

# PHARMACEUTICAL SECURITY INSTITUTE, INC.

October 2024

## **Privacy Statement**

The Pharmaceutical Security Institute, Inc. (“PSI” or “we”) is a membership organization all of whose activities implicate efforts to remedy the Counterfeiting and distribution of pharmaceuticals in violation of law (“*Counterfeiting*”), through interaction with its members and coordination as need be with governments, medical control agencies, and law enforcement and other authorities.

PSI respects your privacy and provides this Privacy Statement to inform you particularly of our privacy practices and choices you can make about the way your Personal Data is collected and how that information is used as well as your privacy rights. “Personal Data” means any information relating to an identified or identifiable natural person.

PSI complies with the EU-U.S. Data Privacy Framework (“EU-U.S. DPF”) and the UK Extension to the EU-U.S. DPF, and the Swiss-U.S. Data Privacy Framework (“Swiss-U.S. DPF”) (altogether “DPF Programs”) as set forth by the U.S. Department of Commerce. PSI has certified to the U.S. Department of Commerce that it adheres to the EU-U.S. Data Privacy Framework Principles (“EU-U.S. DPF Principles”) with regard to the processing of Personal Data received from the European Union and the United Kingdom in reliance on the EU-U.S. DPF and the UK Extension to the EU-U.S. DPF. PSI has certified to the U.S. Department of Commerce that it adheres to the Swiss-U.S. Data Privacy Framework Principles (Swiss-U.S. DPF Principles) with regard to the processing of Personal Data received from Switzerland in reliance on the Swiss-U.S. DPF. If there is any conflict between the terms in this Privacy Statement and the EU-U.S. DPF Principles and/or the Swiss-U.S. DPF Principles (altogether the “DPF Programs Principles”), the DPF Programs Principles shall govern. To learn more about the Data Privacy Framework (DPF) program, and to view our certification, please visit <https://www.dataprivacyframework.gov/>.

PSI is the data controller responsible for your Personal Data.

### **1. Notice**

#### **Information collected and stored automatically**

PSI does collect and store information automatically collected from its website.

#### **Cookies**

A “cookie” is a file placed on your computer’s hard drive or in memory by a website that allows the website to monitor your use of the website, usually without your knowledge. PSI uses no cookies to track the activities of website users outside of the purpose set out in the following paragraph, but it may use cookies to establish state and flow control for applications accessible over the Web.

## **Security and Consent to Monitor**

For site security purposes, and to ensure that this website remains available to all visitors, all network traffic may be monitored in order to identify unauthorized attempts to upload or change information, or otherwise cause damage or conduct criminal activity. To protect the system from unauthorized use and to ensure that the system is functioning properly, individuals using this computer system are subject to having their activities monitored and recorded by authorized systems personnel. Anyone using this system expressly consents to such monitoring and is advised that if such monitoring reveals evidence of possible abuse or criminal activity, system personnel may provide the results of such monitoring to appropriate courts, public authorities (including law enforcement authorities), or legal counsel for the establishment, exercise or defense of legal claims or for important reasons of public interest.

As it relates to ensuring the security of our website and performing the related monitoring, we also rely on IT service providers who are processing the relevant data on our behalf.

Unauthorized attempts to upload or change information, or otherwise cause damage to this website, are strictly prohibited and may be punishable under applicable law.

**Except for visitors who voluntarily provide PSI with Personal Data, and except for the aforementioned purposes, no attempts are made to identify individual visitors to this website or their usage habits while visiting this website.**

## **Personal Data Otherwise Provided To and Processed By PSI**

Personal Data may be collected or provided to PSI about alleged Counterfeiting incidents and related activities by telephone, letter, facsimile, e-mail to [psi@psi-inc.org](mailto:psi@psi-inc.org), or other means of communication.

PSI uses such Personal Data only for the purposes for which it was voluntarily submitted or originally collected or subsequently authorized by the individual, namely (i) the collection of data about alleged pharmaceutical Counterfeiting and related activities, (ii) the analysis of such data, the use of such data or analyses in connection with formulating and implementing anti-Counterfeiting strategies, (iii) facilitating investigations of suspected criminal activity, and/or (iv) communicating and sharing information with courts, public authorities (including law enforcement authorities), or legal counsel for the establishment, exercise or defense of legal claims or for important reasons of public interest.

