REGULATORY FRAMEWORK FOR DIETARY SUPPLEMENTS IN THE REPUBLIC OF MOLDOVA

Radu RUSU, Ovidiu TAFUNI, Olga CERNELEV

Nicolae Testemitanu State University of Medicine and Pharmacy, Republic of Moldova

Corresponding author: Radu Rusu, e-mail: radu.rusu@usmf.md

Keywords: *dietary supplements, regulatory framework, registration, safety.*

Introduction. Dietary supplements have gained increased popularity worldwide due to their potential health benefits and their use is often driven by the desire to supplement an individual's diet with essential nutrients. However, their regulatory status is often unclear, leading to concerns starting with their definition and ending with their quality and safety. In the Republic of Moldova (RM), there is a growing market for dietary supplements (DS), and there is a need for a clear regulatory framework to ensure the safety, efficacy and quality of these products.

Aim. The aim of this study is to examine the regulatory framework regarding DS in the RM, including their registration, labeling, marketing, and safety requirements. This study seeks to provide a comprehensive overview of the regulatory landscape for DS in Moldova, and to identify any gaps or shortcomings in the current regulatory framework.

Material and methods. A literature review was conducted to identify relevant legal documents, policies, and guidelines related to DS in the RM. Additionally, information was collected from National Agency for Public Health, responsible for regulating DS and from industry sources.

Results. The regulatory framework for DS in the RM is governed by two main state structures: Ministry of Health of RM and National Agency of Public Health (NAPH), within the Law no. 306 of 30.11.2018 on food safety and the sanitary regulation on DS, approved by Government Decision no. 538 of 02.09.2009, which includes provisions for the registration, notification, labeling, marketing, and safety of DS, that were based on the legislative transpositions of Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002. According to this directive, DS must be registered or notified with the NAPH and meet certain quality and safety standards. Additionally, DS labeling must include specific information about the product's ingredients, dosage, and intended use. DS are not subject to the same level of pre-market testing and approval as medications. This means that companies can sell DS without first demonstrating that they are safe and effective. DS can contain fillers or other inactive ingredients, and the amount of active ingredient can vary from batch to batch, and may also be contaminated with harmful substances, such as heavy metals, pesticides or even prescription drugs. Many DS make claims about their health benefits, but these claims are not always supported by scientific evidence, and companies can make false claims or exaggerate the effectiveness of their products without consequence.

Conclusions. The regulatory framework for DS in the RM provides some protections for consumers, including requirements for registration, labeling, dosage and some proof of safety. However, the enforcement of these regulations may be inadequate. There is a need for continued efforts to ensure that consumers have access to safe DS. This may include improving the enforcement of existing regulations, creation of a more standardized and rigorous regulatory framework that include stricter rules on labeling and advertising, mandatory safety testing, and clearer guidelines on dosage and ingredients, and increasing public awareness of the risks and benefits of DS.