

# Vitamin Dietary Supplement: Changes and Challenges with the New ANVISA Regulations

## *Suplemento alimentar de vitaminas: mudanças e desafios com as novas Regulamentações da ANVISA*

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### Abstract

In July 2018, the Brazilian National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária, ANVISA, in Portuguese) published new regulations for food supplements, leading to changes both in the sales denomination and labeling statements, and in the composition of these products. Among dietary supplements, those containing vitamins are the most consumed by the population. The objective of the present work is to discuss the changes in the parameters established for the products containing vitamins, mainly in relation to the required and allowed concentrations of micronutrients, and to verify the impact of these changes for the population since the publication of the new standards. Until July 2018, vitamin-based products containing between 15% and 100% of the recommended daily intake (RDI) of these micronutrients were classified as vitamin supplements; above this dosage, they were considered medicines. The new legislation changed the minimum and maximum limits allowed for vitamin food supplements. Taking into account the maximum vitamin limits established for adults, the most relevant differences were the increase in these limits in a proportion of 100, 76 and 43 times in regarding vitamins E, B6 and C respectively, when compared to those previously established. For the required minimum limits, the major difference was observed for vitamin D, with a four-fold increase in its concentration. In conclusion, changes in legislation can influence the health of the population, so the ideal amounts of vitamin in supplements and the recommendation to consume these products require extensive discussion and reflection.

### Keywords

- ▶ dietary supplement
- ▶ vitamins
- ▶ legislation
- ▶ ANVISA

### Resumo

Em julho de 2018, a Agência Nacional de Vigilância Sanitária (ANVISA) publicou as novas regulamentações sobre suplementos alimentares, levando a modificações tanto na denominação de venda e dizeres de rotulagem quanto na composição destes produtos. Dentre os suplementos alimentares, aqueles contendo vitaminas são os mais consumidos pela população. O objetivo do trabalho foi discutir as mudanças nos parâmetros

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**Palavras-chave**

- ▶ Suplemento alimentar
- ▶ vitaminas
- ▶ legislação
- ▶ ANVISA

estabelecidos para os produtos à base de vitaminas com a publicação das novas normas, principalmente em relação às concentrações de micronutrientes exigidas e permitidas nestes produtos e verificar o impacto destas mudanças para a população. Até julho de 2018, os produtos à base de vitaminas contendo entre 15% e 100% da ingestão diária recomendada (IDR) destes micronutrientes eram classificados como suplementos vitamínicos; acima desta dosagem, eram considerados medicamentos. A nova legislação alterou os limites mínimos exigidos e máximos permitidos nos suplementos alimentares de vitaminas. Levando-se em consideração os limites máximos de vitaminas estabelecidos para adultos, as diferenças mais relevantes foram o aumento destes limites em proporção de 100, 76 e 43 vezes nos teores de vitaminas E, B6 e C, respectivamente, quando comparados aos estabelecidos anteriormente. Para os limites mínimos exigidos, a maior diferença foi observada para a vitamina D, com um aumento de 4 vezes na sua concentração. Concluiu-se que as mudanças nas legislações podem influenciar a saúde da população, assim, as quantidades ideais de vitaminas em suplementos e a recomendação de consumo destes produtos requerem ampla discussão e reflexão.

**Introduction**

Dietary supplements are a topic currently in evidence. The laws related to these products have been discussed and questioned for a long time due to their complexity, the lack of harmonization with international standards, and the need for updating.<sup>1</sup> In July 2018, the Brazilian National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária, ANVISA, in Portuguese) published new regulations for dietary supplements, setting a 5-year deadline for companies to comply with these standards. According to the agency, this new regulatory framework had, as its main objectives, to reduce the level of information provided in this market, especially regarding the dissemination of allegations without scientific evidence, and to modernize the regulation to reduce obstacles to the commercialization and innovation of the sector.<sup>2</sup>

Changes in the laws pertaining to dietary supplements may cause doubts among the manufacturers, the health professionals who prescribe and recommend their use, the inspection agencies, and especially the consumers, who, for the most part, take dietary supplements without the prescription of a qualified professional, basing their choices on what is presented on the label or on the influence of the media.<sup>3</sup>