Personal Data may particularly comprise one or more of the following: names and nationalities, dates of birth, the grounds for suspecting that the subjects are engaged in illegal conduct and related background information, and any prior criminal activity. This processing is necessary for the purposes of the legitimate interests pursued by PSI to protect the public health, share information on the counterfeiting of pharmaceuticals as well as to establish, exercise or defend of legal claims and initiate enforcement action through the appropriate authorities.

For the aforementioned purposes, PSI may also forward Personal Data to its members.

Apart from the disclosures described above, we could also become subject to lawful requests by public authorities, including to meet national security or law enforcement requirements, which could require us to disclose Personal Data in response.

Except as stated in this Privacy Statement, PSI does not send any Personal Data to any third party.

### **International Transfers of your Personal Data.**

Your Personal Data may be transferred to and stored in countries outside of the jurisdiction you are in where we and the recipients of the data have operations. If you are located in the European Economic Area ("EEA"), UK or Switzerland, your Personal Data will be processed in the United States of America; these international transfers of your Personal Data are generally made pursuant to the DPF Programs to ensure an adequate level of protection for that Personal Data.

### **Onward Transfer**

If PSI transfers Personal Data which it has received under the DPF Programs to a recipient in the United States or another third country (i.e., a country located outside of the European Economic Area, the UK, and Switzerland), the following applies:

PSI may transfer Personal Data to a court, a public authority, or legal counsel and at a minimum only for the purpose of establishing, exercising, or defending of legal claims including for the prevention, investigation, or detection of violations of law or for important reasons of public interest. PSI may also transfer Personal Data in response to lawful requests by public authorities, including to meet national security or law enforcement requirements. Neither PSI nor any of its members has control over courts or public authorities that may be potential transferees. Applicable law in different jurisdictions may affect the confidentiality of the information voluntarily submitted by an individual to PSI and transferred to such courts or authorities. As a result, PSI cannot make any assurances as to whether or not any such court or authority will keep such Personal Data confidential.

For the purposes set out under the Section "Personal Data Otherwise Provided To and Processed By PSI" above, PSI may also forward Personal Data to its members in conformity with the DPF Programs, including without limitation pursuant to an agreement requiring that a member provide at least the same level of protection as is required from PSI under the DPF Programs Principles.

In the context of an onward transfer, PSI has responsibility for the processing of personal data it receives under the DPF Programs and subsequently transfers to a third party acting as an agent on its behalf. PSI remains liable under the DPF Program Principles if its agent processes such personal data in a manner inconsistent with the DPF Program Principles, unless PSI proves that it is not responsible for the event giving rise to the damage.

### **Inquiries and Complaints**

If you have any questions or complaints in relation to this Privacy Statement or PSI's processing of Personal Data, please contact us under the following contact information.

In compliance with the EU-U.S. DPF and the UK Extension to the EU-U.S. DPF and the Swiss-U.S. DPF, PSI commits to resolve DPF Programs Principles-related complaints about our collection and use of your Personal Data. EEA and UK and Swiss individuals with inquiries or complaints regarding our handling of Personal Data received in reliance on the EU-U.S. DPF and the UK Extension to the EU-U.S. DPF, and the Swiss-U.S. DPF should first contact PSI at:

The Pharmaceutical Security Institute, Inc.  
8100 Boone Blvd Ste 220  
Vienna, Virginia 22182-2683  
[psi@psi-inc.org](mailto:psi@psi-inc.org)  
Phone: (703) 848-0161

Please include the following information to enable PSI to verify that it originates from you:

Your unique username and password, or if you did not supply PSI with a username and password when you first submitted the information, a physical or electronic signature;

Identification of the individually identifying information to which your inquiry or complaint relates;

Identification of any material that you are requesting that PSI remove or disable access to, and information reasonably sufficient to permit PSI to locate the material;

Information reasonably sufficient to permit PSI to contact you, such as your address, telephone number, and if available, an electronic mail address at which PSI may contact you; and

A statement that the information in the inquiry or complaint is accurate.

