

General Terms and Conditions for the use of the Website of The Association Bulgarian Medicines Verification Organization

These General Terms and Conditions (the “**General Terms**”) govern the use of the website of the Bulgarian Medicines Verification Organization, located at www.bgmvo.org (the “**Website**”).

In order to use the Website, users have to accept and agree to the General Terms.

I. Information about Bulgarian Medicines Verification Organization

This Website is created and maintained by the Bulgarian Medicines Verification Organization (the “**BgMVO**”). BgMVO is a private non-profit association with UIC 177021524, with seat and business address: Sofia, 36 Dragan Tsankov Blvd., email: office@bgmvo.org.

II. Purpose and Designation of the Website

1. The main purpose of the Website is to provide information on the BgMVO’s organization and operations as well as on the functioning of the National System for Verification of Medicinal Products (the “**National System**”) within the European System for Verification of Medicinal Products (the “**European System**”), including the applicable regulations for its establishment. This information is publicly available.
2. On the Website there is a section accessible only to manufacturers of medicinal products (the “**Manufacturers**”); holders of a marketing authorization for a medicinal product valid for the territory of the Republic of Bulgaria and representatives in the Republic of Bulgaria of the holders of marketing authorizations for medicinal products valid for the territory of the Republic of Bulgaria (the “**MAHs**”), parallel importers of medicinal products in the Republic of Bulgaria (the “**Parallel Importers**”), wholesalers of medicinal products (the “**Wholesalers**”), retailers of medicinal products (the “**Pharmacies**”), IT providers of pharma software (the “**IT Providers**”) and other users of the National System. These entities have access to the relevant section of the Website after registration in compliance with Section III below. This section provides to the persons listed above information for their co-operation with BgMVO in respect to the functioning of the National System and methods of accessing the European system.
3. The Website contains a free-access section with answers to the most frequently asked questions about the BgMVO and the National System, as well as a news section.

III. Registration

1. Registration is required only to access the Website's section entitled "*Users of the system*".
2. Only Manufacturers, MAHs, Parallel Importers, Wholesalers, Pharmacies, IT Providers and other users of the National System have access to the section "*Users of the system*". In order to register, they have to enter the following data on the website: name, BULSTAT, names of the contact person (first name and family name) and e-mail address.
3. The person's access will be activated within 3 (three) business days from the registration.

IV. Personal Data

1. BgMVO uses the personal data provided only for the purpose of registering on the Website when required under the General Terms.
2. The provision by the contact persons of personal data marked in the registration form with a "*" in the section "*Users of the system*": first name, family name, e-mail address, is a mandatory condition for registration on the Website.
3. Personal data will be processed in accordance with the applicable Bulgarian Personal Data Protection Act (the "**PDPA**"). BgMVO will keep the personal data for a period no longer than it is necessary to achieve the purposes for which they are being processed.
4. BgMVO takes the necessary technical and organizational measures to protect the personal data provided to the BgMVO. BgMVO is a registered administrator of personal data in the Personal Data Protection Commission with identification № 430220). BgMVO is responsible for the protection of personal data processed by it except in case of: force majeure, unforeseeable circumstances or malicious actions by third parties, and when the contact persons have themselves made this information available to third parties.
5. In accordance with the PDPA, the contact persons providing their personal data have the following rights: (a) access to their own personal data; (b) request from BgMVO at any time to erase, correct or block such personal data that is not processed in compliance with the PDPA and to notify third parties to whom such data has been disclosed of any erasure, correction or blocking unless this is impracticable or involves excessive efforts on the part of BgMVO; (c) object to BgMVO against the processing of their personal data, provided there is a legitimate reason for doing so and if the objection is well founded, BgMVO shall discontinue the processing of such personal data; also other rights under the PDPA.
6. In the cases as described in paragraph 5 of this Section above, the contact person, personally or through another person expressly authorized by him/her,

shall send to the correspondence address of BgMVO a written application containing: name, e-mail address, address for correspondence, as well as other data for the identification of the former person, with the request for deletion and/or correction of the personal data or the refusal to provide it to third parties and/or the preferred form for providing the data (where applicable under the PDPA). The application must be signed and dated. When the application is submitted by an authorized person, a notarized power of attorney shall also be attached.

7. By registering on the Website, the contact persons: (a) declare that they have read, understood and agree with the contents of these General Terms, (b) when filling in the registration form, they submit their personal data and submit them of their own free will; (c) agree that they are aware of the purpose, nature and conditions of the submitting and processing of their personal data, (d) agree of their own free will (in accordance with article 4 of PDPA) to their personal data being processed by the BgMVO and/or by a person(s) appointed by BgMVO for the purpose, (e) accept that they are aware of all legal possibilities under the PDPA concerning their personal data processing, including but not limited to objecting at any time to the way their personal data is processed.

V. Cookies

1. BgMVO uses cookies as described in this Section. BgMVO notifies of the use of cookies when the user visits the Website for the first time. Information about the use of cookies is received every time one logs in to the Website unless the user has already agreed to their use.
2. Cookies are small text files that are stored on the computer of each user of the Website to improve its performance according to his/her preferences. Every time the Website is re-visited, the cookies will automatically recognize that the user is a returning user, as well as the settings and preferences he/she has already selected.
3. Cookies shall not be used for purposes other than those specified in this paragraph. BgMVO uses the following types of cookies:
 - i. Preferences: BgMVO uses preference cookies to store information about the user's browser and the way the user uses the Website. Preferences cookies make the use of the Website more efficient and responsive to the user's preferences.
 - ii. Security: BgMVO uses security cookies to provide user access to the Website and to protect their profile and information, including personal data, against fraud and unauthorized access by third parties with dishonest intent.

- iii. Functional: BgMVO uses functional cookies to make better use of the Website, such as saving the sound volume of videos that the user launches for viewing.
 - iv. Session State: BgMVO uses session-based cookies to collect information about how the user uses the Website. This is necessary for the better functioning of the Website.
 - v. Analytics: BgMVO uses analytics cookies, such as Google Analytics, to understand better how the user is using the Website and to address more effectively his/her interests while using the Website. This type of data is completely anonymous and is not connected to any disclosure of personal data.
4. The user of the Website may control and/or delete cookies whenever he/she wishes to do so. All cookies that are already saved on the user's computer can be deleted, and most browsers can be set up to block them. More information about this can be found at: www.aboutcookies.org.

VI. Trademarks and Copyrights

1. Trademarks published on the Website are the property of BgMVO or, as the case may be, its members, contractors and partners.
2. Copyrights and other intellectual property rights in the materials posted on the Website are the property of BgMVO or of such third parties as indicated.

VII. Miscellaneous

1. BgMVO reserves the right to modify the Website, as well as to supplement and amend the General Terms at any time when deemed necessary.
2. BgMVO does not guarantee the permanent and continuous functioning of the Website and access to it. BgMVO shall not be liable for damages to property or to a user when using the Website when such damages are not a direct and immediate consequence of such use.
3. The Website may contain links to other websites, information sources and advertisements. BgMVO is not responsible for the content of such information sources.
4. Possible disputes arising from the use of the Website shall be resolved by negotiation or, as a last resort, in the case of the impossibility of reaching an agreement, by the intervention of the competent authorities. Nullity or inapplicability of any provision of these General Terms shall not affect the validity or enforceability of other provisions. The nullity of individual provisions does not involve the nullity of the General Terms when they are legally superseded by mandatory law. The content of these General Terms shall be governed by the applicable legislation of the Republic of Bulgaria.
5. The General Terms are in force as of October 16, 2017.