Review paper
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FOOD SUPPLEMENT REGULATION ON HEALTH CLAIMS LABELLING IN NON-EU COUNTRIES

Marjan Dzeparoski[1,2]

[1]Bionika Pharmaceuticals, Skupi 57, 1000 Skopje, Macedonia
[2]Pharmacy Department, Faculty of Medical Sciences, Goce Delcev University, Krste Misirkov, 10 A, 2000 Stip, Macedonia

[*]e-mail: marjan.dzeparoski@bionikapharm.com

Abstract

This research is important to show that marketing as part of advertising is correlated with the regulation of health claims labelling of food supplements, which is product-specific. Hence, this research aimed to compare the regulation for health claims labelling in the European Union and non-EU countries.

For this research, we made a comparative analysis of legal regulations for health claims labelling in European Union and non-EU countries: Macedonia, Serbia, Bosnia and Herzegovina, Montenegro, Albania and Kosovo. This kind of analysis is made for the first time. The results of this research showed that all countries are following the European regulations for food supplements, but there are differences within single countries, as well as between countries. We also noticed that the least harmonization of regulation exists in food supplements that contain herbal substances. Given the summary of results, this research shows a divided picture concerning alignment with the EU health claims labelling in non-EU countries. Macedonia, Serbia and Montenegro fully follow this EU regulation, while in Bosnia and Herzegovina, it is followed only partly. Food supplement marketing is more liberal in Albania and Kosovo.

This research has contributed towards understanding that there is no harmonization, nor mutual recognition between the mentioned countries, which is applicable in the EU. Harmonization opportunities which are discussed in this research are applicable and realistic and can contribute in a positive, more economical way to better placement of food supplements in different markets.

***Key words**: Food supplements, Regulation, Health claims, Labelling, non-EU Countries.*

1. Introduction

Food supplements are concentrated sources of nutrients or other substances with a nutritional or physiological effect, whose purpose is to supplement the normal diet. Food supplements are marketed 'in dose' form, for example as pills, tablets, capsules or liquids in measured doses etc. Supplements may be used to correct nutritional deficiencies or maintain an adequate intake of certain nutrients [1].

Nutrition and health claims in European Union (EU) are governed by the following European Council Regulations: 1924/2006 [2]; 107/2008 [3]; 109/2008 [4]; 116/2010 [5]; 432/2012 [6]; 1047/2012 [7]; 907/2013 [8]; and 1066/2013 [9].

The objectives of these Regulations are to protect consumers by ensuring that there are no false or misleading claims, to improve the free movement of goods in the internal market by harmonizing the rules, and to promote innovation in the agri-food sector.

Health claims are classified as other health claims (Regulation (EC) No 1924/2006, Article 13), and reduction of disease risk claims and claims referring to children's development and health (Regulation (EC) No 1924/2006, Article 14).

Other health claims are related to the role of a nutrient or other substance in growth, development and the functions of the body; psychological and behavioural functions; or slimming or weight control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet. These claims (based on generally accepted scientific evidence) are published by the European

Food Safety Authority (EFSA) in the web register after the evaluation of the dossier by the Agency and the final decision of the European Commission.

Reduction of disease risk claims means that EFSA has published specific guidance on the scientific requirements for health claims [10], such as those related to the immune system, the gastrointestinal tract and defence against pathogenic microorganisms; antioxidants, oxidative damage and cardiovascular health; appetite ratings, weight management and blood glucose concentrations; bone, joints, skin and oral health; physical performance; functions of the nervous system, including psychological functions. Reduction of disease risk claims is subject to rigorous scientific evaluation of extensive dossiers. They should be confirmed with clinical studies.

The use of nutritional and health claims is not mandatory. It is used for commercial purposes and if the operator wants to emphasize some properties of his product with these claims, then the food operator must comply with the rules of the regulation. Of course, the constituent must be contained in sufficient quantity to produce the effect of the claim [11].

Health claims should not be false, ambiguous or misleading to consumers; give rise to doubt about the safety or nutritional adequacy of other foods; encourage excess consumption; suggest that a balanced and varied diet cannot provide appropriate quantities of nutrients [2].

Hence, this research is important to show that marketing as part of advertising is correlated with the regulation of health claims labelling of food supplements, which is product-specific. This research aimed to compare the regulation for health claims labelling in the European Union and non-EU countries.