## **2. Choice**

To the extent that PSI processes Personal Data under the DPF Programs the following applies:

PSI will give the opportunity to any individual about whom Personal Data has been provided to choose (“opt out”) that PSI will not (a) disclose such individual’s Personal Data to a third party except as consistent with the DPF Programs, or (b) use such Personal Data for a purpose that is materially different from the purpose(s) for which it was originally collected or subsequently authorized by such individual. Please note that this choice does not apply to disclosures to a third party that is acting as an agent to perform task(s) on behalf of and under the instructions of PSI.

### **Opt-in Regarding Sensitive Information**

PSI does not generally solicit or collect Personal Data specifying an individual’s medical or health conditions, racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership or information specifying the individual’s sex life (collectively “*Sensitive Information*”). PSI will only collect and use Sensitive Information as permitted by the DPF Programs and applicable law and will obtain affirmative consent (“*opt in*”) from an individual if such information is to be (i) disclosed to a third party or (ii) used for a purpose other than those for which it was originally collected or subsequently authorized by the individuals through the exercise of opt-in choice, if no exception to the requirement to obtain affirmative consent applies under the

DPF Programs, such as, where processing is necessary for the establishment of legal claims or defenses.

In the event that you wish to exercise any of your choices, please contact PSI at [psi@psi-inc.org](mailto:psi@psi-inc.org).

### **3. Security**

PSI has taken reasonable measures to assure that Personal Data that it collects or has been supplied to it is retained in a secure manner. Only authorized users, bound by confidentiality agreements, are granted access to the data stored by PSI. Remote access to the Personal Data is not available.

PSI has appointed a Chief Security Officer (“CSO”) who is in charge of PSI’s security policy and who monitors compliance with this policy. PSI also requires employees to review and adhere to this Privacy Statement, in addition to their general agreement as to the maintenance of confidentiality.

PSI holds periodic security training and compliance evaluation sessions for all its employees which include a discussion of PSI’s Privacy Statement, awareness of its discipline process, how to take action to protect data and equipment in the event of disaster, and training on PSI’s back-up procedures and methods of safe disposal of data

### **Data Integrity**

PSI seeks to ensure that all Personal Data that it maintains is up to date, accurate, complete and relevant.

PSI will retain Personal Data only for as long as necessary to fulfil the purposes it was collected it for as set out above. To determine the appropriate retention period for Personal Data, PSI consider the amount, nature, and sensitivity of the Personal Data, the potential risk of harm from unauthorized use or disclosure of Personal Data, the purposes for which PSI processes that Personal Data and the applicable legal requirements.

### **4. Your Rights in Relation to Your Personal Data**

If you are based in the EEA, UK, Switzerland or another jurisdiction with similar privacy laws, or your Personal Data is (otherwise) governed by such privacy laws, subject to any exemptions and limitations provided for under applicable law that we may rely on, you have the following rights in respect of Personal Data that we hold about you:

- **Right to object.** *You have a right, in some circumstances, to object to any processing based on our legitimate interests. There may, however, be compelling reasons for continuing to process your Personal Data, and we will assess and inform you if that is the case.*
- **Right of access.** You have the right to obtain access to your Personal Data along with certain related information.

- **Right of portability.** You have the right, in certain circumstances, to receive a copy of the Personal Data you have provided to us in a structured, commonly used, machine-readable format that supports re-use, or to request the transfer of your Personal Data to another person.
- **Right to rectification.** You have the right to obtain rectification of any inaccurate or incomplete Personal Data we hold about you without undue delay.
- **Right to erasure.** You have the right, in some circumstances, to require us to erase your Personal Data without undue delay if the continued processing of that Personal Data is not justified.
- **Right to restriction.** You have the right, in some circumstances, to require us to limit the purposes for which we process your Personal Data if the continued processing of the Personal Data in this way is not justified, such as where the accuracy of the Personal Data is contested by you.

You also have the right to lodge a complaint to your local EEA data protection authority. Further information about how to contact your local data protection authority is available at: [http://ec.europa.eu/justice/data-protection/bodies/authorities/index\\_en.htm](http://ec.europa.eu/justice/data-protection/bodies/authorities/index_en.htm).

Irrespective of the aforementioned rights, if your Personal Data is subject to the DPF Programs, with the exemptions and limitations permitted thereunder, you particularly have the right, without the need for justification, to obtain from PSI confirmation of whether it is processing Personal Data related to you and have the data communicated to you as well as to have the Personal Data corrected, amended or deleted where it is inaccurate or processed in violation of the DPF Programs Principles.

