in the use of lycopene after the publication of results suggesting it reduces prostate cancer risk, resulted from the inclusion of this compound in multivitamins rather than purchases of singular formulations. The use of glucosamine and chondroitin decreased after the GAIT trial in 2006 suggesting it had no impact on joint structure, function or pain outcomes (Di Nubile, 2018). Recent data suggests that taking Vitamin D together with calcium increases the risk of stroke, which may or may not produce a market response. In almost all cases, effect sizes are so low (in either direction) that they cast doubt on any of these associations (Kahn et al., 2019).

↘ Figure 10. **Per capita drug reimbursement by compulsory schemes in the EU (2016)**



Source: own work based on OECD (2018).

In summary, access and trust in the healthcare system can influence demand for supplements, but the direction of the effect may be ambiguous and depends on other factors. Access and trust in the healthcare system may also affect the kinds of supplements sought by consumers.

Success of advertising

According to the Institute for Media Monitoring, in 2018 the pharmaceutical industry spent 4.2 bn PLN on advertisement in TV, press, and radio (Instytut Monitorowania Mediów,

2019). Most advertised products included anti-inflammatory medications, painkillers, vitamin and mineral supplements and beauty products.

Direct to consumer (DTC) advertising of OTC drugs is legal in Poland, under specific regulations and conditions listed in the Act from the 6th of September 2001 "Pharmaceutical Law". Advertisements cannot, among others, be directed at children, claim that the product is beneficial to healthy people, or claim that efficacy and safety of the product is ensured by its natural origin. Moreover, the advertised drug cannot be presented by people publicly known, scientists, people with medical degrees or suggesting that they have such degrees. Meanwhile, dietary supplements are not subject to such regulations, since they are considered to be food products and not pharmaceuticals.

Low margins on prescription medications

A report from the Association of Polish Pharmacists and Pharmacy Owners (Związek Aptekarzy Pracodawców Polskich Aptek) linked margins in pharmacies with pressures related to new laws limiting margins on prescribed medications. As a consequence of the 2012 pharmaceutical law, prices of pharmacy products eligible for refund (which includes most prescribed medication) are contained by a fixed cap on margins (Jahnz-Różyk et al., 2017). This was part of an effort to reduce consumer drug prices. As a consequence, pharmacies struggle to generate profits from refundable medications and instead focus efforts inducing footfall into their retail space to purchase dietary supplements for which there are different pricing rules, thus creating a form of a supplier-induced demand.

Policy proposals

Taking a patient-centred approach to policy-making

The central principle of any policy program related to dietary supplements should be protecting citizens against public health threats, while respecting consumers' right to have access to a diversity of safe supplements, even if evidence for their efficacy is mixed or non-existent. Rather than beginning with the goal of "punishing" manufacturers, the starting principle should be thinking about citizens and how to best help them lead healthy lives in a society based on free-market principles.

Imposing a fee on the registration of new supplements

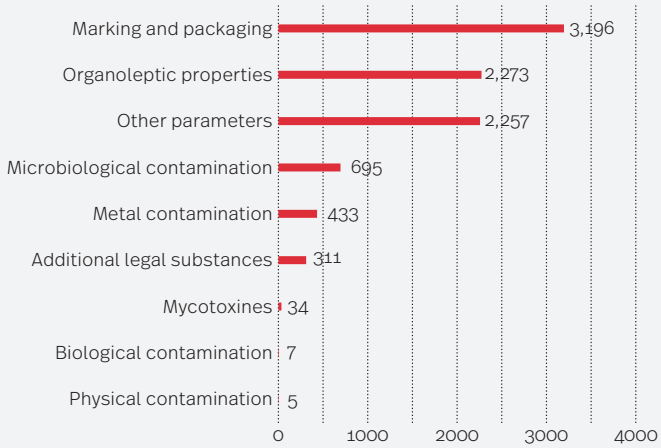
As there is no notification fee required by GIS to bring a new dietary supplement product to market, some applications are submitted with no intention of bringing those products to the market (the already discussed "trial balloons"). This phenomenon increases workload on GIS experts and limits their capability to fulfil other duties. A fee on the registration of new supplements could highly curtail such actions, though it could, at the same time, have a negative effect on the level of market competition.

