

# Health claims made on multivitamin and mineral supplements

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## Abstract

**Introduction:** Basic purpose of health claims is consumers' benefit by providing information about healthy eating habits. It is necessary for health claims to be scientifically substantiated and truthful. Health claims should not attribute to food the property of preventing, treating or curing a human disease. Use of health claims should be followed by a statement indicating the importance of a varied and balanced diet and a healthy lifestyle. The objective of this research was to examine the compliance of health claims made on multivitamin and mineral dietary supplements' labels on the Serbian market with national regulation concerning health safety of dietary products.

**Methods:** An assessment of labels of MVMs was done in two privately owned pharmacies in Novi Sad, Serbia in August 2010.

**Results:** In total, 48 MVMs were sampled and 22 health claims were detected. Seven out of 22 health claims were in compliance with the national regulation. The main reason for health claims on foreign MVMs not to be compliant with the regulation in Serbia was inadequate or nonexistent translation of original labels.

**Conclusion:** Detected use of terms such as "prevention", "treatment" and "indications" on vitamin and mineral dietary supplements' labels is both forbidden and misleading to consumers. Coupled with inadequate or nonexistent translation of the labels, it leads to a low level of protection of Serbian consumers. It is necessary to establish an effective monitoring system for dietary supplements' labeling on a national scale in order to protect consumers and their wellbeing.

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*Keywords: health claims, consumers, perception of health claims, dietary supplements*

## Introduction

Food safety is the one of the leading public health issues. Taking into account that dietary supplements are a specific category of food, health claims often used on dietary supplements' labels, are contributing factors for public health. Codex Alimentarius, joint body of Food and Agriculture Organization of the United Nations (FAO UN) and World Health Organization (WHO) defined health claims in 1997 as "any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health" (1). This definition was incorporated in the Regulation 1924/2006 of the European Com-

mission on the use of health claims on foods (2). Health claims are a fairly new health related addition to the label in Serbia, regulated for the first time in July 2010 (3,4). Serbian regulation is the customized translation of the European Regulation (2). Requirements and limitations for use of health claims are well defined (1-3). It is necessary for health claims to be scientifically substantiated in accordance with criteria set by the PASSCLAIM project (5, 6). Health claims should not be false, ambiguous or misleading, nor should they attribute to food the property of preventing, treating or curing a human disease (1-3). Use of health claims is allowed if followed by a statement indicating the importance of a varied and balanced diet and a healthy lifestyle, a statement addressed to persons who should avoid using the food (where appropriate) and an appropriate warning for products that are likely to present a health risk if consumed to excess (1-3).

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Basic purpose of health claims is consumers' benefit by providing information about healthy eating habits (7). The underlying principle of use of health claims is for them to be truthful, clear and understandable. In practice, this seems to be the most controversial and scientifically challenging principle. It has been shown that consumers aren't always capable of understanding the given messages (8, 9). Inadequate wording of health claims may mislead consumers. Promises of "prevention" or "treatment" of disease are seen as strongly affirmative by an average consumer (10). Multivitamin and mineral supplements (MVMs) are the best-selling category of dietary supplements. Regardless of the fact that clinical deficiency of vitamins and minerals in developing and developed countries are uncommon (except for iron deficiency), half of the adult population in United States uses dietary supplements and one third reported regular use of multivitamin and mineral supplements (11). There are no available data on the percentage of MVM supplement users in the Republic of Serbia, but some preliminary results show that the number is even greater than in the US (unpublished material). The fact that in Serbia, vitamin and mineral supplements are sold not only in pharmacies, but in supermarkets as well is of special concern because of lack of available expert assistance from pharmacists to MVM users during the decision making process, making consumers more exposed and vulnerable to unsubstantiated, misleading and false health claims made on MVM supplements' labels. The objective of this research was to examine the compliance of health claims made on multivitamin and mineral dietary supplements' labels on the Serbian market with national regulation concerning health safety of dietary products.