In the event that you wish to exercise any of these rights, please contact PSI at [psi@psi-inc.org](mailto:psi@psi-inc.org). In order to be able to access your Personal Data, please provide PSI with your unique username and password, or if inapplicable, a physical or electronic signature.

PSI may restrict access to Personal Data to any individual as may be permitted under the DPF Programs or applicable law. Under DPF Programs, such restrictions may particularly arise to the extent that disclosure is likely to interfere with the safeguarding of important countervailing public interests, such as national security, defense, or public security; or generally for the following reasons (i) interference with the execution or enforcement of the law or with private causes of action, including the prevention, investigation or detection of offenses or the right to a fair trial; (ii) disclosure where the legitimate rights or important interests of others would be violated; (iii) breaching a legal or other professional privilege or obligation; (iv) prejudicing employee security investigations or grievance proceedings or in connection with employee succession planning and corporate re-organizations; or (v) prejudicing the confidentiality necessary in monitoring, inspection or regulatory functions connected with sound management, or in future or ongoing negotiations involving the organization.

PSI may charge a reasonable fee for providing access to Personal Data under the DPF Programs.

## **5. Recourse and Enforcement**

The DPF Programs Principle which covers the recourse and enforcement particularly involves the following aspects:

### **a) Independent Dispute Resolution Procedure**

If you have an inquiry or complaint regarding PSI's compliance with the DPF Programs Principles, you should first contact PSI in writing to inform us of any specific inquiry or complaint you may have about PSI's collection, retention or usage of your Personal Data.

In compliance with the EU-U.S. DPF and the UK Extension to the EU-U.S. DPF and the Swiss-U.S. DPF, PSI commits to refer unresolved complaints concerning our handling of Personal Data received in reliance on the EU-U.S. DPF and the UK Extension to the EU-U.S. DPF and the Swiss-U.S. DPF to the International Centre for Dispute Resolution of the American Arbitration Association, an alternative dispute resolution provider based in the United States. If you do not receive timely acknowledgment of your DPF Programs Principles-related complaint from us, or if we have not addressed your DPF Programs Principles-related complaint to your satisfaction, please visit [ICDR-AAA DPF IRM Service](#) for more information or to file a complaint. The services of International Centre for Dispute Resolution of the American Arbitration Association are provided at no cost to you.

### **b) DPF Programs Verification**

On a periodic basis, but not less frequently than once every year, PSI conducts its own objective DPF Programs compliance review procedure. PSI also verifies that its Privacy Statement, as set forth herein, is accurate, comprehensive, prominently displayed, and completely implemented, including implementation of appropriate employee training and other internal procedures.

### **c) Remedies and Sanctions**

The result of any remedies provided by the independent dispute resolution body should be that the effects of non-compliance are reversed or corrected by the organization, insofar as feasible, and that future processing by the organization will be in conformity with the DPF Programs Principles and, where appropriate, that processing of the personal data of the individual who brought the complaint will cease.

The sanctions for non-compliance with the DPF Programs Principles range from suspension from the DPF Programs to compensation for individuals for losses incurred as a result of non-compliance. Other sanctions include public notice of non-compliance and injunctions.

### **d) Possibility to Invoke Arbitration**

For resolution of any claimed violations of the DPF Programs Principles not resolved by any of the other DPF Programs mechanisms, you have the option to invoke arbitration to determine, for residual claims, whether PSI has violated its obligations under the DPF Programs Principles as to you, and whether any such violation remains fully or partially unremedied. This option is available only for these purposes. You may find more information on this option under [Annex I](#) of the DPF Programs.

## **e) Jurisdiction of the Federal Trade Commission**

The Federal Trade Commission has jurisdiction over PSI's compliance with the EU-U.S. DPF and the UK Extension to the EU-U.S. DPF and the Swiss-U.S. DPF.