Improving the capabilities of market surveillance

There is no gold-standard set of policy interventions that have proven successful in protecting people from the potential dangers of supplements. In the EU, as supplements are considered food products, it is up to the manufacturers, importers and distributors to ensure their safety. Poland, like other EU member states, requests notification for new products coming to market. Unfortunately, due to budget and staff shortages, the body responsible for market authorisation and market surveillance of dietary supplements in Poland, i.e. the Chief Sanitary Inspectorate (GIS) does not fulfil those responsibilities properly. According to the NIK report (Najwyższa Izba Kontroli, 2017) between 2014 and 2016, GIS commenced the verification procedure, on average, 240 days after it had been notified about the product by the manufacturer. Afterwards, the average time of verification was equal to 455 days (several times longer than the maximum time of 60 days defined in the Act on Food Safety and Nutrition). Current regulations make it possible for producers to introduce the product to the market immediately after sending the notification (i.e. regardless of the pending verification process). This means that unverified (and potentially illegal or dangerous) products can be bought from retailers for approximately two years before GIS verifies their composition and documentation. Other regulatory procedures were also severely delayed.

GIS has the legal capability to perform controls of dietary supplements available on the market. These controls are done through two channels: random sampling and controls of products, for which there is a suspicion of not adhering to the regulations (e.g. reports from consumers or independent laboratories). Unfortunately, only a small proportion of supplements undergoes such scrutiny (Najwyższa Izba Kontroli, 2017). In 2017, GIS performed 4,280 checks of supplements out of which an astounding 6.24% had negative, disqualifying results (Interpellation No. 22662, 2018). This would suggest that one out of every 16 dietary supplement brands offered in Poland does not adhere to the regulations. Given that GIS controls are incomprehensive and focus on a particular aspect of the product, as well as the fact that relatively few of the controls are directed at detecting contamination (Figure 11), the true percentage of dietary supplements that ought to be disqualified could be even higher.

↘ Figure 11. **Number and targets of dietary supplement controls performed by GIS in 2017**



Source: Interpellation No. 22662.

It is impossible to calculate the percentage of products that have undergone testing as the number of available products is unknown. Still, given relatively meagre minimum standards related to contamination and composition, as well as the significant number of flagged products, Polish authorities should increase their efforts in dietary supplement market surveillance. The theory of the economics of crime (together with empirical studies) suggest that to combat illegal behaviour both degree of punishment and probability of detection must be optimised (Freeman, 1999). That is why, in order to deter manufacturers from launching harmful products, not only should fine increases be considered (as it is often suggested), but new systems to increase the probability of detection of illegal practices should be evaluated. Allocating more funds to GIS for the purpose of dietary market surveillance would accomplish this goal.

Improving the informative capabilities of the dietary supplement register

Manufacturers of dietary supplements and other specialist foodstuffs have to notify GIS if they intend to introduce a new product to the market, as mentioned. GIS maintains a registry of these products, which is made available to general public. Unfortunately, in its current state, the registry neither constitutes a trustworthy source of information on supplements for consumers nor a reliable data source for researchers and Polish authorities. Shortcomings of the registry include:

- The registry does not currently hold information on whether a product is still available on the market. Manufacturers do not have to inform GIS about market withdrawals. Thus, it is impossible to assess several key features of the market, including the number of available brands. Manufacturers should be obligated to inform GIS if they have ceased to distribute the product. Two columns should be added to the registry: date of market introduction and date of market withdrawal. The latter should remain empty if the product is available and contain a date of market withdrawal if the product is no longer sold.
- Currently the registry does not hold any information about current or past audits/testing of supplements. Nor does it include information on recalled products. An additional table ought to be added which includes the results of product testing and auditing. This table could contain the following columns: product identifier, control identifier, date of sampling, date of the final results, scope of testing, results, reason for product audit (random sampling vs. control due to suspected wrongdoing). Additionally, these tables should include information on recalled products including date of recall, details on the company, and the class of supplement.
- The registry does not adhere to good database design practices and should be evaluated. Problematic examples include:
  - Several columns that should be designed in the format of a drop-down list do not have such a feature, which results in typographical errors and varying inputs for the same information, rendering it impossible to reliably use the database without prior extensive cleaning.
  - The database is unnormalised. At the very minimum, the downloadable version of the dataset should adhere to the properties of the first normal form (Codd, 1970).

