

Privacy Impact Assessment APHIS Pharmacovigilance

Technology, Planning, Architecture, & E-Government

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Privacy Impact Assessment for the APHIS Pharmacovigilance Application

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Abstract

This Privacy Impact Assessment (PIA) is for the USDA/APHIS/Veterinary Services (VS)/Center for Veterinary Biologics (CVB) APHIS Pharmacovigilance. Pharmacovigilance is designed to fully automate the management of detection, collection, analysis, reporting, investigation, communication, action, and closure of the adverse effects of the use of licensed Veterinary Biological Products (VBPs) thru Adverse Event Reports (AERs). This PIA was conducted because the system collects personally identifiable information.

Overview

The system is owned by the VS Science, Technology, and Analysis Services (STAS) Center for Veterinary Biologics. Pharmacovigilance is designed to fully automate the management of the adverse events following the use of licensed Veterinary Biological Products (VBPs) to include the following management tasks:

- detection
- data collection
- analysis
- reporting
- investigation
- communication
- action
- closure

To accomplish this Pharmacovigilance supports the lifecycle of Adverse Event Reports (AER) using Commercial off the Shelf (COTS) software. The process starts when a reporter encounters an adverse event during the use of a VBP. Reporters include but are not limited to:

- veterinarians
- veterinary technicians
- clinic staff
- impacted consumers
- animal owner

Pharmacovigilance operates primarily from the USDA Digital Infrastructure Service Center (formerly NITC) in Kansas City, KS, with a small amount of infrastructure in Ames, IA to facilitate reporting and action. Management and the Ames, IA tasks are conducted on the APHIS Enterprise Infrastructure General Support Systems (GSS). This information system is comprised of Ennov software on an application server, an Oracle database on a database server, and Crystal reports software.

Section 1.0 Characterization of the Information

The following questions are intended to define the scope of the information requested or collected as well as reasons for its collection as part of the program, system, rule, or technology being developed.

1.1 What information is collected, used, disseminated, or maintained in the system?

Pharmacovigilance collects the following Personally Identifiable Information if volunteered by the report submitter:

- First and last name
- Address
- Phone number or Fax number
- Email address

Pharmacovigilance collects non-PII associated to the adverse event that is not limited to:

- Product information
- Animal information
- Event descriptions

1.2 What are the sources of the information in the system?

The source of information in the system is incident reporters submitting forms that detail adverse effects following the use of licensed Veterinary Biological Products (VBPs) thru Adverse Event Reports (AERs).

1.3 Why is the information being collected, used, disseminated, or maintained?

The information is being collected, used, and maintained to meet a regulatory requirement. Under the 1913 Virus–Serum–Toxin Act, the U.S. Department of Agriculture’s (USDA) Animal and Plant Health Inspection Service (APHIS) is responsible for ensuring that all veterinary biologics produced in or imported into the United States are pure, safe, potent, and effective. This regulatory activity is accomplished by the Center for Veterinary Biologics (CVB) in Ames, IA.

The information is not being disseminated.

1.4 How is the information collected?

Reports can be provided to the USDA by any of the following means:

- A web-based AER form hosted on the public facing portion of Pharmacovigilance, and which is submitted directly into the

Pharmacovigilance system. Completed forms are submitted to Pharmacovigilance in a secure environment and then reviewed by USDA.

- A telephone call directly to the USDA’s Center for Veterinary Biologics. These reports are entered manually into the Pharmacovigilance system.
- An email, fax or letter with the downloadable PDF AER form. These reports are entered manually into the Pharmacovigilance system. An acknowledgement letter will be sent to the reporter.

1.5 How will the information be checked for accuracy?

Regardless of the method of collection (phone, fax, email, or Internet) the report is reviewed manual for accuracy by USDA CVB employees.

1.6 What specific legal authorities, arrangements, and/or agreements defined the collection of information?

1913 Virus–Serum–Toxin Act.

1.7 Privacy Impact Analysis: Given the amount and type of data collected, discuss the privacy risks identified and how they were mitigated.

Privacy rights of the employees and external parties and persons will be protected by USDA, APHIS, and VS management by the following means:

- All access to the system is limited to USDA employees by username and password.
- The application limits access to relevant information by assigned user roles, which enforce need-to-know and least privilege concepts.
- Access to Pharmacovigilance is internal to USDA APHIS staff.
- The USDA warning banner must be acknowledged at system login.
- Public sources submitting reports have no direct access to Pharmacovigilance.
- PV-Express uses RSA 128 encryption for data protection.