2. Food supplement regulation on health claims labelling in non-EU countries

Countries of interest in this research are Macedonia, Serbia, Montenegro, Bosnia and Herzegovina, Albania and Kosovo. These countries follow the European regulation for food supplements.

2.1 European Union

If some product is legally manufactured or sold in one of the European Union Member States, because of the principle of mutual recognition, the same can be sold in all Member States, according to Article 28 of the Treaty [12], where a Member State may not quantitatively prohibit the sales among the Member States, and concerns also the not yet harmonized aspects of food supplements.

The least harmonization of regulation in the European Union exists in food supplements, especially for herbal food supplements. The current situation of approval of health claims for herbal supplements in the European Union is on hold or in most cases results in rejections, and therefore these products are regulated differently by different nations.

In the current regulations for herbal food supplements, more stringent clinical trials are required for approval of health claims as opposed to traditional herbal medicines, which do not require proof of effectiveness. This unsettled situation is used by some manufacturers using health claims put on hold because they have not been rejected. It represents a legal grey zone.

EU countries continue to use national regulation based on tradition, which is a divided picture for non-EU countries which want to sell their products in the European countries [13, 14, 15, and 16]. This is also true for the non-EU countries.

2.2 Macedonia

In Macedonia, food supplements are regulated by the Law on Food Safety [17, 18], and the Rulebook for nutrition and health claims which are used in commercial communications relating to labelling, presentation and advertising [19].

It is the first of the countries that are not members of the European Union, which has implemented 2014 the regulation on nutrition and health claims. Notifications are governed by the Food and Veterinary Agency and they are based on the EFSA website.

2.3 Serbia

Serbia also follows EU legislation on nutrition and health claims. Notifications are governed by the Ministry of Health, but only those related to the reduction of disease risk.

Other health claims may be used without approval if they are based on generally accepted scientific data are understandable to the average consumer and are published on the EFSA website. Commercial use of nutrition and health claims labelling is according to the Rulebook on the Declaration, Labelling and Advertising of Food [20].

2.4 Bosnia and Herzegovina

Since 2014, registration of food supplements has been required according to the Law on the safety of food supplies and items of general use (Official Gazette of BiH 2/92, and 13/94) [21], and the Rulebook on health safety of food which can be released on the market [22].

Bosnia and Herzegovina follows European regulations on nutrition and health claims partially.

Commercial use of nutrition and health claims labelling is allowed if it is according to the Law and the Rulebook.

2.5 Montenegro

In Montenegro, there is no need for food supplements registration. The country has aligned the regulations with the EU in connection with the content of allowed substances and their labelling [23].

If there are some differences, the importer should ask for labelling declaration approval from one of the 2 official state institutions - the Center for Ecotoxicological Research (CETI), or the Institute for Public Health.

2.6 Albania and Kosovo

In Albania and Kosovo, there is no need for registration of food supplements, and they follow EU legislation only partly. These countries recognise the health claims labelling in the country of origin and they should not be false and misleading to consumers, so can be used that way.

3. Conclusions

- There is a divided picture concerning alignment with the EU health claims labelling in the non-EU countries. All countries of interest follow the European regulation for food supplements, but there are differences within single countries, as well as between countries.
- Macedonia, Serbia and Montenegro fully follow this EU regulation, while in Bosnia and Herzegovina, it is followed only partly. Food supplement marketing is more liberal in Albania and Kosovo and it is not subject to approval.
- There is no harmonization, nor mutual recognition between these countries. The least harmonization of regulation exists in food supplements that contain herbal substances, which unsettled the situation and allowed the manufacturers to put health claims on hold, which represents a legal grey zone.
- Food supplement marketing and advertising should be in correlation with the current national regulation. It would be positive, also from an economic point of view, if similar principles for harmonization and mutual recognition like in the EU for the neighbouring countries in other markets are applied.

4. References

[1] European Parliament and Council. (2002). *Directive 2002/46/EC* of *10 June 2002 on the approximation of the laws of the member states relating to food supplements.* O.J.L 183.

[2] European Parliament and Council. (2006). *Regulation (EC) No 1924/2006 of 20 December 2006 on nutrition and health claims made on foods*. O.J.L 404.

[3] European Parliament and Council. (2008). *Regulation (EC) No 107/2008 of 15 January 2008 amending Regulation (EC) No 1924/2006 on nutrition and health claims made on foods as regards the implementing powers conferred on the Commission*. O.J.L 39.