Amending advertising and packaging rules

The Polish Society of Physicians and Dentists has advocated for an outright ban on all advertising of OTCs and dietary supplements (Naczelna Izba Lekarska, 2016), however it is unclear whether such a measure would be in accordance with EU law which demands that "national regulations of the member states on the advertising of medicinal products cannot be more restrictive than the provisions of the directive 2001/83/EC." Other advertising solutions have been implemented, including a ban on images suggestive of medical environments or practitioners (in the physician's ethical code of conduct). The reality is that many producers of

OTCs and supplements have found loopholes by displaying the images of individuals whose status as connected to the medical establishment is not straightforward. Others have claimed they are only showing "experts with white coats" who are not doctors, medical professionals, or scientists. An array of advertising recommendations has been put forward recently (Ministerstwo Zdrowia, 2016; Najwyższa Izba Kontroli, 2017), many of which could reliably tackle the problem of information asymmetry between producers and consumers of supplements. Drawing on those recommendations, the list of potentially most effective solutions includes:

- Requiring that all laws on the advertisement of OTCs (as specified in the Pharmaceutical Law Act) apply equally to dietary supplements,
- Increasing the fines levied on non-compliant advertisements,
- Outlawing the practice of "umbrella branding" (which creates uncertainty about whether a product is a medicine or supplement because of similar packaging) by introducing the requirement that all packages of dietary supplements should have legible, clearly visible text, in large print, that the product is a dietary supplement,
- Requiring language attesting to the fact that dietary supplements are not required to undergo testing for efficacy, that they are food products and not drugs, and that they do not confer health benefits apart from those that can be achieved by a healthy and balanced diet (in a leaflet attached to packages),
- Banning advertising with implied claims of clinical efficacy (for example, advertising a product as a weight loss aid claims a clinical result for which there is no required testing),
- An inclusion of the following (or similar) warning message in all TV, radio, billboard, leaflet, internet, and press advertisements: "Dietary supplements are foodstuffs whose purpose is to supplement a normal diet".

Taxation: Demand elasticity of various supplements?

Taxation of dietary supplements could decrease sales of these products, but would carry unintended consequences, making it a less attractive policy alternative. First, the demand elasticity of specific dietary supplements is unclear. It may be the case that implementing a tax most affects the sales of supplements that are the most benign or those that might even have a positive effect (vitamins and minerals), while sales of weight loss products which carry greater safety risks would be less affected. These empirical questions remain without answers in the literature and represent policy risks. Moreover, if these products are taxed, but still are the only products to generate profit margins, pharmacies may be further incentivised to promote the sales of supplements.

However, taxing high risk supplements with the justification that these revenues would be used for safety testing, could have salutary effects. If additional taxation of dietary supplements was to be introduced, the easiest way to conduct such a reform would be to increase the VAT rate for supplements from the currently used reduced rate of 8% to the standard 23% rate. Doubtless, such a solution would curtail the sales of all types of supplements, however the exact degree is impossible to assess (and the result could be far from the desired one, as mentioned). Moreover, there is no guarantee

that additional funds gained from increasing tax rates on supplements would be used to increase market surveillance or conduct educational campaigns for consumers.

Utilising pharmacies for short clinical encounters

In many countries, pharmacies are sites of small clinics offering basic medical services such as blood pressure checks, diabetes management, mental health screening, weight loss counselling, vaccinations and travel medicine. These clinics are often operated by nurse practitioners or pharmacists themselves. Using these high traffic medical institutions for such purposes could help divert individuals with health concerns to the medical system rather than to dietary supplements (Knapp et al., 2019). Empowering pharmacists as care providers has been debated in Poland, due to the fact that Poland has a relatively low supply of physicians and nurses and a relatively high supply of pharmacists (Deloitte, 2018).

Despite obvious benefits, this solution presents significant drawbacks. Pharmacies in Poland are private businesses connected with the healthcare system by reimbursement laws. This means that virtually all pharmacies in Poland are for-profit. Integrating pharmacists into the provision of healthcare could incentivise them to sway patients towards supplements (for which the profit margins are highest, as mentioned) and away from seeking traditional medical help.

Cracking down on internet sales

According to SW Research survey data from 2017, about 10% of Poles who purchase dietary supplements do so through the internet (SW Research, 2017). Internet sales introduce less regulatory control as they decrease the barrier to entry for new, smaller companies that may have less capacity for internal safety testing. Additionally, products sold over the internet may have production origins in places with more concerning safety records. One way of restricting internet sales could be to require e-commerce sales of dietary supplements to be linked to brick-and-mortar locations, or to brands that also have large prescription medication arms, and experience meeting higher safety standards. In other words, we would propose required registration for e-commerce sales in Poland, with a reliability test. This is akin to the kind of self-regulation promised by many of the big manufacturers after publication of the 2017 NIK report. Large manufacturers have more to lose from bad press generated by adverse events caused by sales of dangerous supplements by small players, than the small players do, and thus have an interest in self-regulation.