The dietary pattern of the population has changed over the years because of changes in lifestyle. The increase in life expectancy and the concern with a healthy life, combined with the constant advertising of food supplements, resulted in a significant increase in the consumption of these products by the population.<sup>4</sup> With the Covid-19 pandemic, for example, the consumption of dietary supplements has further intensified, especially regarding products containing vitamins A, B<sub>6</sub>, B<sub>12</sub>, C, and D, for which claims related to the immune system can be used in their labels.<sup>4,5</sup>

Among dietary supplements, those containing vitamins are the category most consumed by the population.<sup>6</sup> Vitamins comprise a class of 13 compounds, and each of them has a specific recommended daily intake (RDI) ranging from 2.4 µg (vitamin B<sub>12</sub>) to 45 mg (vitamin C).<sup>7</sup> Until the publication of the

new regulations in July 2018, the minimum and maximum concentrations of vitamins in supplements were established based on the RDIs, with the minimum and maximum limits corresponding respectively to 15% and 100% of the RDIs.<sup>8</sup> In the new regulations, the maximum limits of vitamins allowed in supplements are primarily based on the tolerable upper intake level (UL), that is, the highest value of continued daily intake of a nutrient that apparently offers no adverse health effects for almost all individuals in any stage of life or of any gender.<sup>9-11</sup> As established for the RDI, UL values are also specific for each vitamin, so there is a diversity of vitamin-based products on the market with compositions and concentrations that widely differ from each other.

The objective of the present work was to discuss the parameters established for vitamin-based products, comparing them before and after the publication of the new regulations, mainly in relation to the concentrations of micronutrients required and allowed, and to verify the impact of these changes on consumer supervision and safety.

**Methodology**

The discussions were based on current regulations and those repealed to establish a chronological understanding.

The primary repealed legislation is in the following ordinances and resolutions:

- Ordinance n° 59/1995 of the Department of Health Surveillance (Secretaria de Vigilância em Saúde, SVS, in Portuguese) of the Brazilian Ministry of Health (Ministério da Saúde, MS, in Portuguese): approved the technical standard for nutritional complements;<sup>12</sup>
- SVS/MS ordinance n° 40/1998: regulation that establishes standards for levels of daily dosages of vitamins and minerals in medicines;<sup>13</sup>
- SVS/MS ordinance n° 120/1999: approved the technical regulation regarding the manual of procedures and technical analysis for the registration of foods, additives, technology adjuvants. and packaging;<sup>14</sup>

- ANVISA's Collegiate Board of Directors Resolution (Resolução da Diretoria Colegiada, RDC, in Portuguese) n° 24/2005: technical regulation that approves the use of food additives and technology adjuvants, establishing their functions and limits, and vehicle substances for vitamin and or mineral supplements;<sup>15</sup>
- SVS/MS ordinance n° 32/1998 of the: approves the technical regulation for vitamin and/or mineral supplements;<sup>8</sup> and
- RDC n° 278/2005: approves the categories of food and packaging exempted from registration, and those with mandatory registration.<sup>16</sup>

Among the laws in force, the most discussed are listed below:

- Statutory order n° 986/1969: establishes basic food standards;<sup>17</sup>
- Resolution n° 23/2000: establishes the manual of basic procedures for registration and exemption from the obligation to register products relevant to the field of food (partially revoked);<sup>18</sup>
- RDC n° 259/2002: approves the technical regulation on the labeling of packaged foods;<sup>19</sup>
- ANVISA RDC n° 360/2003: approves the technical regulation on the nutritional labelling of packaged foods, making nutritional labelling mandatory;<sup>20</sup>
- ANVISA RDC n° 269/2005: technical regulation on the RDI of protein, vitamins, and minerals;<sup>21</sup>
- RDC n° 27/2010: establishes the categories of food and packaging exempted from sanitary registration and those with mandatory sanitary registration;<sup>22</sup>
- RDC n° 54/2012: establishes the technical regulation on complementary nutritional information;<sup>23</sup>
- ANVISA RDC n° 239/2018: establishes food additives and technology adjuvants authorized for use in food supplements;<sup>24</sup>
- ANVISA RDC n° 240/2018: Amends RDC resolution n° 27/2010, which establishes the categories of food and packaging exempted from sanitary registration and those with mandatory sanitary registration;<sup>25</sup>
- ANVISA RDC n° 242/2018: regulates the registration of vitamins, minerals, aminoacids, and proteins for oral use, classified as specific medicines;<sup>26</sup>
- ANVISA RDC n° 243/2018: establishes the health requirements of food supplements;<sup>27</sup> and
- Normative instruction n° 28/2018: establishes the lists of constituents, limits of use, claims and complementary labeling of food supplements.<sup>5</sup>

## Legislation regarding vitamin-based products: brief history

### Definitions

With the progress in research on the importance of vitamins for health and, consequently, the development and commercialization of products for supplementation as nutritional and dietary supplements, there was a need for regulations pertaining to these products, which were being updated over time.

