

THE APPLICABLE REGULATION CONCERNING VITAMINS AND VITAMINIC SUPPLEMENTS USED BY ALBANIAN POPULATION

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Abstract

Choosing the right diet and healthy food is becoming a challenge nowadays taking in consideration the lifestyle we are having. Sometimes it is difficult to consume fresh and secure alimentary products. Moreover consuming more food outside the house makes it difficult to rate the products we are having, their freshness, way of being cooked and therefore their nutritive characteristics.

Vitamins are organic compounds which are needed in small quantities to sustain life. Vitamins help the metabolism in general, they are crucial to growth, to fitness, and to healthy mental and physic conditions. We get vitamins from food because the human body does not produce them. Due to the lifestyle and the characteristic of vitamins, it is becoming difficult to get the right amount of vitamins by simply consuming food; therefore a lot of people are getting these elements through pharmaceutical preparations, the so called food supplements.

The pharmaceutical environment is rich in such products therefore, it is important to know what we are taking, and make a curative assessment of what is really needed in order not to exceed and have the opposite result of toxic amounts of vitamins in the body. On these terms, it is interesting to have more information also on applicable regulations concerning these products. What are the laws and by-laws that regulate their placement on the market? What is allowed for use during production and the respective allowed quantities? Even though these products might seem "easy and light products" compare to the real pharmaceutical drugs still their extended use and accessibility from different range of populations makes it even more important this level of knowledge.

The paper here presented intends to give a short overview of applicable laws and regulation in regards to

these products in Albania compare to EU/USA. Moreover, it is an introduction of a two year study related with the recent situation of the consumption of vitamins and food supplements reach with vitamins in Albanian population.

Key words: Vitamins, Food supplements, Knowledge, Healthy food, Law, Regulation.

1. Introduction

Vitamins are micro-compounds that assist body in many important physiological and biological processes such as: growth, metabolism, and ability to fight infections and in general on the well-being mental and physical state. In addition, they create the right conditions for the effective use of carbohydrates, proteins and fats by being the catalyst of many biochemical processes of the body. Even though vitamins are involved in energetic processes, themselves are free from energetic values.

The most practical way of classifying the vitamins is the one based on their solubility in water. Taking in consideration this ability, vitamins are divided in two big groups:

- Hydrosoluble vitamins (Biotin, Vitamin C, and group of Vitamins B (Thiamin - B1, Riboflavin- B2, Niacin- B3, Pantothenic acid - B5, Pyridoxine - B6, Folic acid - B9 and cobalamin - B12). These vitamins are easily spread in the body tissues and are not stored or deposited. The quantity of vitamins not used by the body is metabolized and excreted from the body.
- Liposoluble vitamins (Vitamin A, D, E and K). These vitamins are stored and deposited in the body. The main deposit places are the liver and fat tissues.

We get vitamins through food and diet. Even though vitamins are present in food, sometimes consuming just food does not satisfy our daily need for certain vitamins. Vitamins are very susceptible to storage conditions of the food and to cooking processes. So many times the food product has lost the vitamin value for which it is consumed on the first place.

Nowadays, food supplements as pharmaceutical preparations are being used frequently. Vitamins usually combined with minerals and other supplements can be easily found in the pharmacy in the form of: capsules, tablets, syrups, ampules, or injections. Their main use is to increase the daily intake amount of vitamins.

Despite their importance on completing the needs for vitamins, food supplements are not intended as regular substitutes of healthy food. The natural healthy food provides elements and natural form of vitamins which are way more important than synthetic products.

Nevertheless, almost all nutritionists and doctors advise the use of pharmaceutical supplements for the following groups:

- Pregnant women and during lactation.
- People under vegetarian or vegan diets.
- People under low-fat diets.
- People under certain healthy conditions which does not allow the right metabolism of vitamins taken by food.
- People under long term use of antibiotics or other medication.

There is a visible difference in the culture of food supplements usage between countries. The so called modern cultures, even though their stress on the value of natural food, are more focused on the use of such pharmaceutical products than other countries. Sometimes it is not just a general culture or approach towards these products, but the lack of possibilities on getting them. In most of the developing countries, food supplements are more seen as luxury products. These people go to a pharmacy just to get a real drug for a real disease.

On these terms, where do Albanians stand, are they regular or occasional users? How are these products placed on the market? Are there any regulations for this in Albania compared to ones by EU or FDA?

2. Materials and Methods

Based on the respective legislations in EU and USA regarding food supplements and through a comparative analyze, we will give information on the allowed substances, allowed quantities and the regulatory bases for placing them on the market compared to the regulatory situation in Albania.

In order to have more information on the knowledge and awareness of Albanians towards food supplements, there were many surveys among different ranges of population. From all of them, there were selected and compared already analyzed 100 surveys which were considered more representative of the general situation. The main questions were focused on what do Albanians know about vitamins in general, whether they are using pharmaceutical products containing vitamins or ever used? In case of parents the questioning was focused also on the usage of these products for their children. For the terms of this article we will focus our results on the usage of these products from Albanian population.

