Privacy Impact Assessment
APHIS Pharmacovigilance

Policy, E-Government and Fair Information Practices

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United States Department of Agriculture

Privacy Impact Assessment for the

APHIS Pharmacovigilance

March 2022

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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 (PV-Works). 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 (PII).

Overview

The Pharmacovigilance information system is designed and used to fully automate the management of adverse events reported following the use of licensed Veterinary Biological Products (VBP). These automated management tasks include:

- Data collection
- Analysis
- Investigation
- Communication
- Reporting
- Detection
- Action
- Closure

To accomplish this, Pharmacovigilance supports the lifecycle of Adverse Event Reports (AER) using commercial off the shelf (COTS) software offered by Ennov, and additional supporting software vendors. This information system is managed by the USDA/APHIS/Veterinary Services (VS) Diagnostic and Biologics (D&B) Center for Veterinary Biologics (CVB) in Ames, IA. It operates primarily from the MRP Azure environment, with a small amount of infrastructure in Ames, IA to facilitate reporting, action, and closure. Management and the Ames, IA tasks are conducted on the MRP Enterprise Infrastructure (MEI) 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. There are no notable updates to this system security plan.

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
- licensed veterinary biologics manufacturers

Section 1.0 Characterization of the Information

The following questions are intended to define the scope of the information requested and/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 manually for accuracy by USDA CVB employees.

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

Legal authority for collection by USDA APHIS Veterinary Services (VS) Diagnostics and Biologics (D&B) Center for Veterinary Biologics (CVB) is:

- P.L. 430 of 1913, as amended; 21 U.S.C. 151-158 (Virus-Serum-Toxic Act)
- 9 CFR 101.2 & 116.9
- CVB Notice 18-09
- VS Memorandum 800.125

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 AES 256 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 CVB 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 publicly 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 using Veterinary Services (VS) 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, under Disposal Authority NCI 463-85-2, Veterinary Biologics.

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. 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?

The data received is not shared with any other internal or external orgnizations.

4.2 How is the information transmitted or disclosed?

The information is not transmitted or disclosed to any entity. All data remains within the system.

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?

Information is not transmitted or disclosed to organizations external to the USDA.

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.

Not Applicable.

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

Not Applicable.

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

Not Applicable.

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, for individuals that voluntarily wish to provide their PII, notice for collection is provided in the Adverse Event Reporting directions website. The PII is not a required item when submitting and adverse event into the PV-Works applications. The directions for Adverse Event Reporting, as of March 29th, 2022 can be found at https://www.aphis.usda.gov/animal_health/vet_biologics/publications/pv-express2guidance.pdf.

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

Yes. Data is submitted from the public voluntarily. Licensed veterinary biologic manufactures are required to submit the information as per 9 CFR 101.2 & 116.9.

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.

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 in two methods, the first is via the posting of this Privacy Impact Assessment on the USDA Privacy website. The second method is on the Adverse Event Reporting website directions, https://www.aphis.usda.gov/animal_health/vet_biologics/publications/pv-express2guidance.pdf.

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. Individuals may utilize contact the Center for Veterinary Biologics (CVB) via the "Contact Us" link on the CVB homepage. Individuals may also make the request via the "Contact Us" now page on the application or via the APHIS Privacy Act officer. The Privacy Act officer can be contacted via the following manners:

VIA MAIL:

USDA – Animal and Plant Health Inspection Service
Tonya Woods, FOIA/PA Director
4700 River Road, Unit 50
Riverdale, MD 20737

VIA FACSIMILE: 301-734-5941

VIA E-MAIL: APHISPRIVACY@usda.gov

VIA Web Request Form: Located at the following link

https://efoia-pal.usda.gov/App/Home.aspx

The USDA Privacy Policy can be located at the following:

URL: https://www.usda.gov/privacy-policy

Information about FOIA requests can be found at:

https://www.aphis.usda.gov/aphis/resources/lawsandregs/privacy-act/privacy

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

Correcting inaccurate information may be done via the point of contact in section 7.1 or via the point of contact found in the PV-Express 2 guidance document: https://www.aphis.usda.gov/animal_health/vet_biologics/publications/pv-express2guidance.pdf

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

The owners of the information identified in Section 1.1 requesting corrections to voluntary information submitted would be required to contact either office identified in section 7.1 or the contact information on the USDA CVB PV-Works public site https://www.aphis.usda.gov/animal_health/vet_biologics/publications/pv-express2guidance.pdf (as of October 2021).

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.

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 Form 513, APHIS User Account Control Form. APHIS Form 513s for access to PV Works are contained within User Management System (UMS).

8.2 Will Department contractors have access to the system?

No. The system is maintained by government personnel. The user base are all government personnel.

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

APHIS staff 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 Security Awareness Training that includes a section dedicated to Privacy. Each user 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 into the system

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

Yes, Assessment and Authorization has been completed for this system. Pharmacovigilance received an authority to operate (ATO) in September 2021.

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 Federal Information Processing Standard (FIPS) 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 exported out of the system does not contain PII information.

Section 9.0 Technology

The following questions are directed at critically analyzing the selection process for any technologies utilized 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.

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

Not Applicable.

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.

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.

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

Not Applicable.

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.

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.

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.

10.10 Does the system use web measurement and customization technology?

Not Applicable.

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.

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.

Responsible Official

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Approval Officials

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