In Brazil, the Ordinance of the Health Surveillance Secretariat of the Ministry of Health (SVS/MS) n° 59/1995 approved the Technical Standard for a nutritional supplement. In this regulation, the combined vitamins, also called vitamin complexes, and the vitamin source products, legally regulated by Identity and Quality Standard (PIQ) such as cod-liver oil, shark-liver oil, wheat-germ oil, yeast or beer yeast, were classified as nutritional complements. These should contain at least 25% and a maximum of 100% of the recommended daily doses (RDDs) for each nutrient in the daily serving indicated by the manufacturer.<sup>12</sup> The RDD values were close to the RDI values currently used as a reference.<sup>21</sup>

In 1998, considering the need to normalize the use of vitamin and mineral supplements in Brazil, control their production and commercialization, and improve these products' sanitary control SVS/MS ordinance n° 32/1998 was enacted.<sup>8</sup> This ordinance approved the technical regulation to fix of the identity and quality of vitamin and/or mineral supplements and repealed SVS/MS ordinance n° 59/1999, creating a specific category for vitamin and/or mineral supplements. From then on, the following definition was adopted: *"Vitamin and mineral supplements are nourishment that serves to complement with these nutrients the daily diet of a healthy person, in cases in which their intake, from food, is insufficient, or when the diet requires. They must contain a minimum of 25% and, maximum, up to 100% of the recommended vitamins and/or minerals daily intake, in the daily part indicated by the manufacturer, and may not replace the foods, nor be considered as an exclusive diet."*<sup>8</sup> On the same date, SVS/MS ordinance n° 40/1998 was enacted, a regulation that established the standards for the daily dosage levels of vitamins and minerals in medicines. According to this standard, vitamin-based products whose daily dosing regimens were above 100% of the RDI were classified as medicines.<sup>13</sup>

In July 2018, a new regulatory framework for dietary supplements in Brazil was published, consisting of 5 standards, among them, ANVISA RDC n° 243/2018, which establishes the sanitary requirements for dietary supplements, and normative instruction n° 28/2018, which establishes the lists of constituents, limits of use, claims, and complementary labeling of dietary supplements.<sup>5,9</sup> According to the new regulation, dietary supplement is defined as a *"Product for oral intake, presented in pharmaceutical forms, intended to supplement the diet of healthy individuals with nutrients, bioactive substances, enzymes or probiotics, isolated or combined"*. Vitamin and mineral supplements became part of this broad category of dietary supplement, which includes in its definition products other than vitamin-based products.<sup>9</sup>

The new regulation revoked and changed several laws, such as Ordinances SVS / MS n° 32/1998<sup>8</sup> and n° 40/1998<sup>13</sup>, ANVISA RDC Resolutions n° 2/2002<sup>27</sup> and n° 18/2010<sup>28</sup>, in addition to some items of ANVISA Resolution n° 16/1999<sup>29</sup> and Ordinance SVS/MS n° 29/1998<sup>30</sup>. These laws were related to vitamin and mineral supplements, bioactive substances and probiotics, athlete's foods, new food products and/or new ingredients, among other categories, which are currently included in the new regulations, all of which are called dietary supplements.<sup>9</sup>