3. Results and Discussion

3.1 Regulations

EU regulation defines Food Supplements as concentrated sources of nutrients or other substances with a nutritional or physiological effect whose purpose is to supplement the normal diet. They are marketed 'in dose' form i.e. as pills, tablets, capsules, liquids in measured doses etc. The Directive 2002/46/EC of the European Parliament and Council of 10 June 2002 on the approximation of the laws of Member States relating to food supplements establishes harmonized rules for the labelling of food supplements and introduces specific rules on vitamins and minerals in food supplements. Annex II of the same directive is a list of permitted vitamin or mineral preparations that may be added for specific nutritional purposes in food supplements.

- In order to ensure a high level of protection for consumers and facilitate their choice, the products that will be put on to the market must be safe and bear adequate and appropriate labelling. The labelling, presentation and advertising must not attribute to food supplements the property of preventing, treating or curing a human disease, or refer to such properties. The labelling, presentation and advertising of food supplements shall not include any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients in general.
- Only vitamins and minerals normally found in, and consumed as part of, the diet should be allowed to be present in food supplements although this does not mean that their presence therein is necessary. Therefore, it is appropriate to establish a positive list of those vitamins and minerals.
- Maximum amounts of vitamins and minerals present in food supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following into account:

- (a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different consumer groups;
- (b) intake of vitamins and minerals from other dietary sources.
- The amounts of the nutrients or other substances declared shall be those per portion of the product as recommended for daily consumption on the labelling.
- To facilitate efficient monitoring of food supplements, 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 market by forwarding it a model of the label used for the product.

FDA regulates both finished dietary supplement products and dietary ingredients under a different set of regulations than those covering "conventional" foods and drug products (Dietary Supplement Health and Education Act of 1994 (DSHEA)) based on which:

- Manufacturers and distributors of dietary supplements and dietary ingredients are prohibited from marketing products that are adulterated or misbranded. All claims and information on the product label and in other labeling are truthful and not misleading. The manufacturers are responsible for evaluating the safety and labeling of their products before marketing to ensure that they meet all the requirements of DSHEA and FDA regulations.
- All domestic and foreign companies that manufacture, package, label or hold dietary supplement, including those involved with testing, quality control, and dietary supplement distribution in the U.S., must comply with the Dietary Supplement Current Good Manufacturing Practices (CGMPs) for quality control.
- In addition, the manufacturer, packer, or distributor whose name appears on the label of a dietary supplement marketed in the United States is required to submit to FDA all serious adverse event reports associated with use of the dietary supplement in the United States.
- FDA is responsible for taking action against any adulterated or misbranded dietary supplement product after it reaches the market.
- FDA regulates dietary supplement labels and other labeling, such as package inserts and accompanying literature. The Federal Trade Commission (FTC) regulates dietary supplement advertising.

Regarding Albanian legislation, we could find slight information and rules for food supplements only on the previous "Law on Drugs" No. 9323 dt.25.11.2004 and the respective "Regulatory Regulations". The newly approved law has no reference at all on this topic.

Indeed the previous law was not that accurate as the laws in EU and USA but it was a start point for distributors and companies for placing the products on the market. Besides the regulatory background on the registration aspect of the products, it gave information on labeling, amounts of the nutrients or other substances, approved list of allowed substances. The new law has improved certain topics related to medical environment in Albania but can we say the same for food supplements? Are the products marketed in Albania safe? Are the claims in their labeling trustful?

3.2 Survey results

In the Figure 1 are presented the number of current vitamins users compared to the nonusers and in the Figure 2 are presented the number of past's vitamins users compared to the ones that have never used vitamins.

As it can be seen from the above Figures and the general feedback from the survey, the usage of vitamins through food supplements are rather low, only 20% of the respondents were taking vitamins. Among them,

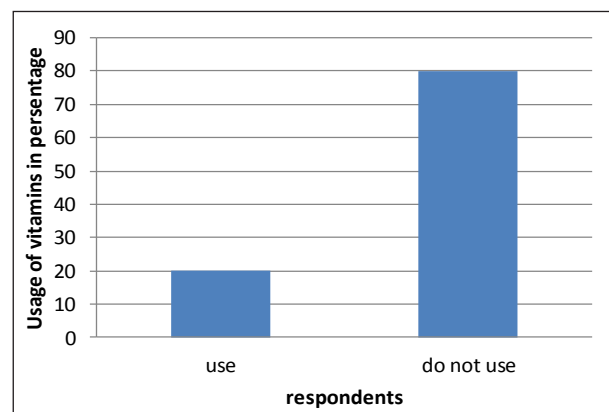


Figure 1. How much are the vitamins used?

