

PRIVACY POLICY_EMVO PORTAL

EMVO'S ON-BOARDING PARTNER PORTAL

Our Privacy Policy at a glance

Who we are. We are the European Medicines Verification Organisation A.S.B.L., and we process your Personal Data in the context of this Portal. [See more.](#)

Personal Data we collect and process. We process the Personal Data that you share with us when registering, accessing or using this Portal and that we automatically collect by means of cookies and similar technologies, as described in our Cookies Policy. [See more.](#)

Purposes and legal bases of the processing. We have legal grounds to process your Personal Data for various reasons. The main reason is that we need to process your Personal Data to operate the European Medicines Verification System, the EMVS On-boarding process and this Portal. [See more.](#)

Sharing your Personal Data. We share your Personal Data with service providers who provide us with assistance or support and the National Medicines Verification Organizations, mainly within the European Economic Area. **See more.**

Your rights. You have the right to access, rectify or delete your Personal Data. In certain cases, you are also entitled to other rights, such as, for example, to object to us using your data, as explained in depth below. [See more.](#)

How to contact us. If you have any questions or concerns about this Privacy Policy, or if you wish to exercise any of your rights, please send a request by using our contact details provided below. [See more.](#)

PRIVACY POLICY

1. Introduction

European Medicines Verification Organisation, A.S.B.L., with registered office at rue du Commerce 123, 1000 Brussels, Belgium, VAT BE 0638.801.022 RPR/RPM Bruxelles ("**EMVO**", "**we**", "**us**", or "**our**"), as data controller of Personal Data about you, respects your concerns about privacy and value the relationship we have with you.

This EMVO Portal [Privacy Policy](#) ("**Privacy Policy**") describes the types of information you provide us with or we collect when you are accessing or using this Portal, including information relating to identified or identifiable individuals ("**Personal Data**"), for which purposes we use such Personal Data, with whom we may share it and the rights and choices available to you regarding our use of Personal Data about you. This Privacy Policy also describes and how Personal Data about you are secured and how you can contact us about our privacy practices.

Please read this Privacy Policy before using or submitting any Personal Data on the Portal.

By accessing and using EMVO's On-boarding Partner Portal at <https://emvo-portal.eu> (the "**Portal**") before using or submitting Personal Data on your private secured area of the Portal, you confirm that you have read and that you understand the way we collect, process, use and disclose Personal Data about you as described in this Privacy Policy.

The EMVO Portal allows you to access:

- EMVO's On-boarding Partner Portal: your private secured area and proceed with the provision of diverse information and the signing of the Participation Agreement
- The Alert Management System Portal (AMS Portal): The AMS Portal is the user interface that can be used to manage alerts. The AMS Portal was developed against the AMS User Requirements Specifications and together with the EMVO Stakeholders to fulfil the EMVO Stakeholders' needs.

Please note that before using or submitting Personal Data on your private secured area of the Portal, you might be also asked to confirm electronically your acceptance of this Privacy Policy by clicking on a button or ticking a box. Your affirmative action in clicking on that button and/or ticking that box and your use of the Portal signify that you agree to the collection, processing, use and transfer of Personal Data about you as described in this Privacy Policy. Our records of your acceptance of this Privacy Policy, the date thereof, and of all future amendments to this Privacy Policy, shall be regarded as conclusive and written evidence of your consent

You and EMVO also agree to perform your rights and obligations as part of the use of the Portal (including, without limitation, the collection, use, processing, storage and maintenance of Personal Data) in accordance with all applicable data protection and privacy laws and regulations, including the General Data Protection Regulation (EU) 2016/679 of 27 April 2016 ("**GDPR**") and applicable implementing national laws (collectively, the "**Data Protection Laws**"). This Privacy Policy makes

integral part of the [Terms of Use](#) of our Portal. By accepting these Terms of Use, you also consent to this Privacy Policy.

2. Which Personal Data we collect and process

2.1. Information you provide

When registering, accessing or using the Portal, you will provide Personal Data about you (i.e. any information that relates to you as an identified or identifiable individual), or about your or your OBP employee(s), agent(s), representative(s), including but not limited to, the SPOC(s), authorised officer(s) or other Portal users referred to during the registration process on the Portal. This Personal Data includes:

- name, function, e-mail address, telephone number;
- username and password.