**Methods**

*Design, materials and methods*

For the purpose of this research, the term "MVM supplements" was used for every dietary supplement containing 2 or more vitamins and minerals and no other active components. Only MVMs intended for use in adult population were taken into consideration. An assessment of labels of MVMs was done in two privately owned pharmacies in Novi Sad, Serbia in August 2010. Compliance of health claims with the national regulation was assessed using the following parameters:

- whether a statement indicating the importance of a varied and balanced diet and a healthy lifestyle was included in the label;
- whether the label information attributed medicinal properties to the MVM supplement (prevention or treatment of disease);
- whether adequate Serbian translation of health claim of the original MVM supplement label (in case of foreign products) was present on the product.

**Results**

Total of 48 MVMs found on the market met the set criteria for inclusion in the research (Figure 1). The majority of the MVMs in the sample were in the form of effervescent pills. Only 25 % of the sampled MVMs were of domestic origin, while the others were imported mainly from European Union countries. About two thirds of the sample was made up of MVMs

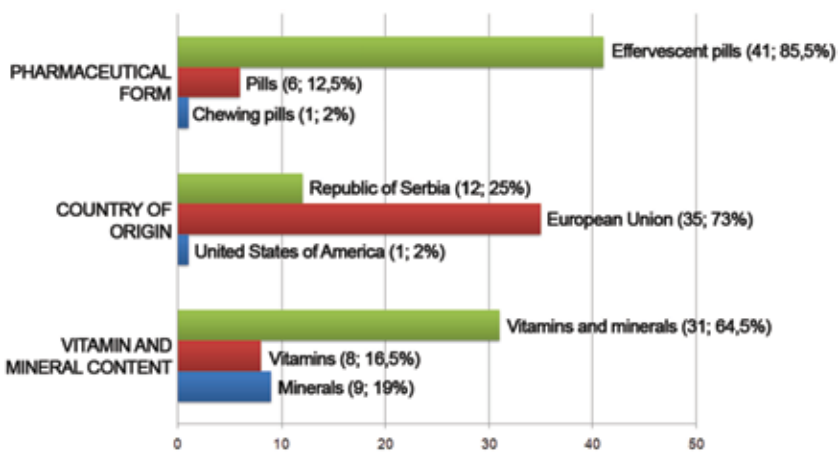


FIGURE 1. Sample characteristics.

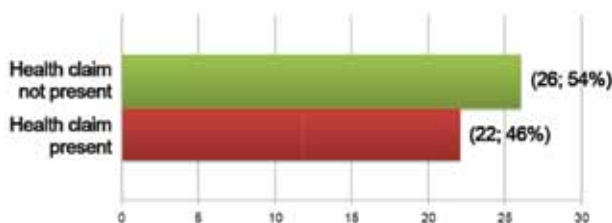


FIGURE 2. MVMs with and without health claim present.

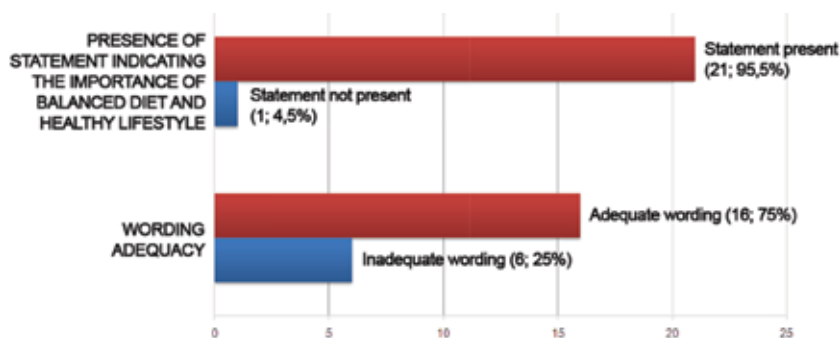


FIGURE 3. Compliance of health claims with national regulation.