Section 2.0 Uses of the Information

The following questions are intended to delineate clearly the use of information and the accuracy of the data being used.

2.1 Describe all the uses of information.

The information is used to ensure that animal immunobiologics are in compliance with the Virus-Serum-Toxin Act. Reports are assessed for the possibility of a product deficiency. Reports from Pharmacovigilance are used by CVB managers to support decisions to perform testing in CVB laboratories or seek additional information from the CVB systems or repositories.

2.2 What types of tools are used to analyze data and what type of data may be produced?

Pharmacovigilance includes PV-Analyzer for use by USDA employees. Raw data is provided to CVB statisticians for statistical analysis. Pharmacovigilance uses Crystal Reports to format and output reports. Summary reports are produced on an annual basis and are available to the public without PII. These reports are stripped of all PII information and provide trending data to help guide further investigations and possible regulatory actions.

2.3 If the system uses commercial or publicly available data please explain why and how it is used.

The reporter may volunteer to provide a publically available commercial address as their point of contact, however, this does not change the use of the data.

2.4 Privacy Impact Analysis: Describe any types of controls that may be in place to ensure that information is handled in accordance with the above described uses.

Privacy rights of the customer and employees will be protected by USDA/APHIS/VS/CVB management. Target systems also have security controls to address access to and security of information.

- All access to the data in the system is controlled by user authorization. Each individual's supervisor must identify (authorize) what functional roles that individual needs in the Pharmacovigilance system.
- All access to the system is limited by username and password.
- The application limits access to relevant information by assigned user roles, which enforce need-to-know and least privilege concepts.

- Users are trained and are required to formally confirm that they understand value and sensitivity of data in the system. (Veterinary Services Memorandum #800.2)
- Before being provided access to the system, all users receive formal system training in accordance with the APHIS Directive 3575 – *User Account Management Policy*.
- Warning banner must be acknowledged before logging in.

Section 3.0 Retention

The following questions are intended to outline how long information will be retained after the initial collection.

3.1 How long is information retained?

CVB will delete PII from APHIS Pharmacovigilance 7 years after AER submission. CVB will maintain the product specifics for the Adverse Event Report until 7 years after termination of the Product License.

3.2 Has the retention period been approved by the component records officer and the National Archives and Records Administration (NARA)?

Yes. The retention period conforms to APHIS' *VS Record Retention Guidelines* document citing disposal authorities NCI 310-77-2 and NCI 463-85-2. APHIS/VS management authors the aforementioned document and CVB implements the directives within their environment.

3.3 Privacy Impact Analysis: Please discuss the risks associated with the length of time data is retained and how those risks are mitigated.

Risks associated with data retention include the possibility of the data being accessed by unauthorized personnel. Pharmacovigilance uses role based access to mitigate this risk. The login interface reminds users of their responsibility every time they log in. However, submission forms contain data of limited use. The data stored are limited in their sensitivity. Personally Identifiable Information (PII) volunteered by the public would be limited to name, address, email, and phone numbers.

Section 4.0 Internal Sharing and Disclosure

The following questions are intended to define the scope of sharing within the United States Department of Agriculture.

4.1 With which internal organization(s) is the information shared, what information is shared and for what purpose?

Raw data is provided to statisticians in CVB for statistical analysis. Summary reports are produced on an annual basis, and are available to USDA employees. These reports are stripped of all PII information and provide trending data to help guide further investigations and possible regulatory actions.

4.2 How is the information transmitted or disclosed?

Reports and information are transmitted verbally, in print, and electronic postings.

4.3 Privacy Impact Analysis: Considering the extent of internal information sharing, discuss the privacy risks associated with the sharing and how they were mitigated.

Risks associated with data retention include the possibility of the data being accessed by unauthorized personnel. It is the intent of Pharmacovigilance that the uses of information remain in accordance with the stated purpose and use of the original collection at all times. Steps will be taken to ensure that access to the information system is provided only to authorized users.

- All access to the data in the system is controlled by user authorization.
- All access to the system is limited by username and password.
- The application limits access to relevant information and prevents access to unauthorized information.
- Users are trained and required to formally confirm that they understand value and sensitivity of data in the system.
- Warning banner must be acknowledged before logging in.
- All information disseminated out of the VS control is stripped of PII information.