## **OTHER PROVISIONS**

### **Notice and Procedure for Making Claims of Copyright Infringement**

Alleged Copyright Infringement: If you believe that material posted on this website infringes your copyright, you must submit a notification in writing. To be effective, your notification must include the following:

A physical or electronic signature of a person authorized to act on behalf of the owner of the exclusive right that you claim has been infringed;

Identification of the copyrighted work you claim has been infringed;

Identification of the material that you are requesting that PSI remove or disable access to, and information reasonably sufficient to permit PSI to locate the material;

Information reasonably sufficient to permit PSI to contact you, such as your address, telephone number, and if available, an electronic mail address at which PSI may contact you;

A statement that you have a good faith belief that use of the material in the manner complained of is not authorized by you, or the law; and

A statement that the information in the notification is accurate, and under penalty of perjury, that you are authorized to act on behalf of the owner of an exclusive right that is allegedly infringed.

Upon receipt of the written Notification containing the information set forth above:

PSI shall remove or disable access to the material that you allege is infringing;

PSI shall forward your written notification to the party who provided the material;

PSI shall take reasonable steps to promptly notify the party who provided the material that PSI has removed or disabled access to the material.

### **Counter Notification**:

If you object to PSI's removal or disabling of access to your material in response to a written notification, you may serve PSI with a Counter Notification. To be effective, a Counter Notification



must be a written communication provided to PSI's Designated Agent that includes substantially the following:

A physical or electronic signature of the person submitting the Counter Notification;

Identification of the material that has been removed or to which access has been disabled and the location at which the material appeared before PSI removed it or disabled access to it;

A statement under penalty of perjury that the person submitting the Counter Notification has a good faith belief that the material was removed or disabled as a result of mistake or misidentification of the material;

The name, address, and telephone number of the person submitting the Counter Notification, and a statement that the person submitting the Counter Notification consents to the jurisdiction of Federal District Court for the judicial district in which the person submitting the Counter Notification is located, or if the address of the person submitting the Counter Notification is outside of the United States, for any judicial district in which PSI may be found, and that the person submitting the Counter Notification will accept service of process from the party who provided the original Notification or an agent of such person.

Upon receipt of a Counter Notification containing the information set forth above:

PSI shall promptly provide the party who served the original Notification with a copy of the Counter Notification; and

PSI shall inform the party who served the original Notification that it will replace the removed material or cease disabling access to it within ten (10) business days.

PSI shall replace the removed material or cease disabling access to the material within ten (10) to fourteen (14) business days following receipt of the Counter Notification, provided PSI's Designated Agent has not received notice from the party who served the original Notification that an action has been filed seeking a court order to restrain the person submitting the Counter Notification from engaging in infringing activity relating to the material on PSI's website.

**DISCLAIMER**

PSI is not responsible for the content of any off-site pages that are referenced by or that reference to the PSI website. PSI is not responsible for any defamatory, offensive, misleading, or illegal conduct of other users, links, or third parties, and the risk of injury from the foregoing rests entirely with the visitor.

Links from the PSI website to other sites, or from other sites to the PSI home page, do not constitute an endorsement by PSI. The links are for convenience only. It is the responsibility of the visitor to evaluate the content and usefulness of information obtained from other sites.

All information provided by PSI at this website is for the convenience of interested visitors and visitors. The information is based on reports from various third party sources whose credibility and knowledge are unknown to PSI. PSI has not independently verified the accuracy of any information. PSI updates information only as new information is submitted. Individual visitors may use the information as they see fit. PSI does not guarantee the accuracy, completeness, timeliness, or correct sequencing of information, PSI is not responsible for errors or omissions, or for the use of, or results obtained from the use of, the information.

Reference to any specific commercial products, processes, or services by trade name, trademark, manufacturer, or otherwise does not constitute or imply endorsement, recommendation, or favoring by PSI.

### **Modification of This website Privacy Statement and Terms of Use.**

PSI reserves the right to amend this website Privacy Statement and Terms of Use and will alert you that changes have been made by indicating the date they were last updated. Your continued use of this website after the website Privacy Statement and Terms of Use have been amended signifies that you have agreed to any and all new terms.

PSI'S WEBSITE PRIVACY STATEMENT AND TERMS OF USE WERE LAST UPDATED ON October 24, 2024.

### **Contact Information.**

If you have any questions or comments regarding PSI's Privacy Statement, privacy practices or Terms of Use, please contact PSI at [psi@psi-inc.org](mailto:psi@psi-inc.org).