 **Amendments have been made to the legislation on sales of dietary supplements**

*FAO manufacturers, distributors, retailers of dietary supplements, medical and pharmaceutical companies, and marketplaces.*

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Pepeliaev Group advises that, on 7 June 2025, [**Federal Law No. 150-FZ dated 7 June 2025**](http://publication.pravo.gov.ru/document/0001202506070026?index=4) was signed by the Russian President and published. **The law provides for changes to the rules for selling dietary supplements, including for healthcare professionals to prescribe dietary supplements.**

The law will come into force as of 1 September 2025.

**Dietary supplements prescribed by doctors**

A new article 25.7 “Specific aspects of regulating the use of dietary supplements” has been added to Federal Law No. 29-FZ “On the quality and safety of foodstuffs” dated 2 January 2000 (“Federal Law 29-FZ”). The relevant amendment has also been made to Federal Law No. 323-FZ “On the fundamentals of protecting the public's health in Russia” dated 21 November 2011 (“Federal Law 323-FZ”), specifically, in the form of part 1.7 being added to article 37 “Arranging for medical assistance to be provided”.

Healthcare professionals will be entitled to prescribe registered dietary supplements under the procedure established by the Russian Ministry of Healthcare and agreed with the Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing (“Rospotrebnadzor” or the “consumer rights authority”) when the following conditions are simultaneously met:

1) The dietary supplements have been included in the list approved by the Ministry of Healthcare and agreed with the consumer rights authority;

2) the prescription is in line with the dosage schedule for the dietary supplement established by methodological guidelines approved by the Ministry of Healthcare and agreed with the consumer rights authority;

3) the prescription must fall within the indications for the use of a particular dietary supplement. The list of such indications must also be approved by the Ministry of Healthcare and agreed with the consumer rights authority.

In view of the blanket nature of the new rules, at present the matters in question are: (i) the content of the list of dietary supplements permitted to be prescribed and of the corresponding methodological guidelines, as well as (ii) the timeframes for such list of supplements and guidelines to be approved. Unless the necessary regulations are approved by 1 September, the coming of the law into force will not, in itself, create the necessary conditions for doctors to be able to prescribe dietary supplements.

An important aspect for organising medical assistance is the connection between clinical guidelines for how such assistance should be provided and methodological guidelines for dietary supplements to be prescribed. For instance, observance of methodological guidelines formally must not be taken into account for assessing the quality of medical assistance being provided, because such guidelines do not form criteria for the quality of medical assistance (see article 64(2) of Federal Law 323-FZ). In addition, nor are the methodological guidelines included in the list of documents that serve as the basis for medical assistance to be provided (see article 37(1) of Federal Law 323-FZ).

Therefore, we believe that, where there are any discrepancies between methodological and clinical guidelines, the latter will take precedence.

[[1]](#footnote-1)
At the moment it is still not entirely clear what the prospects are of dietary supplements being included in the programme of government guarantees that medical assistance will be provided and whether it is possible to supply dietary supplements to patients in the form of state benefits.

Pepeliaev Group’s comment

At present, some clinical guidelines already contain recommendations for dietary supplements to be applied. For instance, in the clinical guidelines “Disorders of mitochondrial β-oxidation of fatty acids”, the following is specified “Recommended: sodium benzoate (dietary supplement) to be prescribed for blood ammonia levels above 150-200 µmol/l to patients with FAOD if a metabolic crisis develops”.

**Restrictions on healthcare professionals interacting with manufacturers / sellers of dietary supplements**

The law provides that restrictions established with respect to the ways and forms in which healthcare professionals liaise with pharmaceutical companies (article 74 of Federal Law 323-FZ) will now extend to how doctors liaise with manufacturers / sellers of dietary supplements.