Section 5.0 External Sharing and Disclosure

The following questions are intended to define the content, scope, and authority for information sharing external to USDA which includes Federal, state and local government, and the private sector.

5.1 With which external organization(s) is the information shared, what information is shared, and for what purpose?

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, records maintained in the system may be disclosed outside USDA as follows:

(1) To the State animal health official in each State, State veterinary examining or licensing boards, and the American Association of Veterinary State Boards to certify accreditation or license status or exchange information regarding disciplinary action(s);

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- (2) To the public for the purpose of locating and contacting an accredited veterinarian who has granted APHIS permission to provide business contact information;
 - (3) To the appropriate agency, whether Federal, State, local, or foreign, charged with responsibility of investigating or prosecuting a violation of law or of enforcing, implementing, or complying with a statute, rule, regulation, or order issued pursuant thereto, of any record within this system when information available indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and either arising by general statute or particular program statute, or by rule, regulation, or court order issued pursuant thereto;
 - (4) To the Department of Justice when: (a) The agency, or any component thereof; or (b) any employee of the agency in his or her official capacity; or (c) any employee of the agency in his or her individual capacity where the Department of Justice has agreed to represent the employee; or (d) the United States is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice is deemed by the agency to be relevant and necessary to the litigation; provided, however, that in each case, the agency determines that disclosure of the records to the Department of Justice is a use of the information contained in the records that is compatible with the purpose for which the records were collected;
 - (5) For use in a proceeding before a court or adjudicative body before which the agency is authorized to appear when: (a) The agency, or any component thereof; or (b) any employee of the agency in his or her official capacity; or (c) any employee of the agency in his or her individual capacity where the agency has agreed to represent the employee; or (d) the United States is a party to litigation or has an interest in such litigation, and the agency determines that use of such records is relevant and necessary to the litigation; provided, however, that in each case, the agency determines that disclosure of the records to the court is a use of the information contained in the records that is compatible with the purpose for which the records were collected;
 - (6) To appropriate agencies, entities, and persons when: (a) The agency suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised; (b) the agency has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, a risk of identity theft or fraud, or a risk of harm to the security or integrity of this system or other systems or programs (whether maintained by the agency or another agency or entity) that rely upon the compromised information; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the agency's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm;
 - (7) To contractors and other parties engaged to assist in administering the program. Such contractors and other parties will be bound by the nondisclosure provisions of the Privacy Act;
 - (8) To USDA contractors, partner agency employees or contractors, or private industry employed to identify patterns, trends, or anomalies indicative of fraud, waste, or abuse. Such contractors and other parties will be bound by the nondisclosure provisions of the Privacy Act;
 - (9) To a congressional office from the record of an individual in response to an inquiry from the congressional office made at the written request of that individual; and
 - (10) To the National Archives and Records Administration or to the General Services Administration for records management inspections conducted under 44 U.S.C. 2904 and 2906.
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- 5.2 Is the sharing of personally identifiable information outside the Department compatible with the original collection? If so, is it covered by an appropriate routine use in a SORN? If so, please describe. If not, please describe under what legal mechanism the program or system is allowed to share the personally identifiable information outside of USDA.**

Pharmacovigilance does not share personally identifiable information with external organizations.

- 5.3 How is the information shared outside the Department and what security measures safeguard its transmission?**

Pharmacovigilance does not share personally identifiable information with external organizations. Information available to the public does not contain PII.

- 5.4 Privacy Impact Analysis: Given the external sharing, explain the privacy risks identified and describe how they were mitigated.**

There are no risks. Pharmacovigilance does not share personally identifiable information with external organizations.

Section 6.0 Notice

The following questions are directed at notice to the individual of the scope of information collected, the right to consent to uses of said information, and the right to decline to provide information.

- 6.1 Does this system require a SORN and if so, please provide SORN name and URL.**

No.

- 6.2 Was notice provided to the individual prior to collection of information?**

Yes. Notice is provided prior to collection of information. Data is submitted voluntarily.

- 6.3 Do individuals have the opportunity and/or right to decline to provide information?**

Yes. Data is submitted voluntarily.

- 6.4 Do individuals have the right to consent to particular uses of the information? If so, how does the individual exercise the right?**

No. There is only one use of the Reporter's PII.