### Registration with the Ministry of Health

Statutory order n° 986/1969 establishes basic food standards and defines food types, procedures for registration, control, and supervision. Despite presenting revoked items and some definitions and procedures that were later incorporated into other publications, this decree remains in force to this day due to its scope. According to this standard, it was mandatory that all food products be registered with the competent body of the MS.<sup>17</sup> Over the years, and with the increase in the demand for registrations, there was a need to improve health control actions in the field of food, standardize these procedures, as well as to promote measures to rationalize the process, aiming to reduce the deadlines to grant the registration. Thus, SVS/MS ordinance n° 120/1999 approved the technical regulation regarding the manual of procedures and technical analysis for the registration of food products, additives, technology adjuvants and packaging, with the objective of guiding the basic procedures for registration of products relevant to the field of food. In this regulation, the registration of all food products, except raw materials, fresh food, intentional additives inscribed in the pharmacopeia, and bakery and bakery-related products, remained mandatory, when they were intended exclusively for direct sale to the consumer.<sup>14</sup> The following year, ANVISA published resolution n° 23/2000, which establishes the manual of basic procedures for the registration and exemption from the obligation to register products relevant to the field of food. According to this regulation, 45 categories of products were exempted from the obligation to register with the competent body of the MS. In this case, it was established that the company should inform the beginning of manufacturing process of the product(s) to the health authority of the state, the Federal District or the municipality, and may begin its commercialization. The mandatory registration for the category of vitamin and mineral supplements remained.<sup>18</sup>

In 2005, with the update in the PIQ, it was also necessary to update the categories of food and packaging exempted from mandatory registration and those with mandatory registration with the publication of ANVISA RDC n° 278/2005. Annexes I and II of resolution n° 23/2000, which respectively contained the products exempted from and those with mandatory registration, were revoked. The mandatory registration of vitamin and mineral supplements remained.<sup>16</sup>

The list of categories of foods and packaging exempted from and with mandatory health registration was updated in 2010 with the publication of ANVISA RDC n° 27/2010, which revoked RDC n° 278/2005. Since then, vitamin and mineral supplements, along with 14 other food categories, have been exempted from registration with the MS they are considered low-risk by ANVISA.<sup>21</sup>

ANVISA RDC n° 240/2018 amended RDC n° 27/2010, presenting the new category of food supplement in the list of foods and packaging exempted from mandatory sanitary registration.<sup>25</sup>

### Additives and technology adjuvants

With regard to additives and technology adjuvants approved for use in vitamin-based products, the main legislation prior to

the publication of the new standards on dietary supplements was resolution n° 02/2001, which approved the technical regulation on the use of food additives, supporting technology and vehicle substances for vitamin and/or mineral supplements,<sup>31</sup> and ANVISA RDC n° 24/2005, a technical regulation that approved the use of food additives, supporting technology, establishing its functions and limits, and vehicle substances for vitamin and/or mineral supplements, which revoked the previous one.<sup>15</sup> In addition, several other resolutions have approved the extension of the use of food additives for vitamin and/or mineral supplements, such as RDC no 7/2015,<sup>32</sup> n° 57/2011,<sup>33</sup> and n° 55/2014.<sup>34</sup> With the new regulatory framework, food additives and technology adjuvants authorized for use in dietary supplements are established in ANVISA RDC n° 239/2018,<sup>24</sup> which repeals RDC n° 24/2005 and the others for the aforementioned extension of the use of additives.

## Key changes with the new regulations

### Vitamin concentrations

The main changes observed in the parameters established for vitamin-based dietary supplements were regarding the minimum concentrations required and maximum permissible concentrations of these micronutrients in their composition.<sup>5,8</sup>

The maximum vitamin limits aim to ensure that the vitamin concentrations are within safe consumption limits, reducing the risk of excessive consumption and, consequently, the risk of developing the health problems that may be associated with this. In the previous legislation, the value of 100% RDI was established as the maximum limit for all vitamins, and products with concentrations higher than this were considered medicines.<sup>8</sup> The values established in the new legislation follow the recommendations of the *Codex Alimentarius* and of the Institute of Medicine (IOM), which take into account the safety limits for each vitamin, the variation in the sensitivity to its effects of different population groups, and the daily amount consumed of each substance from other food sources.<sup>10,11</sup> The food consumption data for the Brazilian population were based on the results of the 2008–2009 POF (Household Budget Research) and on food composition tables. The maximum limits currently allowed for each vitamin are listed in ►Table 1 with the respective RDI values, also comparing the current values in relation to the previously established ones. The current concentrations range from 113% (pantothenic acid) to 10,000% (vitamin E) RDI, noting that, in previous pieces of legislation, the maximum concentration was limited to 100% RDI for all vitamins.<sup>5,8</sup>