Based on the survey results:

- a) 20% use vitamins
- b) 80% do not use vitamins

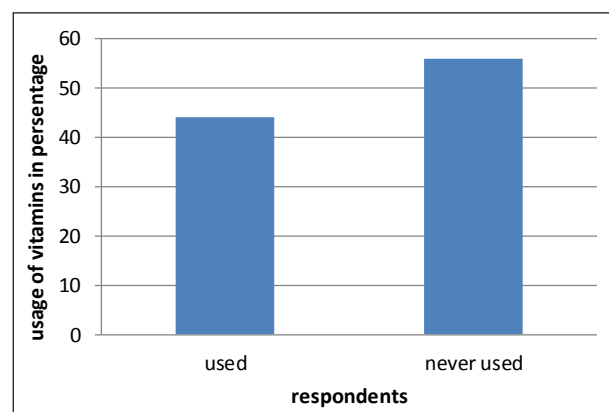


Figure 2. Were vitamins ever used?

Based on the survey results:

- a) 44% have used vitamins
- b) 56% have never used vitamins

very few were taking these products on regular bases, mostly were using after certain disease such as flu or other conditions always on doctors' advice.

From the respondents that were not taking vitamins during the survey time, 56% of the respondents have never used vitamins and 44% have used them before only on doctors' advice for during flu season, anemia, coagulation problems, skin disease, and lack of appetite.

Figures 3 and 4 show the use of vitamins in children. Parents were asked whether they are currently using vitamins for their children and also whether vitamins were ever used.

Based on the feedback from surveyed parents, very few among them were giving vitamins to their children 6.67%, while 93.33% were not giving. From the last ones, 40% had given vitamins to the children only in case of disease. Most of the parents still have the opinion to give the needed amount of vitamins through healthy and so called fresh food.

1. Are parents giving vitamins to their children?

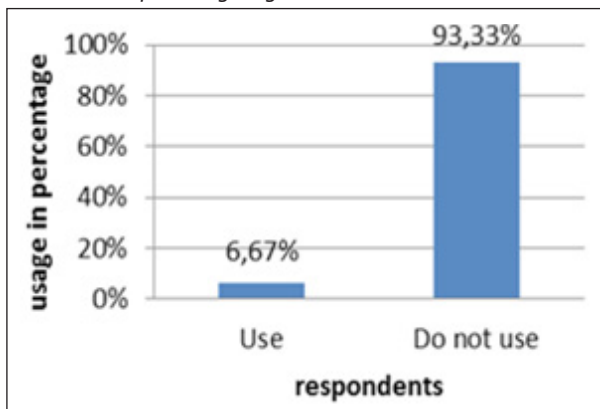


Figure 3. Current users of vitamins in children

Based on the survey results:

- 6.67% of the parents are giving vitamins to their children
- 93.33% of the parents are not giving vitamins to their children

2. Were vitamins ever used?

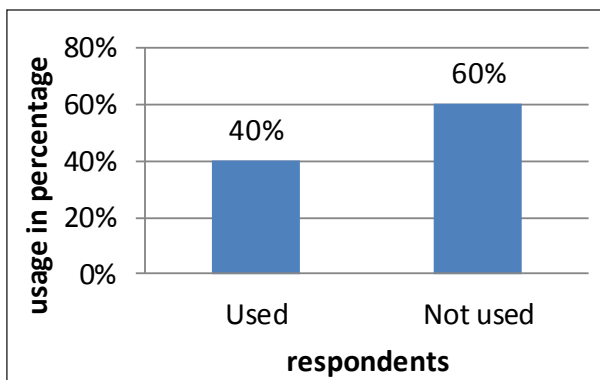


Figure 4. Past users of vitamins in children

Based on the survey results:

- 40% of the parents have given vitamins to their children
- 60% of the parents have never given vitamins to their children

4. Conclusions

- In general, Albanians have good knowledge regarding vitamins, their values and benefits. Most of the knowledge is from school but there are also cases where their knowledge is based on information for proper vitamins that were being taken. (Still are not to be excluded cases of a total lack of knowledge on vitamins and their roles, or even situation of very insufficient or superficial knowledge).

- When are taken, vitamins are taken based on a doctor's advice for health problems or even from nutritionist in cases of losing or getting weight.

- Taking vitamins is still not a routine habit in Albania.

- Most of the respondents find food the best option of getting the amount of vitamins and they admit that they have taken vitamins only in rare and special occasions.

- Almost same situation is with children. Children are taking vitamins on doctor's advice during disease or recovery time from a disease.

- Different studies on the use of vitamins in our country including this one, suggest the efforts done through mass media and different scientific information broadcasted via school, general physicians and nutritionists, to encourage the public opinion to know in more details the usage and benefits from vitamins specially for different ranges of population such as children, in order to get the right amount of vitamins through healthy food and compensate the lacks through pharmaceuticals products.

- The Directive 2002/46/EC of the European Parliament and Council of 10 June 2002 establishes harmonized rules for the labelling of food supplements and introduces specific rules on vitamins and minerals in food supplements.

- FDA regulates dietary supplement products and dietary ingredients under a different set of regulations than those covering "conventional" foods and drug products (Dietary Supplement Health and Education Act of 1994 (DSHEA)).

- Albanian legislation, covered food supplements only on the previous "Law on Drugs" No. 9323 from. 25.11.2004 and the respective "Regulatory regulations". The newly approved law has no reference at all on this topic.

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