[4] European Parliament and Council. (2008). *Regulation (EC) No 109/2008 of 15 January 2008 amending Regulation (EC) No 1924/2006 on nutrition and health claims made on foods*. O.J.L 39.

[5] European Parliament and Council. (2006). *COMMISSION REGULATION (EU) No 116/2010 of 9 February 2010 amending Regulation (EC) No 1924/2006 with regard to the list of nutrition claims*. O.J.L 37.

[6] European Parliament and Council. (2012), *Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and children's development and health.* O.J.L 136.

[7] European Parliament and Council. (2012). *Commission Regulation (EU) No 1047/2012 of 8 November 2012 amending Regulation (EC) No 1924/2006 with regard to the list of nutrition claims*. O.J.L 310.

[8] European Parliament and Council. (2013). *Commission Regulation (EU) No 907/2013 of 20 September 2013 setting the rules for applications concerning the use of generic descriptors (denominations)*. O.J.L 251.

[9] European Parliament and Council. (2013). *Commission Regulation (EU) No 1066/2013 of 30 October 2013 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and children's development and health.* O.J.L 289.

[10] EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies). (2016). *General scientific Guidance for stakeholders on health claim applications*. EFSA Journal, 14, (1). <URL:https://doi.org/10.2903/j.efsa.2016.4367. Accessed 23 June 2023.

[11] Dzeparoski M. (2019). *Impact of the pharmaceutical regulation on the creation of the plan for new product introduction on the market* (in Macedonian). PhD. Thesis, Faculty of Pharmacy, University Ss. Cyril and Methodius, Skopje, Macedonia.

[12] European Union. (2012). *Consolidated versions of the treaty on the European Union and the treaty on the functioning of the European Union - consolidated version of the treaty on the functioning of the European union-protocols - annexes - declarations annexed to the final act of the intergovernmental conference which adopted the treaty of Lisbon, signed on 13 December 2007 - tables of equivalences***.** O.J.C 326.

[13] Gruenwald J. (2014). *A stalled situation for botanicals in Europe.* Nutraceuticals World. <URL:https://www.nutraceuticalsworld.com/issues/2014-11/view_columns/a-stalled-situation-for-botanicals-in-europe/. Accessed 17 December 2023.

[14] Gruenwald J. (2015). *Foods for special medical purposes: an end to the confusion.* Nutraceuticals World. <URL:https://www.nutraceuticalsworld.com/issues/2015-01/view_columns/foods-for-special-medical-purposes-an-end-to-the-confusion/. Accessed 17

December 2023.
[15] Gruenwald J. (2017) *EU botanical health claims: a never-ending story?* Nutraceuticals World. <URL:https://www.nutraceuticalsworld.com/issues/2017-01/view_columns/eu-botanical-health-claims-a-never-ending-story/. Accessed 17 December 2023.
[16] Dzeparoski M., Trajkovic-Jolevska S. (2018). *Impact of regulation on advertising and promotion of traditional herbal medicines and food supplements*. International Journal of Pharmaceutical and Healthcare Marketing, 12, pp. 77-90.
[17] Republic of Macedonia Government. (2010). *Law on Food Safety* (in Macedonian). Official Gazette, 157/10.
[18] Republic of Macedonia Government. (2016). *Law on Food Safety* (in Macedonian). Official Gazette, 39/16.
[19] Republic of Macedonia Food Safety Agency. (2013). *Rulebook on Nutritional and Health Claims for Commercial Purposes in Food Labelling, Presentation and Advertising* (in Macedonian). Official Gazette, 65/13.
[20] The Republic of Serbia Government. (2022). *Rulebook on Declaration, Labelling and Advertising of Food* (in Serbian). Official Gazzette, 23/22.
[21] Republic of Bosnia and Herzegovina Government. (1994). *Law* on *Safety* of *Food Supplies* and *Items* of *General Use* (in Bosnian). Official Gazette, 2/92, 13/94.
[22] Republic of Bosnia and Herzegovina Government. (2017). *Rulebook on health safety of food which can be released on the market* (in Bosnian). Official Gazette of BiH, 7/04; 45/04, 2/13 and 96/17.
[23] Republic of Montenegro. (2018). *Regulation of consumer information on food* (in Montenegrin). Official Gazette of Montenegro, No. 22 (2018).