Drug Supply Chain Security Act

Public Workshop | May 8-9, 2014

Standards for the interoperable exchange of tracing information for finished, human, prescription drugs

Agenda

DAY 1	Thursday, May 8, 2014	Speaker
8:00 – 9:00 am	Registration	
9:00 – 9:15 am	Welcome and Opening Remarks	Dr. Janet Woodcock
9:15 – 10:15 am	Goals of the Workshop Stakeholder Responsibilities Concepts and Terminology	CAPT Connie Jung
10:15 – 10:30 am	Break	
10:30 – 10:45 am	Workshop Logistics	Abha Kundi
10:45 – 12:15 pm	Breakout Session 1 – TI TH, TS Discussion	LCDR Raichell Brown
12:15 – 1:30 pm	Lunch (on own)	
1:30 – 3:30 pm	Breakout Session 2 – Discussion of Supply Chain Options	
3:30 – 3:45 pm	Break	
3:45 – 4:45 pm	Group Summaries of Session 2	
4:45 – 5:00 pm	Closing of Day 1	LCDR Eleni Anagnostiadis
5:00 pm	Adjourn	

DAY 2	Friday, May 9, 2014	Speaker
9:00 – 9:15 am	Welcome & Overview of today	CAPT Connie Jung
9:15 – 10:00 am	Summary of Supply Chain Options and Discussion	LCDR Eleni Anagnostiadis
10:00 – 10:45 am	Session 3: Refine Supply Chain Options	LCDR Raichell Brown
10:45 – 11:00 am	Break	
11:00 – 12:00 pm	Group Summaries of Session 3	
12:00 – 1:00 pm	Lunch (on own)	
1:00 – 2:30 pm	Breakout Session 4 – Fully Electronic	Carolyn Becker
2:30 – 2:45 pm	Break	
2:45 – 3:30 pm	Group Summaries of Session 4	
3:30 – 4:00 pm	Group Discussion	
4:00 – 4:15pm	Closing remarks	Dr. Ilisa Bernstein
4:15 pm	Adjourn	

Goals of the Workshop

- To obtain input from workshop participants on how trading partners can best comply with the requirements for the interoperable exchange of transaction information, transaction history, and transaction statements under the DSCSA on January 1, 2015 using currently available standards or practices.

- To utilize this input to help FDA establish initial standards for the interoperable exchange of transaction information, transaction history, and transaction statements in paper of electronic format that will be issued in the draft guidance required under Sec. 203 (h) of the DSCSA.

Breakout Session 3: Refine Supply Chain Options

Goals:

- To refine Supply Chain Options
- To identify additional guidance stakeholders need from FDA related to TI,TH,TS

What We Heard (1)

- Flexibility, with structure
- Trading partners, varying degrees of sophistication
- Electronic preferred, paper needed
- Issue guidance ASAP, stakeholders moving forward in the meantime
- Great opportunity for dialogue with all stakeholders at the table

What We Heard (2)

- Clarification (examples – not inclusive)
  - NDC code syntax
  - Strength
  - Dosage form
  - Container Size
  - Date of transaction
  - Date of shipment

Summary of Supply Chain Options

- For transactions between manufacturers or repackagers and wholesale distributors and transactions between wholesale distributors and dispenser – the majority of the participants agreed that EPCIS (Electronic Product Code Information Services), EDI (Electronic Data Interchange) (Advance Ship Notice), web portal and package slip are the tools that could be used to meet the requirements
- Group discussion - why the invoice should remain as a possible tool
- Group discussion - why email should remain as a possible tool and whether it should be considered an electronic option

Breakout Session 3: Refine Supply Chain Options

- What other guidance do you need from FDA to comply with the TI, TH, TS requirements that begins on January 1, 2015?

Breakout Session 4: Fully Electronic

Goal:

To determine how stakeholders can transition to fully utilizing electronic practices, processes or systems to interoperably exchange TI, TH, and TS (lot-level information).

Session 4: Thought Starters

- Will the electronic option(s) that have been developed during this workshop work for all stakeholders?
  - Will just one of those options work, or will multiple options be needed?
  - If there are any impediments, how can they be resolved?
- Does the electronic option you would choose for years 1 -4 differ from the option you would choose for years 4 – 9? Can this evolve with stakeholder needs between years 1 - 9? Is it scalable?
- What can FDA do to help facilitate progress?
- Based upon this discussion, would you make any changes to the supply chain option(s) presented earlier?