2.2. Automatic Information Collection

Subject to your consent where required by law, we and our third-party service providers may use a variety of technologies that collect and provide information about how the Portal is accessed and used. Such Information may consist of your internet browser type, operating system, service provider, the webpages you viewed, the time you viewed them and for how long, demographic information about you (such as your age, gender, language, location and interest areas, where available) and what webpages you looked at before viewing the current page. We use this information to get a better idea of how our users interact with our Portal and then tailor and improve our Portal accordingly. Such information generally cannot be linked to you individually, but if we can link it to you then we treat it as Personal Data about you in accordance with this Privacy Policy.

Certain information is gathered by means of cookies. EMVO uses cookies and similar technologies on this Portal as described in our Cookies Policy available [here](#). The EMVO Portal only uses strictly necessary cookies for security purposes to ensure the use of the EMVO Portal is protected by sufficient security safeguards and to ensure that you can browse the Portal and use its features;. A description of the cookies used is available on the log-in/registration page when you access the Portal.

3. For which purposes and on basis of which legal bases we collect Personal Data

In certain sections of this Portal, you are asked to provide your Personal Data, in particular your name, contact details and other information listed in [Section 2](#). When we ask you to provide your Personal Data in order to give you access to any of the functions of the Portal, please note that certain boxes may be marked as mandatory, to the extent this is data we need to give you access to the relevant functionality.

If you do not provide the abovementioned Personal Data, you may not be able to participate to the On-boarding Project and the EMVS in general and perform the tasks described in the Participation Agreement.

EMVO will process your Personal Data for various purposes:

Purposes of processing	Legal Basis
<p>We may use your data to create and manage your online account and profile on the Portal as well as to register and manage the Registration Requesters, the Single Point of Contacts ("SPOCs") and the Authorised Representatives of OBPs.</p>	<p>Your Personal Data will be processed based on:</p> <ul style="list-style-type: none"> • your consent (for example, when you subscribe to the Portal); or • our legitimate interests which consist in (i) implementing, setting up and managing, together with NMVOs and other relevant stakeholders, the EMVS in accordance with the Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (the "Delegated Regulation") and (ii) assisting the On-boarding Partners to correctly and timely on-boarding for the EMVS On-boarding process and be able to participate to the On-boarding project. <p>You can withdraw your consent at any time.</p>
<p>We may use your data to complete the Legitimacy Checks of On-Boarding Partners (OBPs).</p>	<p>Your Personal Data will be processed based on our legitimate interests which consist in (i) implementing, setting up and managing, together with NMVOs and other relevant stakeholders, the EMVS in accordance with the Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (the "Delegated Regulation") and (ii) assisting the On-boarding Partners to correctly and timely on-boarding for the EMVS On-boarding process and be able to participate to the On-boarding project.</p>
<p>We may use your data to set up, manage and operate the European Medicines Verification System ("EMVS") and the EMVS On-boarding process.</p>	<p>Your Personal Data will be processed based on our legitimate interests which consist in (i) implementing, setting up and managing, together with NMVOs and other relevant stakeholders, the EMVS in accordance with the</p>

	<p>Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (the "Delegated Regulation") and (ii) assisting the On-boarding Partners to correctly and timely on-boarding for the EMVS On-boarding process and be able to participate to the On-boarding project.</p>
<p>We may use your data to manage the OBPs and the On-Boarding Project, including the Participation Agreement.</p>	<p>Your Personal Data will be processed based on our legitimate interests which consist in (i) implementing, setting up and managing, together with NMVOs and other relevant stakeholders, the EMVS in accordance with the Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (the "Delegated Regulation") and (ii) assisting the On-boarding Partners to correctly and timely on-boarding for the EMVS On-boarding process and be able to participate to the On-boarding project.</p>
<p>We may use your data to develop, support, promote and invoice the On-Boarding Project.</p>	<p>Your Personal Data will be processed based on our legitimate interests which consist in (i) implementing, setting up and managing, together with NMVOs and other relevant stakeholders, the EMVS in accordance with the Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (the "Delegated Regulation") and (ii) assisting the On-boarding Partners to correctly and timely on-boarding for the EMVS On-boarding process and be able to participate to the On-boarding project.</p>
<p>We may use your data to organise events (e.g. webinars, trainings etc.).</p>	<p>Your Personal Data will be processed based on:</p>