The minimum vitamin limits indicate the minimum amount of these micronutrients provided by the supplements in the daily recommendation of consumption indicated by the manufacturer, and aim to ensure a significant minimum contribution, considering the nutritional recommendations available for the different population groups. In the previous legislation, SVS/MS ordinance n° 32/1998, the minimum limit of 15% RDI for all vitamins was established based on the recommendations of the *Codex Alimentarius*.<sup>8,10</sup> In the new legislation, these values were replaced by the recommendations of the IOM, the most current and internationally recognized reference.<sup>11</sup> The new recommendations also consider

**Table 1** Maximum limits of vitamins allowed in supplements, before and after the new regulations, with their respective percentage (%) increase compared to the previous limit

	Top values			Superior amount
	Before (100% recommended daily intake)*	After**	% recommended daily intake	
E (mg)	10	1,000	10,000	100 x
B6 (mg)	1.3	98.60	7,585	76 x
C (mg)	45	1,916	4,258	43 x
D (µg)	5	50	1,000	10 x
A (µg)	600	2,600	433	4.3 x
B12(mg)	2.4	9.94	414	4.1 x
Folic acid (µg)	240	641.86	267	2.6 x
Vitamin K (µg)	65	149.06	229	2.3 x
Niacin (mg)	16	35	219	2.2 x
Riboflavin (mg)	1.3	2.74	211	2.1 x
Thiamine (mg)	1.2	2.02	168	1.7 x
Biotin (µg)	30	45	150	1.5 x
Pantothenic acid (mg)	5	5.64	113	1.1 x

Notes: \*SVS/MS ordinance n° 32/1998,<sup>8</sup> and RDC n° 269/2005;<sup>21</sup> \*\*normative instruction n° 28/2018.<sup>5</sup>

the variability of different population groups, classified into 8 age groups: infants aged from 0 to 6 months, infants aged from 6 to 12 months, children in early childhood (1 to 3 years), children aged from 4 to 8 years, individuals aged from 9 to 18 years, adults (aged > 18 years), pregnant women, and lactating women. The required minimum limit, which was previously of 15% RDI for all vitamins, started to vary between 15% and 60% RDI<sup>5,8</sup> (► **Table 2**). Pantothenic acid, biotin and thiamine were the vitamins that had the lowest changes in concentration, both in relation to the minimum and the maximum limits. Taking into account the maximum limits of vitamins established for adults, the most relevant differences were the increase in these limits in the order of 100, 76 and 43 times for the levels of vitamins E, B<sub>6</sub> and C respectively, when compared to the previously established limits. For the minimum limits required, the greatest difference was observed for vitamin D, with a 4-fold increase in concentration. On the other hand, there were no differences in the concentrations of vitamins B<sub>12</sub>, niacin, thiamine, biotin, and pantothenic acid, for which the minimum limits of 15% RDI were maintained (► **Table 2**).

With the changes in the limits established for vitamin-based supplements in the new regulation, many of the products that were marketed as medicines, that is, that had concentrations of vitamins above 100% RDI, began to be classified as a dietary supplements, thus becoming exempt from the obligation to register with the MS.

### Labelling

As a general rule, the labelling of food supplements must comply with the requirements described in statutory order n° 986/69, which establishes basic food standards, and the requirements present in ANVISA RDCs n° 259/2002 and n°

**Table 2** Minimum limits of vitamins required in supplements, before and after new regulations, and percentages (%) of recommended daily intake

Vitamins	Limits		
	Before (15% recommended daily intake)*	After**	% recommended daily intake
E (mg)	1.5	2.25	22.5
B6 (mg)	0.19	0.26	20
C (mg)	6.75	13.5	30
D (µg)	0.75	3	60
A (µg)	90	135	22.5
B12(mg)	0.36	0.36	15
Folic acid (µg)	36	60	25
Vitamin K (µg)	9.75	18	27.7
Niacin (mg)	2.4	2.4	15
Riboflavin (mg)	0.19	0.21	16.2
Thiamine (mg)	0.18	0.18	15
Biotin (µg)	4.5	4.5	15
Pantothenic acid (mg)	0.75	0.75	15

Notes: \*SVS/MS ordinance n° 32/1998,<sup>8</sup> and RDC n° 269/2005;<sup>21</sup> \*\*normative instruction n° 28/2018.<sup>5</sup>

360/2003, technical regulations for general labelling and nutritional labelling of packaged foods respectively.<sup>17,19,20</sup>

