

# PHARMACEUTICAL SECURITY INSTITUTE, INC.

## **Privacy Statement**

The Pharmaceutical Security Institute (“PSI”) 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 of our Privacy Policy, which sets forth the practices and choices you can make about the way your information is collected and how that information is used.

PSI self-certifies that it is committed to comply with the requirements of (i) the EU-U.S Privacy Shield as set forth by the U. S. Department of Commerce on July 12, 2016, and (ii) the U.S.Switzerland Privacy Shield as set forth by the U.S. Department of Commerce following Swiss Government approval of the framework on January 12, 2017 (both programs collectively, the “Privacy Shields”) with respect to all Personal Data<sup>1</sup> it receives from jurisdictions covered by the Privacy Shields. Among other things, the Privacy Shields set forth seven principles, relating to Notice, Choice, Onward Transfer, Security, Data Integrity, Access, and Enforcement and Verification. You can find more information about the U.S. Department of Commerce Privacy Shield Program at <https://www.privacyshield.gov>. For more information regarding our Privacy Shields certifications, please see: <https://www.privacyshield.gov/list>.

PSI is the data controller responsible for your Personal Data.

### **1. Notice**

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

PSI does not collect or store information from its website automatically, and thus does not give, sell or transfer to third parties any such information.

#### **Cookies**

A “cookie” is a file placed on your computer’s hard drive or in memory by a web site that allows the web site to monitor your use of the web site, usually without your knowledge. PSI uses no cookies to track Personal Data, but it may use cookies to establish state and flow control for applications accessible over the Web.

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<sup>1</sup> This Privacy Policy applies only to “*Personal Data*” meaning information that relates to an identified or identifiable individual.

## Security and Consent to Monitor

For site security purposes, and to ensure that this Web site 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 officials. Unauthorized attempts to upload or change information, or otherwise cause damage to this Web site, are strictly prohibited and may be punishable under applicable law. **Except for visitors who voluntarily provide PSI with personally identifying information, and except for authorized enforcement investigations such as discussed herein, no attempts are made to identify individual visitors to this Web Site or their usage habits while visiting this Web site.**

## Personal Data Otherwise Provided To PSI

Personal Data may be collected or provided to PSI about alleged Counterfeiting incidents and related activities by telephone, letter, facsimile, e-mail to [datacontroller@psi-inc.org](mailto:datacontroller@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 with governmental regulatory or law enforcement personnel or legal counsel. Personal data may 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 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 and initiate enforcement action through the appropriate authorities.

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

## Secondary Notice

PSI will notify any individual if at any time PSI adopts a policy to use the individual's Personal Data in a manner other than for which PSI had originally collected or processed such data, as described above, and inform each such individual of the new policy. In such event, any such individual will be given the opportunity to choose (*opt out*) that PSI will not use such data in accordance with the new policy, as set forth in item 2, Choice, below.

## **Inquiries and Complaints**

Any individual who has any additional questions or has a complaint about this Privacy Policy or how PSI applies it with respect to such individual's Personal Data, is encouraged to contact PSI in writing, addressed to:

Data Controller  
PSI  
8100 Boone Boulevard  
Suite 220  
Vienna, VA 22812  
Fax: (703) 848-0164

or by e-mail to:

[datacontroller@psi-inc.org](mailto:datacontroller@psi-inc.org)

The inquiry or complaint needs to 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**

PSI uses Personal Data only for the purposes for which it was voluntarily submitted or originally collected or subsequently authorized by the individual. 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 Privacy Shields, or (b) use such Personal Data for a purpose that is incompatible with the purpose(s) for which it was originally collected or subsequently authorized by such individual. PSI may disclose Personal Data in response to lawful requests by public authorities, including to meet national security or law enforcement requirements.

## **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 Privacy Shields and applicable law and will ask such individual in advance to agree ("*opt in*") to supply such information. Among other exceptions, PSI will not follow opt-in procedures where processing of data is necessary for the establishment of legal claims or defenses.

### **3. Onward Transfer**

PSI may transfer Personal Data to a regulatory or law enforcement agency where consistent with public interest or law enforcement requirements as provided for in the Privacy Shields. PSI at a minimum would make such a transfer only for the purpose of establishing, exercising, or defending against legal claims, or for the prevention, investigation, or detection of violations of law. Neither PSI nor any of its members has any control over regulatory or law enforcement agencies 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 agencies. As a result, PSI cannot make any assurances as to whether or not any such agency will keep such personally identifying information confidential.

PSI may also forward Personal Data to its Members as may be in conformity with the Privacy Shields, including without limitation pursuant to an agreement requiring that a Member provide at least the same level of privacy protection as is required from PSI under the Privacy Shields Principles. PSI acknowledges that liability may attach in connection with certain acts of onward transfer.

### **4. 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 Policy, 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 Policy, 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.

## **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 our third party recipients have operations. If you are located in the European

Union ("EU"), your Personal Information will be processed in the United States; these international transfers of your Personal Information are made pursuant to the Privacy Shields to ensure an adequate level of protection for that Personal 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.

