

EMVO Privacy Policy

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Privacy Policy

1. Introduction

European Medicines Verification Organisation, A.S.B.L., with registered office at rue de la Loi 28, 1040 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 values the relationship we have with you.

The EMVO's Privacy Policy ("**Privacy Policy**") describes the types of information you provide us with or we collect when you are accessing or using EMVO's website, 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 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 our website.

By accessing and using EMVO's website at <https://emvo-medicines.eu/> (the "**Website**") before using or submitting Personal Data, 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.

Please note that before using or submitting Personal Data, you might be also asked to confirm electronically your acceptance of this Privacy Policy by clicking "*I Accept*". Your affirmative action in clicking "I Accept" and your use of the Website 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 Website (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 Data Protection Directive 95/46/EC and implementing local laws, such as the Belgian Data Protection Act of 8 December 1992 ("**DPA**"), as may be amended, replaced or repealed, including by the General Data Protection Regulation (EU) 2016/679 of 27 April 2016 ("**GDPR**") once it comes into effect on 25 May 2018 (the "**Data Protection Laws**").

This Privacy Policy makes integral part of the [Terms of Use](#) of our Website. 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 Website you will provide Personal Data about you (i.e. any information that relates to you as an identified or identifiable individual), or about your employee(s), agent(s), representative(s). This Personal Data includes:

- name, e-mail address and telephone number.

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 Website 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, the referral website, 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 Website and then tailor and improve our Website 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 may use cookies and similar technologies on this Website as described in our [Cookies Policy](#) available on our Website. By clicking the "ok" button on the EMVO Cookie Banner, you are agreeing to our use of cookies and similar technologies in line with your current cookie setting and in accordance with our Cookie Policy available on our Website. If you do not agree to our use of cookies in this way, you should set your browser settings accordingly. You will always be able to withdraw your consent and change your choice by amending your browser settings in the future. If you disable cookies that we use, this may impact your user experience while on this Website.

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

EMVO will also process the Personal Data for the following purposes:

- the setting-up, management and operation of the European Medicines Verification System ("EMVS"); and the EMVS On-boarding process;
- the organisation of events;
- recruitment;
- the operation of our website (IP addresses, cookies);
- newsletters and other communications; and
- accounting, records keeping, information, claims and complaints management, including the provision of technical support and assistance to you.

The processing of Personal Data by EMVO for the abovementioned purposes is necessary for the purposes of the legitimate interests pursued by EMVO or by a third party (Article 5, §1, f) of the DPA; Article 6, 1., (f) of the GDPR, as of 25 May 2018). EMVO's legitimate interests include (i) implementing, setting up and managing, together with National Medicines Verification Organisations ("NMVOs") and other relevant stakeholders, the European Medicines Verification System 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 Onboarding Partners to correctly and timely on-boarding for the EMVS On-boarding process and be able to participate to the On-boarding project.

We can use Personal Data about you to fulfil other legitimate purposes disclosed to you at the time you provide Personal Data about you or as otherwise permitted or required to comply with applicable laws and regulation, in which case such Personal Data will be processed because the processing is necessary for the purposes of the legitimate interests pursued by EMVO or other third parties (such as existing or potential partners, NMVOs, national competent authorities or courts) and such interests are not overridden by your

interests or fundamental rights and freedoms (Article 5, §1, f) of the DPA; Article 6, 1., (f) of the GDPR, as of 25 May 2018).

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, such as professional advice, support, helpdesk as well as web-related services; or
- the National Medicines Verification Organizations who may receive the Personal Data relating to the Onboarding Partners 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.

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 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 Website or the public.

The above recipients shall be located within the European Economic Area 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 European Economic Area ("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 5, §1, a) and 22, §1, 1° of the DPA; Articles 6, 1., (a), and 49, 1. (a), of the GDPR, as of 25 May 2018).

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 provider and/or processor processing Personal Data on behalf and under the instructions of EMVO takes – appropriate technical and organisational 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 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 Website 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 Website, 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 at the top 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 twenty (20) years 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 details 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 requested to no longer process Personal Data about you.

Personal Data about you will not be used for direct marketing purposes.

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 de la Loi 28, Brussels, Belgium, by phone +372 611 90 44 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 requested action; 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 log

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** —————