**Permitted and prohibited formats of interaction between healthcare professionals and manufacturers (distributors) of dietary supplements**

|  |  |
| --- | --- |
| **Prohibited** | **Permitted** |
|  | To accept money (save in situations that are exceptions), gifts, paid vacations, and entertainment, or participate in leisure activities  |  | Receive remuneration for teaching |
|  | Receive items from companies to be delivered to patients |  | Receive remuneration to conduct R&D work |
|  | Enter into contracts to prescribe or recommend dietary supplements to patients, including contracts to conduct clinical trials |  | Meetings and other events for boosting the level of professional expertise |
|  | Provide inaccurate or incomplete information about a dietary supplement |  |  |
|  | Receive representatives of manufacturers / distributors |  |  |

Unlike pharmaceutical companies, manufacturers and distributors of dietary supplements will not be able to enter into fee-based contracts with doctors to conduct clinical trials of dietary supplements. On the one hand, no obligation is provided for in the law to conduct clinical trials of dietary supplements. On the other hand, the conditions for dietary supplements to be prescribed include the availability of dosage schedules approved under methodological guidelines, as well as the dietary supplements in question being included in the list of supplements that are confirmed as effective. Given that it is impossible to conduct and pay for clinical trials on lawful grounds, there remains the question of how to form the evidence base with a view to dietary supplements being confirmed as effective and making provision for the relevant dosage schedules.

It is noteworthy that manufacturers / sellers of dietary supplements will not be subject to all restrictions in terms of liaising with employees of pharmacies (pharmacists). For instance, the changes have not extended to article 74(2) of Federal Law 323-FZ, in other words, formally companies are NOT prohibited from supplying samples of dietary supplements to pharmacists to give them out to customers and enter into contracts for certain dietary supplements to be offered to the public. Employees of pharmacies do not have the obligation to inform customers that there is a cheaper dietary supplement in stock.

Time will tell whether such an exception being made for manufacturers and sellers of dietary supplements represents a deliberate relaxation of the regulation or whether these gaps will be eliminated in subsequent versions of the law.

The issue of liability for a breach of said restrictions has been discussed on numerous occasions and at the same time there are no grounds to state that some types of liability, such as administrative liability within the framework of article 14.33 (unfair competition), 19.28 (payment of unlawful remuneration on behalf of a legal entity) of the Code of Administrative Offences or criminal liability under articles 204 and 291 of the Criminal Code cannot be applied in the event of that companies and / or their representatives breach the ban established in article 74 of Federal Law 323-FZ.

**Websites trading in prohibited dietary supplements being blocked without recourse to a court**

The law enacts a new rule (article 3(2.1) of Federal Law 29-FZ), as well as article 15.1(5)(1)(m) of Federal Law No. 149-FZ “On information, information technologies and the protection of information” dated 27 July 2006, whereby it is prohibited to distribute information that contains an offer to retail dietary supplements that are prohibited on the market, including remotely. Pursuant to article 3(2) of Federal Law 29-FZ it is prohibited to circulate dietary supplements that:

* are dangerous and/or of low quality in terms of organoleptic indicators;
* contain standardised substances that do not comply with the values established under Russian legislation;
* contain items, particles, substances or organisms that have been formed in or have been added to the dietary supplement, which may adversely affect a person or future generations and that have not been pointed out to the consumer;
* have passed their expiration date or do not have an expiration date specified on their packaging;
* do not meet the requirements established under Russian legislation, including requirements of the applicable Technical Regulations of the Customs Union (TR CU);
* have been established to be counterfeited;
* cannot be confirmed as traceable;
* do not bear labelling with information about foodstuffs as provided for under Russian legislation or if no such information is known about them;
* are not accompanied by shipping documents.

It should be noted that neither are dietary supplements that have not undergone registration under the established procedure (articles 24(1) and 24(2) of TR CU 021/2011) permitted to be produced, stored, transported and distributed.

Therefore, information about an offer to retail dietary supplements that fall under at least one prohibition set out above must not be placed on, among other things, websites, such as marketplaces. If such an offer has been published, this may result in the corresponding website being blocked without recourse to a court (i.e. the domain name or another identifier will be entered in the “Unified Register of domain names, indexes of pages on the Internet and web-addresses that allow for websites that contain information prohibited for distribution in the Russian Federation to be identified in the Internet”[[2]](#footnote-2)). Rospotrebnadzor will be the state authority responsible for identifying the above information with a view to including the data in the Register.

There are already examples in practice when websites containing information about prohibited dietary supplements have been blocked further to claims from Rospotrebnadzor.[[3]](#footnote-3) Consequently, one might say that the approved amendments fall within the general trend, but will reduce the timing required to block similar services, because there will be no need to file a claim with the court.