containing both vitamins and minerals in contrast to 16.5 % MVMs containing only vitamins, and 19 % containing only minerals, as seen on Figure 1. Of the 48 MVMs assessed, 46% carried a health claim (Figure 2). Health claims were present on labels of 67 % MVMs of domestic and 39 % of foreign origin. Statement indicating the importance of a varied and balanced diet, as well as healthy lifestyle was present in all but 1 vitamin and mineral supplement carrying a health claim (Figure 3). Wording of 25 % of health claims contained words such as "prevention", "treatment" or "therapy" indicating that the product had medicinal properties. About 25 % MVMs had inadequate or nonexistent Serbian translation of labels. Majority of the health claims (two out of three) nonspecifically referred to overall wellbeing, while the rest referred to immune, cardiovascular and bone health. In all, only 7 out of 22 health claims (32 %) were in compliance with the national regulation (and, therefore, the EU regulation).

## Discussion

Number of vitamin and mineral dietary supplements included in the sample was limited by the definition of MVMs, as dietary supplements con-

taining 2 or more vitamins or minerals and no other active ingredients. Majority of excluded dietary supplements were combinations of vitamins and minerals with herbal components. Out of the 48 sampled MVM supplements, health claims were detected on 22 labels. Only one health claim was not followed by a statement indicating the importance of a varied and balanced diet, as well as healthy

lifestyle showing good compliance with the regulation concerning this parameter. Different papers pointed the importance of health claim wording (12-14). The more detailed the message, the stronger the impact on the consumer will be (15). As the use of terms such as "prevention" and "treatment" in health claims is forbidden by the regulating bodies, their presence on the labels is highly unexpected in countries with effective mechanism of market control, such as USA and EU. Therefore, there are limited amount of data on the consumers' understanding of health claims that use those terms. In Serbia, no effective control mechanism have yet been installed, leading to the detection of words "prevention" or "treatment" on 25 % of the health claims on MVMs. Four MVMs even had "indications" for use of supplements in question. Although further investigation of consumers' perception of such claims is needed, it is likely that consumers perceive the terms "prevention" and "treatment" as strong evidence that the use of these products will indeed prevent or treat their diseases (10). It has been shown that older people and those with lower levels of education or income were least likely to understand the label (7). Given

that the median age of the Serbian population is estimated to be 41.3 years in 2011 (16) and is on the rise (17) and that only 6 % of the population have a university degree according to the last Census (18), it is safe to assume that the majority of the Serbian population is unable to understand health claims on dietary supplements labels. Obviously, the aforementioned wording of health claims can give producers an unfair advantage on the Serbian market and, at the same time, misleads consumers and compromises public health (19). Yet, the biggest issue noted by this research is that 7 health claims compliant with the national regulation were the ones on the labels of MVMs produced in Serbia, and, in fact, produced by the same pharmaceutical company. Further investigation showed alarming evidence that the reason for health claims on foreign MVMs not to be compliant with the regulation in Serbia was inadequate or nonexistent translation of original labels, otherwise, completely lawful in English language. Seven sampled MVMs (4.5 %) even had health claims on the original label that were not translated to Serbian. This problem is not documented in USA and EU. This preliminary research was done using only a limited number of parameters of health claims use, insufficient for conclusions to be drawn on a larger scale.

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## Conclusions

Use of health claims on MVMs' labels on the Serbian market is widespread, but only one third of health claims on labels of sampled MVMs comply with the national regulation. This research indicated a problem uncommon in USA and EU – inadequate or nonexistent translations of otherwise accurate and lawful health claims of imported MVMs. Translation of imported dietary supplements' labels should be entrusted to a professional trained both in medical and linguistic aspects of health claims. Special attention should be directed toward health claims indicating that dietary supplement could prevent or treat a disease, since such claims can pose a health risk for an average consumer. At the same time, campaigns educating consumers on how to use information on food labels should be carried out. It is necessary to establish an effective monitoring system for dietary supplements' labeling on a national scale in order to protect consumers and their wellbeing.

## Competing interests

The authors declare that we have no financial and personal relationships with other people or organizations that could inappropriately influence this work.

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