US Department of Health and Human Services

Privacy Impact Assessment

Date Signed:

12/22/2016

OPDIV:

FDA

Name:

Pharmacovigilance Workflow Manager

PIA Unique Identifier:

P-3313499-382822

The subject of this PIA is which of the following?

Major Application

Identify the Enterprise Performance Lifecycle Phase of the system.

Operations and Maintenance

Is this a FISMA-Reportable system?

Yes

Does the system include a Website or online application available to and for the use of the general public?

No

Identify the operator.

Agency

Is this a new or existing system?

Existing

Does the system have Security Authorization (SA)?

Yes

Indicate the following reason(s) for updating this PIA.

PIA Validation

Describe in further detail any changes to the system that have occurred since the last PIA.

The Pharmacovigilance Workflow Manager (PV Works) has received a system upgrade to version HL7 ICSR ISO 27953-1.

Describe the purpose of the system.

The Pharmacovigilance Workflow Manager (PV Works) system is a consumer off-the-shelf suite of tools that consists of four modules (PV analyzer, PV agent, PV importer, and PV admin) the FDA's Center for Veterinary Medicine (CVM) uses as a database repository and analytical tool for adverse event reports. FDA and CVM receive these reports from external stakeholders such as animal drug manufacturers, veterinarians and animal owners. CVM employs the system to maintain data regarding reports of drugs that have displayed Adverse Drug Events (ADE) in animals, and to track post-market use of animal drugs to ensure they are safe and effective.

Describe the type of information the system will collect, maintain (store), or share.

Manufacturers, veterinarians, and individuals submit forms FDA 1932 or 1932a to CVM to report an adverse event with a veterinary drug experienced by an animal. Information provided to FDA in these forms includes the contact information of the person making the report (reporter) who will most often be a veterinarian or other health care professional but who may also be an animal owner or other member of the public. Contact information will include name and business e-mail, telephone, and mailing address. Submissions also include a description of the adverse event, an adverse event identification number, and any information regarding the animal that suffered the adverse event (e.g., description of the animal, medical and drug information).

The only individuals who can access the PV Works system are FDA employees and direct contractors who have been approved as PV Works users. They must submit their name, work email address and work phone number in order to have their account created. Once approved, PV Works users access the system using an assigned username and a temporary password. Users reset their temporary password to a password of their choosing that meets complexity standards.

PV Works also maintains the name of the CVM safety reviewer assigned to each adverse event report as well as any comments the reviewer may make while evaluating the report.

Provide an overview of the system and describe the information it will collect, maintain (store), or share, either permanently or temporarily.

PV Works is a data repository and analytical tool used by CVM veterinarian safety reviewers to evaluate the safety of animal drugs based on reported adverse events and the related information submitted to the agency in FDA forms 1932 and 1932a. The agency receives these reports electronically through the FDA Electronic Submissions Gateway (ESG, the subject of a separate assessment) and by mail.

In addition to PV Works there are four modules under the system. PV Analyzer is a signal detection and data analysis tool, that is, an application that sifts bits of data and information that may point to a widespread health risk. PV Importer is an electronic tool used to upload validated reports into the database. PV Agent is a module that executes scheduled system jobs to run as background processes. And, PV Admin allows for configuration of the system to meet individual FDA office/user requirements.

Because PV Works tracks adverse events in animals, the system organizes data primarily according to the active ingredient or the name of the manufacturer. FDA uses the collected data to generate monthly reports that are provided to the public via fda.gov. These reports list adverse events according to the active ingredient and the animal species.

Does the system collect, maintain, use or share PII?

Yes

Indicate the type of PII that the system will collect or maintain.

Name

E-Mail Address

Mailing Address

Phone Numbers

Contact information can be for the reporter (e.g., a veterinarian or animal owner) as well as for a

Username and password.

Indicate the categories of individuals about whom PII is collected, maintained or shared.

Employees

Public Citizens

"Public citizens" includes veterinarians and drug manufacturer's designated point of contact.

How many individuals' PII is in the system?

100,000-999,999

For what primary purpose is the PII used?

The personally identifiable information (PII) collected in the system is used to contact the manufacturer, the veterinarian, or the individual who submitted the report. CVM may contact these individuals to follow up on their submission, clarify information, or request additional information regarding the adverse event. The CVM reviewer name and contact information is collected for internal workflow management purposes.

Describe the secondary uses for which the PII will be used.

None.

Identify legal authorities governing information use and disclosure specific to the system and program.

Federal Food, Drug, and Cosmetic Act: 21 U.S.C. 301, see e.g., section360b.

Are records on the system retrieved by one or more PII data elements?

No

N/A

Identify the sources of PII in the system.

Directly from an individual about whom the information pertains

Hardcopy

Email

Other

Government Sources

Within OpDiv

Non-Governmental Sources

Public

Private Sector

Identify the OMB information collection approval number and expiration date

For both form 1932 and 1932a: OMB 0910-0645; expires May 31, 2019.

Is the PII shared with other organizations?

Yes

Identify with whom the PII is shared or disclosed and for what purpose.

Private Sector

Reporters receive a notice on the Confidentiality Statement on the form for self-reporters informing them that the reporter's identity, including the identity of self-reporter, may be shared with the manufacturer unless requested otherwise. Manufacturers may contact reporters to ask questions and follow up on their submission.