### **5. Access to Your Personal Data**

If you are based in the EU or a jurisdiction with similar privacy laws, subject to any exemptions 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, machinereadable 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 EU 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 where you are based, with exceptions permitted under the Privacy Shields, you have the right to access any Personal Data that PSI retains about you in order to correct, amend or delete inaccurate information.

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

PSI may deny access to Personal Data to any individual as may be permitted under the Privacy Shields or applicable law. For example, such denials may arise where, in PSI's opinion, the information about such individual cannot readily be separated from the information that relates to alleged Counterfeiting and related activities, or any confidential commercial information of PSI's members, or generally where (i) necessary to protect important countervailing public interests, such as national security, public security, or public health, (ii) in PSI's opinion such access would interfere with (a) the execution or enforcement of the law, including the prevention, investigation or detection of offenses or the right to a fair trial, or (b) private causes of action, including the prevention, investigation or detection of legal claims or the right to a fair trial, (iii) employee security investigations or grievance proceedings would be prejudiced, (iv) the confidentiality necessary in monitoring, inspection, and regulatory functions connected with sound management would be prejudiced, (v) in PSI's opinion the burden or expense of providing access would be disproportionate to the risks created to the individual's privacy in the case in question, or (vi) in PSI's opinion the rights of persons other than the individual would likely be violated.

PSI may charge a reasonable fee for providing access to Personal Data.

## **6. Enforcement**

The Privacy Shields Principle relating to enforcement has three components: dispute resolution, verification, and remedies, each of which is a part of PSI's Privacy Policy.

### **A. Dispute Resolution Procedure**

If you have an inquiry or complaint regarding PSI's compliance with the Privacy Shields Principles, you should first contact PSI in writing, informing that person of any specific inquiry or complaint you may have about PSI's collection, retention or usage of your Personal Data.

If within ten (10) business days (i) you do not receive acknowledgment of your inquiry or complaint, or (ii) your inquiry or complaint is not satisfactorily addressed, you may take advantage of the services provided by PSI's independent recourse mechanism, which is provided by the International Centre for Dispute Resolution maintained by the American Arbitration Association (<http://go.adr.org/privacysshield.html>). These services include binding arbitration to the extent required by the Privacy Shields. This procedure for the investigation and expeditious resolution of complaints and disputes is provided at no cost to you. The parties agree that the voluntary dispute resolution procedures provided for here are a compromise negotiation for purposes of all international, federal and state rules of evidence. The entire procedure will be confidential. All conduct, statements, promises, offers, views and opinions, whether oral or written, made in the

course of the mediation by any of the parties, their agents, employees, representatives or other invitees to the mediation and by the neutral, who is the parties' joint agent for purposes of these compromise negotiations, are confidential and shall, in addition and where appropriate, be deemed to be attorney client privileged. Such conduct, statements, promises, offers, views and opinions shall not be discoverable or admissible for any purposes, including impeachment, in any litigation or other proceeding involving the parties and shall not be disclosed to anyone not an agent, employee, expert, witness, or representative for any of the parties. However, evidence otherwise discoverable or admissible in a later proceeding is not excluded from discovery or admission as a result of its use in the mediation. If not entirely enforceable, the parties intend that the court enforce this provision to the extent enforceable by such court.

PSI also is subject to the investigative and enforcement jurisdiction of the Federal Trade Commission (FTC), a government agency with the mandate to enforce the Federal Trade Commission Act, which among other things prohibits unfair or deceptive acts or practices in or affecting commerce. Commerce on the Internet falls within the scope of this statutory mandate. For further information, see <https://www.ftc.gov/tips-advice/business-center/privacy-andsecurity/privacy-shield>

#### **B. Privacy Shields Verification**

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

#### **C. Remedies**

The sanctions for non-compliance with the Privacy Shields principles range from suspension from the Privacy Shields to the award of damages to individuals for privacy violations. Other sanctions include public notice of non-compliance and injunctions. Persistent non-compliance with Privacy Shields principles may result in the loss of its benefit. These sanctions will be enforced by the entities to which a dispute has appropriately been referred. Unless otherwise required by law, sanctions shall not include compensatory or punitive damages.

### **OTHER PROVISIONS**

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

Alleged Copyright Infringement: If you believe that material posted on this Web site 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 Web site.

### **DISCLAIMER**

PSI is not responsible for the content of any off-site pages that are referenced by or that reference to the PSI Web site. 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 Web site 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 Web site 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 Web Site Privacy Policy and Terms of Use.**

PSI reserves the right to amend this Web site Privacy Policy 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 Web site after the Web site Privacy Policy and Terms of Use have been amended signifies that you have agreed to any and all new terms.

PSI'S WEB SITE PRIVACY POLICY AND TERMS OF USE WERE LAST UPDATED ON AUGUST 1, 2018.

**Contact Information.**

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