The main modifications established for vitamin dietary supplement labels with the publication of the new standards are presented in **Box 1**. ANVISA RDC n° 243/2018 establishes, in addition to the change in the designation of the product, some specificities concerning to the declared port, nutritional

**Box 1** Key differences established for vitamin-based product labels before and after the new regulations.

	Before*	After**
Sales denomination	Vitamin supplement; vitamin supplement(s); vitamin(s) supplement	Food supplement (pharmaceutical form) (name, category, or source of nutrient)
Allegations	Only claims fully recognized by the scientific community	Claims authorized in normative instruction n° 28/2018
Required/permitted concentrations of vitamins	15% RDI (minimum); 100% RDI (maximum)	15% to 60% RDI (minimum); 113% to 10,000% RDI (maximum)
Mandatory guidance/warning phrases	“Pregnant women, nursing mothers and children up to 3 (three) years should only consume this product under the guidance of a nutritionist or doctor”; “Consume this product according to the daily intake recommendation on the packaging”	“This product is not a medicine”; “Do not exceed the daily intake recommendation indicated on the package”; “Keep out of reach of children”
Complementary nutritional information	Follows the provisions of RDC n° 54/2012	Follows normative instruction n° 28/2018 (does not apply to RDC n° 54/12)

Abbreviations: RDC, Collegiate Board of Directors Resolution (Resolução da Diretoria Colegiada, RDC, in Portuguese); RDI, recommended daily intake.

Notes: \*SVS/MS ordinance n° 32/1998;<sup>8</sup> \*\*resolution n° 243/2018,<sup>9</sup> and normative instruction n° 28/2018<sup>5</sup>

information and percentage of daily value (%DV). The label of vitamin dietary supplements should also have three warnings (**Box 1**) regarding the recommendation of use, the population group, and the age group for which the product is indicated. The labelling of food supplements should not mislead the consumer with the use of unauthorised phrases and/or expressions. Likewise, they must not present words or any graphic representation that states or suggests that the product has a medicinal or therapeutic purpose; containing unauthorized or prohibited substances; that food is not able to provide the necessary components for health; or that the product is comparable or superior to conventional foods.<sup>9</sup>

ANVISA RDC n° 54/2012, a piece of legislation on complementary nutritional information,<sup>23</sup> does not apply to food supplements included in the new regulations; therefore, any and all declaration of nutritional property, as well as claims, may be used only if present in Annex V of normative instruction n° 28/2018.<sup>5</sup> The labels of all vitamins may contain 3 to 9 authorized claims, which are subject to specific composition and labeling requirements.<sup>5</sup>

With the diversity of food supplements available in the market, the information on the labeling should help the consumer to know their nutritional properties and distinguish the products from each other. Abe-Matsumoto et al.<sup>35</sup>, when evaluating labels of vitamin supplements, observed 48% of samples with one or more items in disagreement with the legislation, with the use of unauthorized expressions being the largest irregularity observed, indicating that it is not always possible to rely on the information on the label. With the changes in legislation, the words on the labels must be in accordance with the requirements established in the legislation, in accordance with the new standards.

## Challenges and questions

Changes in vitamin concentrations determined by the new regulations enable the sale of products with a wide variation in their content. Two supplements may, for example, present in their composition concentrations of 45 mg (the minimum concentration required) and 1,916 mg (the maximum permitted concentration) of vitamin C in each portion, and both be marketed under the same sales name “vitamin C food supplement in capsules”. The price variation can be large between one supplement and another and will not always be proportional to the concentration of vitamins, because the sales price of a product depends on several factors, such as production costs, employee salaries, expenses, and the profits that the company intends to obtain, in addition to the differences that can exist between microenterprises and multinationals.<sup>36</sup>

According to ANVISA, the supplements are intended for healthy people as an option for nutritional complementation, in the case of restrictive diets, metabolic alterations, intense physical activity, among other indications.<sup>37</sup> In order to receive appropriate consumption guidelines, people with specific health conditions should seek a qualified healthcare professional, such as doctors, nutritionists and pharmacists, to prescribe these products.<sup>37–39</sup> However, the consumption of dietary supplements, especially among practitioners physical activity, is mostly not carried out under the guidance of these professionals. Gonçalves das Neves et al.<sup>3</sup> found that only 17% of supplement consumers do so by indication of doctors and nutritionists; most take these supplements after an indication from friends and gym instructors, in addition to consumption on their own. Studies also show that a large part of the population does not read nutritional

information on food labels or often have difficulties interpreting such information, emphasizing the importance of the guidance of a qualified healthcare professional to the safe consumption of supplements.<sup>40</sup>

