

## Personal Data Protection Policy

The Association Bulgarian Medicines Verification Organisation (BgMVO) is committed and takes all necessary measures for the protection of personal data processed in accordance with the requirements of Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (**GDPR**), the Personal Data Protection Act and other related acts.

In fulfillment of its primary obligations for transparent and lawful processing of personal data as a personal data administrator, BgMVO is adopting this Personal Data Protection Policy and informing you of the following:

### I. Who is the administrator of your personal data

1. The administrator of your personal data is the Bulgarian Medicines Verification Organisation, a non-profit association for private benefit, with UIC 177021524, with registered and head address in Sofia, 36 Dragan Tsankov Blvd.
2. All questions and requests regarding your personal data can be sent to: Sofia, 36 Dragan Tsankov Blvd., as well as to the e-mail address: [office@bgmvo.org](mailto:office@bgmvo.org).

### II. Why we process your personal data and on what grounds

1. We process your personal data for the purposes stated herein and on the following grounds:
  - i. Firstly, we receive your names, phone numbers and e-mail addresses as representatives or employees (contact persons) of manufacturers (**Manufacturers**), holders of a marketing authorisation for a medicinal product valid for the territory of the Republic of Bulgaria and representatives in the Republic of Bulgaria of holders of marketing authorisations for medicinal products valid for the territory of the Republic of Bulgaria (**MAH**), parallel importers of medicinal products in the Republic of Bulgaria (**Parallel Importers**) on the basis of the agreements concluded between them and BgMVO for cooperation with regards to the operation of the Bulgarian Medicines Verification System (the Bulgarian System) within the framework of the European Medicines Verification System (**European System**). Our task is to identify you as a representative or employee (contact person) of the relevant organisation, in order to have a smoother and better coordinated relationship with this organisation and to administer the process of implementing the agreements.
  - ii. Secondly, we may receive personal information such as: name, e-mail address, telephone number and unique Master Pharmacist ID when a pharmacy or wholesaler of medicinal products applies for access to the Bulgarian Medicines Verification System. In this application, you may be referred to by the applicant as the responsible Master Pharmacist, as authorized by the Bulgarian Drug Agency, or as the contact person of the IT supplier of the Applicant (pharmacy or wholesaler). We receive this data on the basis of the General Terms and Conditions of Use of the National Medicines Verification System (BgMVS) by End Users (**General Terms and Conditions for End Users**) in relation with the implementation of Directive 2011/62/EU of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the introduction of falsified medicinal products into the legal supply chain (**the Directive**) and Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council (**the Regulation**).
  - iii. Lastly, we receive your details: name and surname, e-mail address and telephone number upon registration of the organisation with which you are in a contractual relationship (Manufacturer, MAH, Parallel importer) for access to the "MAHs" sub-section of the "Users of the system" section of our website [www.bgmvo.org](http://www.bgmvo.org). In this way, we provide the organisations you represent with specialised access to information about their joint activities with BgMVO related to the functioning of the Bulgarian system and how to access the European system. We process these data based on our legitimate interest to fulfill our contractual obligations to our partners.

2. If we do not receive this personal data, we will not be able to fulfill our commitments to the organisations you represent in an accurate and timely manner which could impede the overall functioning of the Bulgarian system as required by the Directive and the Delegated Regulation.

### **III. Who provides us with your personal data**

We receive your personal data from you or from the organisation of which you are an employee, or you have other contractual obligations with, and which has a contractual relationship with us or with one of our partners. We could also receive your personal data from public sources.

### **IV. Who can access your personal data**

Access to your personal data as described above is available to:

- i. Yourself as the subject of personal data;
- ii. Employees and other persons working for BgMVO;
- iii. Persons under a contract with us for the processing of personal data when required, such as IT service providers;
- iv. State authorities, where required by applicable law.

### **V. Providing personal data to countries outside the EU or to international organisations**

BgMVO does not provide your personal data to persons outside of the EU or to international organisations.

### **VI. How long we store your personal data**

We store your personal data for the period of registration in the Bulgarian system and/or our website of the organisation that you represent or are under contract with.

### **VII. Your rights when your personal data are processed**

1. You are entitled, under the terms of the Regulation, at any time and without delay to request from BgMVO the following:
  - i. To provide you with access to your personal data and information about it and the processing they perform in respect of it, as well as a free copy thereof, without adversely affecting the rights and freedoms of others;
  - ii. To request that these data are corrected and stored in an accurate and up-to-date form;
  - iii. To request that your personal data are erased when they are being processed or have been processed without reasons and/or for purposes that are no longer needed;
  - iv. To request that these data are processed under restriction;
  - v. To object to the processing of your personal data;
  - vi. To obtain your data in a structured, widely used and machine-readable format, and ask BgMVO to transfer them directly to another administrator;
2. You have the right to appeal to the competent supervisory authority and seek legal protection.

### **VIII. Automated solutions**

When BgMVO receives and processes your personal data to fulfill its obligations to its partners, we do not use these personal data for automated solutions, including profiling, that would have any legal consequences for you. Our website uses cookies. More information can be found in our Cookie Policy.

This Personal Data Protection Policy is in force as of: January 16th, 2023