6.5 Privacy Impact Analysis: Describe how notice is provided to individuals, and how the risks associated with individuals being unaware of the collection are mitigated.

Notice is provided directly to the recipient on the web interface. No information is collected without the individual's knowledge or voluntary submittal.

Section 7.0 Access, Redress and Correction

The following questions are directed at an individual's ability to ensure the accuracy of the information collected about them.

7.1 What are the procedures that allow individuals to gain access to their information?

Any individual may obtain information from a record in the system that pertains to him or her. All inquiries should be addressed in one of the following manners:

VIA MAIL:

Animal and Plant Health Inspection Service
Director, Freedom of Information and Privacy Act Staff
4700 River Road, Unit 50
Riverdale, MD 20737

VIA FACSIMILE: 301-734-5941

VIA E-MAIL: foia.officer@aphis.usda.gov

(NOTE: While e-mail attachments are often an important and legitimate means of conducting business, they also have the potential to cause great harm to our e-mail infrastructure, as well as to individual workstations. Please place the text of your FOIA request into the 'body' of the email message.)

VIA Web Request Form: Located at the following link:

https://www.aphis.usda.gov/aphis/resources/foia/ct_how_to_submit_a_foia_request

7.2 What are the procedures for correcting inaccurate or erroneous information?

In the individual volunteers an email address, the individual is notified through an acknowledgement email of the transaction reference number. This email will contain information on how to update incorrect or erroneous information.

7.3 How are individuals notified of the procedures for correcting their information?

Procedures for correcting information will be in the acknowledgement email. Procedures are available on the APHIS/VS/STAS/CVB website instructions link to Pharmacovigilance.

7.4 If no formal redress is provided, what alternatives are available to the individual?

N/a. A formal redress is provided.

7.5 Privacy Impact Analysis: Please discuss the privacy risks associated with the redress available to individuals and how those risks are mitigated.

The risks associated with Pharmacovigilance and the available redress process is that the system or the data will be used without correct PII to associate with the Reporter. This risk is mitigated using the acknowledgement message sent to the Reporter. This message matches the method used by the Reporter, and as such will be sent by email, letter, phone, or fax. The mission of Pharmacovigilance is to manage the Adverse Event Report (AER) and to report on licensed Veterinary Biological Products (VBP). The PII submitted by the Reporter is not essential to the mission of the system, and is not retracted from the system. Data is submitted voluntarily. Additionally, the following controls are in place:

- All access to the data in the system is controlled by formal authorization.
- All access to the system is limited by username/password.
- All information disseminated out of the VS control is stripped of all possible PII information.

Section 8.0 Technical Access and Security

The following questions are intended to describe technical safeguards and security measures.

8.1 What procedures are in place to determine which users may access the system and are they documented?

Access to Pharmacovigilance is based on the need to do business and is determined by CVB management. All access to APHIS Pharmacovigilance is authorized and documented by an APHIS 513 form.

8.2 Will Department contractors have access to the system?

No.

8.3 Describe what privacy training is provided to users either generally or specifically relevant to the program or system?

All individuals, prior to being provided access to the application, are briefed in accordance with Veterinary Services Memorandum #800.2. Currently, all individuals provided access to APHIS Pharmacovigilance are required to complete annual Information Technology (IT) Security Awareness Training and must sign APHIS Rules of Behavior form prior to receiving access to the information system. The standard USDA warning banner must also be acknowledged and accepted before logging in to the system.

8.4 Has Certification & Accreditation been completed for the system or systems supporting the program?

Yes, A&A has been completed for this system. Pharmacovigilance received an authority to operate (ATO) in August 2015.

8.5 What auditing measures and technical safeguards are in place to prevent misuse of data?

Technical safeguards and auditing measures are in accordance with FIP 199/200 Moderate baseline security controls. Technical safeguards for Pharmacovigilance include a security model that enables auditing, role-based access views (i.e. access only to authorized information), field-level security, and division of security (i.e. least privilege). This means all events, such as create, modify, soft deletion, and user login activity are audited at the field level. Every change to every field of the case data can be logged in the audit trail table. The audit trail is activated automatically as soon as a case is created.

The audit trail itself is fully compliant with the regulatory requirement, containing:

- the data change (old and new values)
- the name of the user making the change
- the date and time of the change (taken from the network server's clock)

- the reason for the change (either selected from a look-up table of pre-defined reasons or entered as free text).