The consumption of dietary supplements without the indication of a specialized professional and without attentively reading the recommendations and warnings presented on the label can bring health risks. The ingestion of amounts above the safety limits or by population groups for which they have not been indicated are examples of the inadequate use of supplements that can lead to symptoms of intoxication associated with overuse.<sup>41</sup> Or et al.<sup>41</sup> observed an almost three-fold higher risk of severe symptoms associated with the consumption of supplements for increased muscle mass and energy and for weight loss compared to the consumption of vitamin supplements. This, however, does not exclude the risks posed by the abusive consumption of vitamins, especially fat-soluble vitamins, since their excess can also be harmful.

Evidence suggests that increasing the intake above the currently-recommended levels of certain nutrients such as vitamin D may help optimize immune functions, consequently leading to resistance to infections. However, the increasing practice of vitamin D supplementation in recent years is also accompanied by a substantial increase in the number of notifications of poisoning caused by this vitamin. The causes of vitamin D toxicity are multiple, and include the use of irregular and/or error-in-dosage products, the wide availability of over-the-counter supplements, their misuse, and prescription errors.<sup>42</sup>

The first large-scale clinical trials that showed controversial results regarding the protective role of antioxidant vitamins were The Alpha-Tocopherol, Beta-Carotene (ATBC) Lung Cancer Prevention Study,<sup>43</sup> which tested the hypothesis that the increased consumption of  $\alpha$ -tocopherol (vitamin E) and/or  $\beta$ -carotene (provitamin A) in smokers could prevent lung cancer and other types of cancer; and the Beta-Carotene and Retinol Efficacy Trial (CARET),<sup>44</sup> which verified the incidence of lung cancer and other types of cancer with  $\beta$ -carotene and retinol palmitate (vitamin A) supplementation. Both studies demonstrated a higher incidence of cancer in the supplemented group, sparking a warning to the scientific community about the risks of excessive vitamin consumption and inadequate supplementation. Both the scientific community and government agencies need to guide the population to avoid the excessive intake of vitamins without a real need. To make the population aware that all excess is harmful is a major challenge to public health, since the false concept “if it is a vitamin it is not bad for you” prevails for most.

Another major challenge concerns the supervision of food supplements by health authorities. There is an increase in the availability of these products in the market because many products that were once marketed as medicines with mandatory registration with the MS became exempt from registration with the new regulations, facilitating their sale and speeding up the process of launching new products on the market. With the increase in food supplements in the market, there is a consequent increase in the demand for analysis by the Brazilian central public health laboratories for purposes of

inspection and control. The methods already standardized for the quantification of vitamins in concentrations close to 100% RDI require adaptations, or even the development of new methodologies for the quantification of concentrations well above those previously established.

The increase in the consumption of dietary supplements by the population intensifies in periods of increased risk of diseases, such as the Covid-19 pandemic.<sup>4</sup> There was a lack of supplements on the market in some periods during this pandemic, especially multivitamins and those composed of vitamins C and D.<sup>45</sup> This unbridled search for supplements may indicate an abuse of these products on the part of the population, in the hope of guaranteeing immunity, even without the guidance of a specialized professional.

## Conclusions

Dietary supplements are increasingly consumed by the population for various reasons, such as slowing aging, fighting stress, and preventing diseases, although such claims are not allowed in these products.

Changes in legislation can influence the health of the population, because it is not yet known whether they will have the discernment to choose which supplements are most suitable for their health if they do not seek guidance from a qualified professional.

For the health professional to be able to indicate or recommend the product that best meets the needs of the consumer, it is suggested that these professionals, especially physicians, pharmacists, and nutritionists are guided by their class advice on the procedures adopted for the correct prescription of dietary supplements, evaluating the real need for supplementation and prioritizing the benefits of their consumption.

After almost half of the adequacy period, an increasing variety of dietary supplements is available for sale in the market; however, the ideal amounts of vitamins in supplements and the recommendation consuming these products deserve broad discussion and reflection.

## Conflict of Interests

The authors have no conflict of interests to declare.

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