Describe any agreements in place that authorizes the information sharing or disclosure.

None.

Describe the procedures for accounting for disclosures.

N/A

Describe the process in place to notify individuals that their personal information will be collected. If no prior notice is given, explain the reason.

Reporters receive notice that their PII is being collected on the forms FDA 1932 and FDA 1932a, in the associated instructions and guidance documents, and when contacting the FDA when reporting adverse events. CVM personnel (safety reviewers) consent to the agency's use of their work-related PII at the time of hire.

Is the submission of PII by individuals voluntary or mandatory?

Voluntary

Describe the method for individuals to opt-out of the collection or use of their PII. If there is no option to object to the information collection, provide a reason.

Manufacturers are required to submit form FDA 1932 to report an adverse event. Individuals (e.g., manufacturer point of contact) cannot opt-out of this collection. The PII is necessary for monitoring and analyzing adverse event reports and product complaints.

Veterinarians or members of the public who would report using form 1932a, provide PII voluntarily. They may decline to report or to include PII in a report.

CVM safety reviewers may not opt-out of the system's use of their name as the assigned reviewer. This information is necessary to monitor and manage event reports and product complaints.

Process to notify and obtain consent from individuals whose PII is in the system when major changes occur to the system.

If FDA changes its practices with regard to the collection or handling of PII related to the PV Works system, the Agency will adopt measures to provide any required notice and obtain consent from individuals regarding the collection and/or use of PII. This may include e-mail to individuals, adding or updating online notices or forms, or other available means to inform the individual.

Describe the process in place to resolve an individual's concerns when they believe their PII has been inappropriately obtained, used, or disclosed, or that the PII is inaccurate.

Individuals may contact FDA or CVM by phone, mail or email using the contact information provided on fda.gov and the specific fda.gov web pages associated with the adverse event reporting program. CVM safety reviewers who have a concern may contact their management, the FDA Privacy Office or seek assistance via FDA's Employee Resource Information Center (ERIC).

Describe the process in place for periodic reviews of PII contained in the system to ensure the data's integrity, availability, accuracy and relevancy.

Reporter's PII is provided voluntarily by the individual. The individual is responsible for providing accurate information. Accuracy is ensured by individual review at the time of reporting. FDA personnel may correct/update their information themselves and their PII is relevant and necessary to be granted access to the system. Access is granted and restricted at the individual level as appropriate to the individual's duties (role-based access). Integrity and availability are protected by security controls selected and implemented in the course of providing the system with an authority to operate (ATO). Controls are selected based on NIST guidance concerning the ATO process, appropriate to the system's level of risk as determined using NIST's Federal Information Processing Standards (FIPS) 199. CVM performs annual reviews to evaluate user access.

Identify who will have access to the PII in the system and the reason why they require access.

Users:

Receive, review, manage, track, and analyze adverse event data as part of their safety reviews.

Administrators:

Monitor the system and database.

Contractors:

Direct contractors may receive, review, manage, track, and analyze adverse event data as part of their safety reviews.

Describe the procedures in place to determine which system users (administrators, developers, contractors, etc.) may access PII.

System access requests are reviewed and approved by the system/business owner along with the PV Works management team. System accounts are reviewed on a regularly basis to determine if access is still required for each user. Access is granted and restricted at the individual level as appropriate to the individual's duties (role-based access).

Describe the methods in place to allow those with access to PII to only access the minimum amount of information necessary to perform their job.

Supervisors indicate when accounts are created to apply the minimum information system access that is required in order for the user to complete his/her job. The access list for the information system is reviewed on a quarterly basis and users' access permissions are reviewed/adjusted, and unneeded accounts are purged from the system.

Identify training and awareness provided to personnel (system owners, managers, operators, contractors and/or program managers) using the system to make them aware of their responsibilities for protecting the information being collected and maintained.

All FDA personnel complete mandatory security and privacy awareness training at a minimum of once a year. A portion of this training is dedicated to the protection of PII.

Describe training system users receive (above and beyond general security and privacy awareness training).

Users are provided with a User's Guide for PV Works.

Do contracts include Federal Acquisition Regulation and other appropriate clauses ensuring adherence to privacy provisions and practices?

Yes

Describe the process and guidelines in place with regard to the retention and destruction of PII.

FDA-wide records schedules: file codes 6100-6135 regarding Adverse Event/Experience and Product Defect Reports Records in these files are covered by either National Archives and Records Administration Citation No. N1-88-07-2 or General Records Schedules 20-2a, 2b, 4-7, 11a(1), 12, and 16. Most records are temporary with destruction schedules between 10 and 30 years, or when no longer needed.

Describe, briefly but with specificity, how the PII will be secured in the system using administrative, technical, and physical controls.

Administrative safeguards include user training; system documentation that advises on proper use; implementation of Need to Know and Minimum Necessary principles when awarding access, and others. Technical Safeguards include use of multi-factor access authentication, firewalls, and network monitoring and intrusion detection tools. Physical controls include that all system servers are located at facilities protected by guards, locked facility doors, and climate controls. Other appropriate controls have been selected from the National Institute of Standards and Technology's (NIST's) Special Publication 800-53, as determined using Federal Information Processing Standard (FIPS) 199.