Healthcare system interventions

One major concern with dietary supplements is that often doctors do not know their patients are taking them, and potential interactions remain unchecked. Part of this is due to the relative infrequent interactions between doctors and patients. Although the

likelihood of an integrated electronic health record system in the Polish outpatient setting is low in the near term, the introduction of a simple communication system, even based on e-mails or secure messaging, for patients to notify doctors of new health concerns, or new supplements, could mitigate harm associated with the use of these substances. Doctors who receive notice that a patient would like to lose weight and is going to try a supplement, can begin to formulate a plan to help that patient address the issue, and also provide information on potential risks of different supplements. Transparency can be a form of harm reduction.

Packaging and advertising signage within pharmacies

It has been suggested that untested dietary supplements should not be sold in pharmacies (Naczelna Izba Lekarska, 2016). While such a solution has obvious benefits, it might not comport with the EU law (Interpellation no 22662). Moreover, given that the profit margins on supplements, and their importance for the balance sheet of pharmacies (Związek Aptekarzy Pracodawców Polskich Aptek, 2019) such a solution could severely cull the number of operating pharmacies on Poland, and thus lower their accessibility. Consequently, a total ban on the sale of untested supplements in pharmacies may not be viable in Poland.

However, regulating the display of products in pharmacies may be a path forward. In many Polish pharmacies products are organised by category. For example, someone with indigestion first scans the shelves for a sign indicating "digestion related products" under which they find antacids, omeprazole, pantoprazole, and other products. While this serves to assist customers to more quickly find their target product, in some cases, it serves as a way to reinforce health claims that are not founded in medical research. For example, pharmacies often label shelves advertising "weight loss products" thereby lending medical credibility associated with pharmacies to products with mixtures of caffeine, pyruvate, carnitine capsaicin, and other compounds for which evidence is at worst non-existent, and at best, very limited. For patients with high blood pressure, diabetes, heart disease, or liver disease, some of these compounds can even be dangerous.

People trust pharmacies as medical institutions that dispense medications and knowledge. Over 90% of Poles trust pharmacists (Medexpress, 2019). Since supplements are not tested before they reach the market, it is irresponsible for pharmacies to advertise these products under signs confirming the claims made by the manufacturers. That is why, supplement products should be labelled more clearly than is required at present. Another potentially beneficial regulatory measure would be to require pharmacies to display dietary supplements explicitly with signage indicating they are "not medications" as a way of differentiating the products for consumers.

This regulation could also incentivise producers to replace some of the dietary supplements they produce with OTC medications (i.e. products tested for safety and efficacy) in order to gain better exposure in pharmacies.

Conclusion

The global dietary supplement market has grown substantially in recent years. Alongside the growth of this sub-sector, public health advocates and policy makers have raised concerns about potential harms that may arise from limited regulatory oversight and information asymmetry. In Poland, the number of dietary supplement products registered with the Chief Sanitary Inspectorate has increased in the last decade, just as the number of supplements flagged by the EU's RASFF system for recall has increased across the continent.

In this policy paper, we have proposed interventions to serve as guardrails to protect public health as this sub-sector is predicted to grow over the next decade. No governmental authority has arrived at an ideal approach to the issue of regulating dietary supplements, in part because of the definitional challenges in separating them from prescription and OTC medications in the mind of the public. We argue that the highest priority policy changes that should be considered include:

(1) imposing a fee on the registration of new products to help pay for testing,
(2) expanding the capacity for the relevant bodies to test more products (e.g. qualitative and quantitative tests of the composition, tests of microbiological purity,
(3) substantially improving the Chief Sanitary Inspectorates data reporting system for registered products and their testing,
(4) updating rules on packaging, advertising, and pharmacy displays, and,
(5) improving electronic health systems to improve communication between providers and patients.

Additionally, greater research on morbidity associated with improper use of supplements or adulterants found therein is warranted. Further work should evaluate the efficacy of policy interventions across EU countries to identify approaches that may be applicable. In this way, Poland has the opportunity to take European leadership in addressing this important public health concern that has challenged regulatory agencies across the globe.

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