In addition to tracking changes made through Pharmacovigilance, the audit trail also logs changes made through the configuration program provided by Ennov and any other source of database change.

FDA 21 CFR Part 11 Compliance

Pharmacovigilance has been compliant with Part 11, the FDA rule on Electronic Signatures and Electronic Records since its first release. Key functions include:

- The ability to apply electronic signatures to the generation of regulatory reports with recorded authorizations
- An automated audit trail recording every data change
- A timeout function to disable inactive screens
- Access to logged on user name and program module name from every screen
- Record Time-Stamping

Every data record (table row) in every table contains columns that show:

- when the record was first created
- which user group (country) created it
- the name of the actual user who created it
- A similar set of columns holds the same details for the last time that the record was amended.

8.6 Privacy Impact Analysis: Given the sensitivity and scope of the information collected, as well as any information sharing conducted on the system, what privacy risks were identified and how do the security controls mitigate them?

The privacy risks associated with Pharmacovigilance during information sharing are limited to unauthorized sharing and mishandling of shared data. PII is limited to name, address, and phone number of submitters. There is no routine use for this data outside of the system, and it is not shared. All information disseminated out of the VS control does not contain PII information.

Section 9.0 Technology

The following questions are directed at critically analyzing the selection process for any technologies used by the system, including system hardware and other technology.

9.1 What type of project is the program or system?

The system is owned by the CVB and is designed to fully automate the management of the adverse events following the use of licensed Veterinary Biological Products (VBPs). To accomplish this Pharmacovigilance supports the lifecycle of Adverse Event Reports (AER) using Commercial off the Shelf (COTS) software.

9.2 Does the project employ technology which may raise privacy concerns? If so please discuss their implementation.

No.

Section 10.0 Third Party Websites/Applications

The following questions are directed at critically analyzing the privacy impact of using third party websites and/or applications.

10.1 Has the System Owner (SO) and/or Information Systems Security Program Manager (ISSPM) reviewed Office of Management and Budget (OMB) memorandums M-10-22 “Guidance for Online Use of Web Measurement and Customization Technology” and M-10-23 “Guidance for Agency Use of Third-Party Websites and Applications”?

The ISSPM and system owner have reviewed the OMB memorandums listed above.

10.2 What is the specific purpose of the agency’s use of 3rd party websites and/or applications?

Not applicable. Pharmacovigilance does not use Third-Party Websites.

10.3 What personally identifiable information (PII) will become available through the agency’s use of 3rd party websites and/or applications.

Not applicable. Pharmacovigilance does not use Third-Party Websites.

10.4 How will the PII that becomes available through the agency’s use of 3rd party websites and/or applications be used?

Not applicable. Pharmacovigilance does not use Third-Party Websites.

10.5 How will the PII that becomes available through the agency's use of 3rd party websites and/or applications be maintained and secured?

Not applicable. Pharmacovigilance does not use Third-Party Websites.

10.6 Is the PII that becomes available through the agency's use of 3rd party websites and/or applications purged periodically?

Not applicable. Pharmacovigilance does not use Third-Party Websites.

10.7 Who will have access to PII that becomes available through the agency's use of 3rd party websites and/or applications?

Not applicable. Pharmacovigilance does not use Third-Party Websites.

10.8 With whom will the PII that becomes available through the agency's use of 3rd party websites and/or applications be shared - either internally or externally?

Not applicable. Pharmacovigilance does not use Third-Party Websites.

10.9 Will the activities involving the PII that becomes available through the agency's use of 3rd party websites and/or applications require either the creation or modification of a system of records notice (SORN)?

Not applicable. Pharmacovigilance does not use Third-Party Websites.

10.10 Does the system use web measurement and customization technology?

Not applicable. Pharmacovigilance does not use Third-Party Websites.

10.11 Does the system allow users to either decline, to opt-in, or decide to opt-out of all uses of web measurement and customization technology?

Not applicable. Pharmacovigilance does not use Third-Party Websites.

10.12 Privacy Impact Analysis: Given the amount and type of PII that becomes available through the agency's use of 3rd party websites

and/or applications, discuss the privacy risks identified and how they were mitigated.

Not applicable. Pharmacovigilance does not use Third-Party Websites.

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