FDA Adverse Event Reporting Requirements

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FDA MedWatch Program (Voluntary Reporting)

Report adverse events that you observe or suspect for human medical products, including serious drug side effects, product use errors, product quality problems, and therapeutic failures for:

- Prescription or over-the-counter medicines, as well as medicines administered to hospital patients or at outpatient infusion centers
- Biologics (including blood components, blood and plasma derivatives, allergenic, human cells, tissues, and cellular and tissue-based products (HCT/Ps))
- Medical devices (including in vitro diagnostic products)
- Combination products
- Special nutritional products (dietary supplements, infant formulas, and medical foods)
- Cosmetics
- Foods/beverages (including reports of serious allergic reactions)

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FDA MedWatch Program (What not to report via MedWatch)

- Vaccines: Report vaccine events to the Vaccine Adverse Event Reporting System (VAERS) online at https://vaers.hhs.gov/esub/step1

- Investigational (study) drugs: Report investigational (study) drug adverse events as required in the study protocol and send to the address and contact person listed in the study protocol.

- Mandatory reporting by regulated industry:

  – Drugs and Biologics

  – Devices

  – Dietary supplements

- Reporting on Veterinary Medicine Products

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Background on ICH

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is unique in bringing together the regulatory authorities and pharmaceutical industry of Europe, Japan and the US to discuss scientific and technical aspects of drug registration

ICH Work Products

ICH Guidelines

MedDRA

Electronic Standards

    E2B R3

    electronic Common Technical Document (CTD)

CDER Requirements

Current requirements from sponsors:

– Submit individual case safety reports utilizing

–   ICH E2B R2

– <u>ICH E2B R3</u> : Constrained version of ISO/HL7 ICSR currently in testing phase by various regional members of ICH (US, Japan and EU)

CDRH Requirements

- HL7/ ISO ICSR R1

**Will augment, not replace, existing safety monitoring systems

CBER Requirements

ICH E2B R3

CBER is working on infrastructure now to receive ISO/HL7 ICSR based upon the combined data elements of the updated ICH specification, additional data elements from CDER and the data elements on the VAERS-1 (Vaccine AE reporting) and VAERS-2 forms

Center for Veterinary Medicine (CVM)

No ongoing initiatives and do not plan to have any initiative related to EHR for animals.

CVM has implemented the <u>HL7 ICSR message</u> for animal drugs and the vast majority of manufacturers are reporting veterinary AE to FDA electronically.
We recommend that veterinary practices report AE to the manufacturers so that manufacturers can then submit them to FDA electronically.

As a future effort, the HL7 ICSR message could be used for direct reporting from the veterinarian to the manufacturer.

Most large companies already are capable of receiving this message. It would be a significant improvement if veterinary practices with EHR, especially academic institutions and corporate veterinary companies, could use this message for reporting these AE to the manufacturer.

CFSAN Requirements

- Center for Food Safety and Applied Nutrition's (CFSAN's) Adverse Event Reporting System (CAERS) is the only system responsible for capturing adverse events for CFSAN

- Receives reports of adverse health events and product complaints from multiple sources: consumers, health professionals, industry, and others

- Standard in use: HL7 ICSR R1

Center for Tobacco Products (CTP) Requirements

- HL7 ICSR R1.

- CTP intends to collect AE and product problem reports using the FDA Safety Reporting Portal. They currently receive some pdf MedWatch forms regarding AE/PP with tobacco products but the data collected isn't sufficient for our purposes.

- We could accommodate reports coming in from EHRs, we can receive and process the report. We are not already piloting the receipt of *any* data from EHRs. The value is that if the incident has risen to the level of a hospital record, it is likely serious and therefore something the CTP team is interested in seeing.