**Additional criteria for the quality of dietary supplements**

The new article 25.7 of Federal Law 29-FZ contains a regulation that the list of dietary supplements approved by the Ministry of Healthcare may contain only supplements that meet the criteria of quality and effectiveness established by the Russian Government, depending on how they affect the health of an individual, as well as meeting the requirements of technical regulations of the EAEU.

The last clarification might seem excessive, because in a case where dietary supplements do not meet the requirements of the TR CU, and specifically TR CU 021/2011 “On the safety of foodstuffs”, such dietary supplements must not be registered. However, in practice there have been [situations](https://pharmvestnik.ru/content/news/Rospotrebnadzor-zapretil-realizaciu-BAD-s-litiem.html) when dietary supplements registered in the EAEU were classified by Rospotrebnadzor as violating requirements of the technical regulations.

At the same time, the Russian Government has to establish certain additional criteria for the quality of dietary supplements that are compulsory to meet for a supplement to be included in the list. At present, it is impossible to say with certainty what these criteria will be.

However, the new regulations must not by themselves limit the circulation (including registration) of supplements, in other words, such restrictions may be taken into account only for considering whether to include a specific dietary supplement in the list and methodological guidelines.

The law in question sets out in greater detail the rule that prohibits manufacturing dietary supplements for children using alimentary raw materials produced with the use of feed additives, animal growth stimulants (including hormonal agents), certain types of medicines, pesticides, agrochemicals and other substances and compounds that are dangerous to human health. The fact that certain rules have been set out more specifically does not give rise to any extra legal implications, because such a prohibition already existed (albeit formulated in a more general manner) in article 17(3) of Federal Law 29-FZ.

**What to think about and what to do**

Prior to the law coming into force, companies that are manufacturers / sellers of dietary supplements may be recommended:

* To conduct an assessment of business processes connected with the promotion and sale of dietary supplements. What is meant, primarily, are the processes of interaction with healthcare professionals and employees of pharmacies. Apart from creating a hypothetical opportunity for dietary supplements to be prescribed by doctors, the legislation in fact imposes additional obligations on such companies. At the same time, companies whose portfolio includes medicines/medical devices as well as dietary supplements have usually been well known for a long time.
* Monitor developments in subordinate legislation, primarily, keep track of the current information regarding the development and approval of the list of dietary supplements that may be prescribed by doctors, approval of the methodological guidelines, approval by the Russian Government of additional quality criteria for dietary supplements, etc.

Marketplaces, online stores and others involved in the online trade in dietary supplements should conduct an internal audit of the dietary supplements that are sold on their platforms and adopt additional tools of control that prevent sales of dietary supplements that are prohibited from being circulated on the market. It is also possible to consider using contractual tools (such as the reimbursement of losses under article 406.1 of the Civil Code) in agreements with suppliers / sellers of dietary supplements, bearing in mind the additional risks of websites being blocked for reasons that do not at least entirely depend on the online platform.

Finally, good-faith companies that suffer damage from actions of sellers distributing their products illegally through the Internet must bear in mind an additional way of counteracting unfair competition that consists in having the website selling illegal dietary supplements blocked.

Help from your adviser

The lawyers of Pepeliaev Group are ready to provide the necessary legal support in all matters connected with the use of legislation on the circulation of dietary supplements, including to develop and adjust corporate policies / procedures, draft / amend contractual documents, and advise on contentions issues of how the new developments are applied in actual business practice.

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## Contact details

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1. Clinical guidelines: Disorders of mitochondrial β-oxidation of fatty acids, at the URL: <https://cr.minzdrav.gov.ru/recomend/694_1> [↑](#footnote-ref-1)
2. The Unified Register of domain names, indexes of pages on the Internet and web-addresses that allow for websites that contain information prohibited for distribution in the Russian Federation to be identified in the Internet, Roscomnadzor. URL: <https://eais.rkn.gov.ru/> [↑](#footnote-ref-2)
3. See <https://24.rospotrebnadzor.ru/content/1525/166120/>, <https://24.rospotrebnadzor.ru/content/1525/165162/?sphrase_id=138779> [↑](#footnote-ref-3)