	<ul style="list-style-type: none"> • your consent (for example, when you subscribe to the European Medicines Verification System Information); or • our legitimate interest to manage events to which you are participating and to inform you about similar events or services similar to those provided to you. <p>You can withdraw your consent or object to the processing of your data for direct marketing purposes at any time. Your Personal Data will be processed based on our legitimate interest to manage events to which you are participating and to inform you about similar events or services similar to those provided to you.</p>
<p>We may process your data for accounting, records keeping, information, claims and complaints management, including the provision of technical support and assistance to you.</p> <p>We may also use your data to fulfil other legitimate purposes disclosed to you at the time you provide your Personal Data or as permitted or required to comply with applicable laws and regulations to which we are subject.</p>	<p>Your Personal Data will be processed because the processing is necessary:</p> <ul style="list-style-type: none"> ▪ for the purposes of the legitimate interests pursued by EMVO which consist in operating the EMVS and related corporate activities and defending itself against potential claims; or <p>to comply with a legal obligation of EMVO such as tax and accounting obligations.</p>

4. How we may share Personal Data

For the purposes and based on the legal bases described under the Section 3 above, EMVO may need to disclose and transfer Personal Data as detailed in this Section.

When required to achieve the above purposes, EMVO may share Personal Data with:

- third party services providers acting on our behalf and under our instructions, that provide services to us, namely professional advice, IT and business, support, implementation, helpdesk and web-related services; or
- the National Medicines Verification Organizations ("**NMVOs**") who may receive the Personal Data relating to the SPOCs where necessary for the purposes of the legitimate interests pursued by EMVO or the NMVOs (article 6, 1., (f) of the GDPR) to implement, manage and set up the EMVS in a timely fashion in accordance with the Delegated Regulation, as well as other possible stakeholders that interact with EMVO and NMVOs in pursuing such purposes at European or national level.

Except as expressly set forth herein, EMVO shall not provide Personal Data about you to other third parties without obtaining your prior permission, unless it is required to do so under a statutory

provision or court order. In particular, EMVO may disclose Personal Data about you in the following circumstances:

- to the competent authorities to comply with our legal obligations;
- to respond to authorized information requests from law enforcement authorities or judiciary or when otherwise required or permitted by law;
- to respond to an emergency; or
- otherwise to protect the rights, property, safety, or security of third parties, visitors to this Portal or the public.

The above recipients shall be located with the European Economic Area (“**EEA**”) or another country that is covered by an adequacy decision of the European Commission.

However, in the event the On-boarding Partner is located outside the EEA, your Personal Data may be transferred outside the EEA in the country where the OBP is established, where the level of protection of your Personal Data may not be equivalent as in the EEA due to the absence of an adequacy decision and appropriate safeguards for such transfer. Such transfer will be based on your explicit consent (Articles 6, 1., (a), and 49, 1. (a), of the GDPR) or another valid data transfer mechanism or derogations in accordance with applicable Data Protection Laws.

Only a limited number of individuals within EMVO (e.g., EMVO individuals responsible for the Website, for the organisation of events etc) will be granted access to Personal Data about you on a need to know basis.

5. How we protect Personal Data

EMVO takes – and requires that any third party services providers and/or processor processing Personal Data on behalf and under the instructions of EMVO takes – appropriate technical and organizational measures to protect Personal Data about you against accidental or unlawful destruction or accidental loss, misuse, unauthorized access, disclosure, alteration or destruction, and against any other unlawful form of processing of information as defined by applicable Data Protection Laws.

However, please note that no electronic transmission or storage of information is 100% secure. Therefore, despite the security measures that we have put in place to protect Personal Data about you, we cannot guarantee that loss, misuse, or alteration of data will never occur.

6. Personal Data about other individuals

If (i) you provide us with Personal Data about your representatives (including, but not limited to, the SPOCs or your authorized officer, employee, agent, and OBP Connection Provider) and/or any other individuals and/or (ii) such Personal Data are transferred to or by you outside the EEA in a country not recognised as providing an adequate level of protection, you undertake and warrant that you have informed such individuals about the processing, use and transfer of their Personal Data by us for the purposes and in the manner described in this Privacy Policy, about their right as described in Section 10 below in accordance with Data Protection Laws, as well as to obtain their explicit consent, where necessary, to the processing and transfer of their Personal Data as set out in this Privacy Policy.

