Privacy Impact Assessment for Pharmacovigilance (PV-Works)

Technology, Planning, Architecture, & E-Government

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of Agriculture

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Privacy Impact Assessment for the Pharmacovigilance (PV-Works) Application

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Abstract

- This Privacy Impact Assessment (PIA) is for the USDA, APHIS, Veterinary Services (VS), Center for Veterinary Biologics (CVB) Pharmacovigilance (PV-Works).
- PV-Works is designed to fully automate the management of detection, data collection (and 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 overview is the most important section of the PIA. A thorough and clear overview gives the reader the appropriate context to understand the responses in the PIA. The overview should contain the following elements:

- The PV-Works system is owned by USDA, APHIS, VS, CVB.

- The PV-Works Veterinary System (Vet) system is a Commercial Off The Shelf system that supports automation for management of adverse effects resulting from the use of licensed VBPs utilizing AERs.

- PV-Works contains information about veterinarians, animal owners, adverse effects and resulting tracking information.

- Users of the PV-Works system, which are USDA employees, enter data regarding the adverse effects from the Adverse Event Report Form. This form is received from PV-Express (electronic copy), email (electronic copy), fax (printed copy), telephone (verbal) or mail (hard copy).

- The PV-Works system does not currently have an Authority To Operate (ATO).

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?

The application collects the following types of information:
Veterinarian:
- Contact Name

- Contact Address
- Contact Phone Number/Fax
- Contact e-mail

Animal Owner:
- Contact Name
- Contact Address
- Contact Phone Number/Fax
- Contact e-mail

Other:
- Product Information
- Animal Identification Information
- Event Descriptions

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

The sources of information in the system are from submission forms that are submitted detailed 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?

Under the 1913 Virus–Serum–Toxin Act, further amended by the 1985 Food Security 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.

1.4   How is the information collected?

The information is collected from submission forms (Adverse Events Report) that are submitted detailing adverse effects following the use of licensed Veterinary Biological Products (VBPs).

1.5   How will the information be checked for accuracy?

Both the application database and the PV-Express collection point maintain a data schema to validate the type of information entered into the system. This applies to information received electronically or entered manually by USDA employees.

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

1913 Virus–Serum–Toxin Act, further amended by the 1985 Food Security Act.

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

All access to PV-Works is internal to USDA, APHIS, VS staff only. Submitting sources have no direct access to PV-Works. 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. When necessary, testing is performed or additional information sought. Summary information is also shared with the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products to facilitate international cooperation.

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

PV-Works is Commercial-Off-The Shelf (COTS) software that uses a centralized Oracle database, an Oracle/Arc Spatial Database Engine, Crystal reports software which stores information and does not analyze or produce data. PV-Works does not use open source software. PV-Works maintains a self-contained analyzer for parsing the data. Raw data is provided to statisticians in CVB for statistical analysis. Also, summary reports are produced on an annual basis that is available to the public. 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 information is not from commercial or publicly available sources.

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/security of information.

- All access to the data in the system is controlled by formal authorization. Each individual's supervisor must identify (authorize) what functional roles that individual needs in the PV-Works system.

- All access to the system is limited by username/password.

- Application limits access to relevant information and prevents access to unauthorized information.

- 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)

- All users receive formal system training being given access to the system 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 PV works 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)?

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 are minimal and include the possibility of the data being accessed by unauthorized personnel. However, submission forms contain data of limited use. Very little, if any, of the data stored are of a sensitive nature. Personally Identifiable Information (PII) would be limited to names, addresses, email and phone numbers of submitters; data that are usually easily accessible by other means.

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. Also, summary reports are produced on an annual basis that is available to the public and 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.

All access to the data in the system is controlled by formal authorization.

All access to the system is limited by username/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 all possible 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?

The PV-Works system does not share information with external organizations which are outside of 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.

The PV-Works system does not share information with external organizations which are outside of USDA.

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

The PV-Works system does not share information with external organizations which are outside of USDA.

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

The PV-Works system does not share information with external organizations which are outside of USDA.

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 Was notice provided to the individual prior to collection of information?

Notice is provided prior to collection of information.

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

All information provided is voluntary.

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

See 6.1. Information is provided voluntarily and individual acknowledges intended use of information.

6.4 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 interface. No information is collected without the individual's knowledge.

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?

Information is provided to individuals only through FOIA requests.

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

Once information is submitted, through either PV-Express or other means, 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?

See 7.2. Procedures for correcting information will be in the acknowledgement email and also available on the APHIS CVB website instructions link to PV-Express.

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

Not applicable.

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

All access to the data in the system is controlled by formal authorization.

All access to the system is limited by username/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 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 PV-Works is based on the need to do business and determined by USDA, APHIS, VS, CVB management. Criteria, procedures, and controls are documented. Access must be formally requested in writing and approved by the supervisor in accordance with the APHIS Directive 3575 – User Account Management Policy.

8.2   Will Department contractors have access to the system?

Access is based on need and limited to USDA, APHIS, VS, CVB employees.

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. All employees complete IT Security and Rules of Behavior training prior to being granted access to any

government computer systems and this training is mandatory for all employees on an annual basis.

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

No, this is the initial (Phase 1) Certification & Accreditation process.

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

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).

APHIS "IMSOP1003-01-Oracle Auditing.doc" details exactly what is audited.

In addition to tracking changes made through PV-Works the audit trail also logs changes made through the configuration program provided by Assured and any other source of database change.
- FDA 21 CFR Part 11 Compliance

PV-Works (vet) 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?**

Given the sensitivity and scope of the information collected, as well as any information sharing conducted on the system, no privacy risks were identified.

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 PV-Works system is a collection of information regarding the management of detection, data collection (and 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) that is received at the USDA, APHIS, VS, CVB. Summary information is also shared with the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products to facilitate international cooperation.

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

This application does not employ technology which may raise privacy concerns

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"?**

Not applicable. PV-works does not use Third-Party Websites.

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

Not applicable. PV-works 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. PV-works 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. PV-works 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. PV-works 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. PV-works 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. PV-works 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. PV-works 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. PV-works does not use Third-Party Websites.

10.10 Does the system use web measurement and customization technology?

Not applicable. PV-works 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. PV-works 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. PV-works does not use Third-Party Websites.

Responsible Officials

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