7. Links to other websites

Our Portal may provide links to other websites for your convenience and information. These websites operate independently from us. As outlined in the [Terms of Use](#) of this Portal, we are not responsible for any use of these websites nor for any data processing and privacy practices associated with such websites. We invite you to review these websites' privacy notices if you visit them or provide any Personal Data to them.

8. How we may update this Privacy Policy

Except to the extent limited by applicable law, EMVO reserves the right, in its sole discretion, to change, modify, and/or add all or parts of this Privacy Policy, at any time. Any change to this Privacy Policy will be posted on this page and notified to you by e-mail (where appropriate or required by law and to the extent that we have your e-mail address). We shall indicate in the footer of the Privacy Policy the date when it was most recently updated.

9. How long we may keep Personal Data

Personal Data about you will not be kept for longer than necessary for the purposes identified herein, generally for up to ten (10) years after the end of the contractual relationship with you (if any), unless shorter or longer retention periods apply as per applicable statutory obligations.

10. What are your rights

You, as individual whose Personal Data is processed as described in this Privacy Policy, have a number of rights which are summarized in broad terms as laid down in the following list. Please note that exercising these rights is subject to certain requirements and conditions as set forth in applicable law.

If you wish to access Personal Data about you or exercise any of the rights listed below, you should apply in writing to the contact person identified in Section 11 below.

10.1. Right to withdraw consent

If you have declared your consent for any Personal Data processing activities as described in this Privacy Policy, you can withdraw this consent at any time with future effect. Such a withdrawal will not affect the lawfulness of the processing prior to withdrawal of the consent.

10.2. Right of access

You have the right to obtain confirmation from us as to whether or not your Personal Data is processed, and, where that is the case, to request access to that Personal Data including, without limitation, the categories of Personal Data concerned, the purposes of the processing and the recipients or categories of recipients. We do have to take into account the rights and freedoms of others, so this is not an absolute right. If you want to request more than one copy of the Personal Data, we may charge a reasonable fee based on administrative costs.

10.3. Right to rectification

You have the right to obtain from us the rectification or completion of inaccurate or incomplete Personal Data concerning you.

10.4. Right to erasure ('right to be forgotten')

You have the right to obtain from us the erasure of Personal Data concerning you in certain circumstances as defined under applicable law.

10.5. Right to restriction of processing

In certain circumstances as defined under applicable law, you have the right to request that we restrict processing of Personal Data about you.

10.6. Right to data portability

In certain circumstances as defined under applicable law, you have the right to receive Personal Data concerning you, which you have provided to us, in a structured, commonly used and machine-readable format and you may have the right to transmit that Personal Data to another controller.

10.7. Right to object

In certain circumstances as defined under applicable law, you have the right to object, on grounds relating to your particular situation, at any time to the processing of Personal Data about you by us and we can be required to no longer process Personal Data about you.

When your Personal Data is processed for direct marketing purposes, you have the right to object at any time to the processing of your Personal Data for such direct marketing purposes (including profiling insofar as it relates to such direct marketing).

11. How to contact us

If you have any questions or concerns about this Privacy Policy, or if you wish to access Personal Data about you or exercise any of the rights listed in Section 10 above, please send a written request at EMVO asbl, Rue du Commerce 123, 1000, Brussels, Belgium, by phone to +32 2 657 00 08 or by e-mail to helpdesk@emvo-medicines.eu.

You must provide evidence of your identity in order to exercise any of the rights listed in Section 10 above.

Any communication from us in relation to your rights as detailed in Section 10 above will be provided free of charge. However, in case of requests that are manifestly unfounded or excessive, in particular because of their repetitive character, EMVO may charge a reasonable fee taking into account the administrative costs of providing the information or communication or taking the action requested; or refuse to act on the request.

We invite you to report any complaints about processing of your Personal Data to EMVO in its capacity as data controller. EMVO will investigate and attempt to resolve the complaint. You also have the

right to lodge such complaint with the competent authority, in particular in the Member State of your habitual residence, place of work or of an alleged infringement of the GDPR.

————— **END OF DOCUMENT** —————