Dispensers: What you should know about DSCSA (Drug Supply Chain Security Act)

American Pharmacists Association

November 2021
Learning objectives

- Describe the Drug Supply Chain Security Act (DSCSA or track and trace law)
- Identify pharmacists’ responsibilities under the DSCSA
- Discuss how pharmacists can protect patients from getting substandard and counterfeit drugs
Why DSCSA?

Case Study: Lipitor® US Recall

It was the largest recall of counterfeit medicines to date in the US. Just one counterfeit case, but over 18 million Lipitor® tablets affected. In the short time from discovery to recall the fake medicines had spread to 15 US states.

COMBATING COUNTERFEIT DRUGS
A Report of the Food and Drug Administration
February 2004

FDA Warns About Fake Avastin In U.S.
February 15, 2012 - 2:40 PM ET

TREATMENTS

The Food and Drug Administration says counterfeit Avastin, a costly cancer drug, has made its way to doctors in the United States.

The counterfeit doesn’t contain the active ingredient, Genentech, the Roche unit that makes Avastin, said Tuesday it’s aware of the problem and is working with the FDA and law enforcement.

Last week, the agency sent 10 letters to cancer specialists in California, Texas and Illinois who are believed to have purchased the fake Avastin.

Counterfeit Drugs: A Real Cause for Alarm
December 1, 2004
Monica Holmberg, PharmD
Pharmacy Times, Volume 0,0
What is DSCSA?

Drug Quality and Security Act of 2013 (Public Law 113-54)

- Title I: Drug Compounding
  - Established 503B outsourcing facilities

- Title II: Drug Supply Chain Security
  - Product tracing
  - Wholesale distribution standards
**Drug Supply Chain Security Act of 2013**

**Goal:** Implement an interoperable, electronic tracing of products at the package level by 2023 that will:

| Facilitate electronic exchange of transaction information for each sale of prescription drugs | Use product identifiers to verify product at the package level | Enable prompt response to suspect and illegitimate products when found | Improve efficiency of recalls |

**Goal:** Establish national standards for licensure for wholesale distributors and third-party logistics providers.
DSCSA terms

Dispenser:
- A retail pharmacy, hospital pharmacy, or a group of chain pharmacies under common ownership or control, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities.

- Excludes: –
  - if such entity acts as a wholesale distributor;
  - a person who only dispenses products used with animals.
DSCSA terms

Product:
- Prescription drug in finished dosage form for administration to a patient without further manufacturing (such as capsules, tablets, lyophilized products before reconstitution)
- Not included:
  - Blood or blood components intended for transfusion
  - Radioactive drugs/biologics
  - Imaging drugs
  - Certain IV drugs
  - Medical gas
  - Homeopathic drugs
  - Lawfully compounded drugs
Authorized Trading Partner
- Buy only from authorized trading partners with valid registration or licensure

Product Tracing
- Exchange transaction documentation

Product Verification
- Quarantine and investigate
- Respond if receive notification of illegitimate product
- Notify FDA if illegitimate product found
- Recordkeeping

Serialization
- Product identifier in human readable and 2D bar code on all covered products
- Only purchase serialized product
Only do business with an **authorized trading partner**

- Manufacturer and repackager
  - Must be registered with FDA
- Wholesalers
  - Must have valid state or federal license and report license to FDA
  - Check FDA database
- Dispensers
  - Must have valid state license
Have and follow processes for product tracing information

**Receive**
- Only accept Rx drugs with product tracing information

**Provide**
- Generate and provide product tracing info when you sell to another trading partner
- Not needed when dispense to a patient or sell to a pharmacy for a specific patient

**Respond**
- For recall or to investigate suspect or illegitimate product respond within 2 biz days

**Store**
- At least 6 years

**Return**
- Only to trading partner where you bought it
Know what is a suspect or illegitimate product

**Suspect Product**: reason to believe that product potentially is:
- counterfeit, diverted, stolen
- subject of fraudulent transaction
- intentionally adulterated or appears otherwise unfit for distribution such that would result in serious adverse health consequences or death to humans

**Illegitimate Product**: credible evidence shows that product is:
- counterfeit, diverted, stolen
- subject of fraudulent transaction
- intentionally adulterated or appears otherwise unfit for distribution such that would result in serious adverse health consequences or death to humans
Have and follow processes for product verification for suspect and illegitimate product

**Quarantine and investigate**
- Suspect prescription drugs to determine if illegitimate

**Investigation**
- Validate transaction information and history
- Verify lot number
- Retain sample if illegitimate

**Notify**
- If product is illegitimate, notify FDA (using Form FDA 3911) and trading partners you bought from and sold to, within 24 hours

**Respond**
- If illegitimate, coordinate and work with manufacturer to keep drug from reaching patients

**Store**
- Keep records of investigation of suspect and product disposition of illegitimate product for at least 6 years
FDA Form 3911

https://www.fda.gov/about-fda/reports-manuals-forms/forms
Only buy/sell product with serialized product identifier on package

• Some exceptions:
  • Not “product”
  • Grandfathered
  • Waiver/exempt
• If unsure:
  • Check product tracing information
  • Check with manufacturer, repackager, or wholesaler

Product identifier/serialization is placed on product package by manufacturer or repackager

For Every Pharmacist. For All of Pharmacy.
DSCSA Timeline
(For dispensers)

Since 2015....
• Lot level tracing
• Verification of suspect/illegitimate product
• Only do business with authorized trading partners

Since 2019....
• Item level serialization begins

Since 2020....
• Dispensers can only buy serialized product
• Dispensers must verify product identifiers for certain packages of suspect products

In 2023....
• Item level tracing
• Electronic, interoperable tracing system in place
Prepare for November 27, 2023

- Be ready to exchange transaction information (with specific product identifier for each package) and transaction statements electronically

- Implement systems/processes for package-level verification, including the standardized numerical identifier

- Implement systems/processes to facilitate the gathering the information necessary to produce the transaction information and statement for each transaction going back to the manufacturer if FDA or trading partner requests for investigation

- Can enter into an agreement with a 3rd party to maintain transaction documentation
How to prepare for 2023

• Talk to your wholesaler. They likely are already planning.
• Volunteer to help or be a sounding board. FDA and private sector groups need pharmacist input and advice.
• Review FDA guidances when they are published. Do they make sense? Is it doable? Provide feedback/comment.
• Keep an eye out for FDA’s small dispenser feasibility study.
• Learn more about DSCSA.
  • Check out FDA’s website.
  • Check out Dispenser specific Qs and As prepared by the Pharmaceutical Distribution Security Alliance https://pdsaonline.org/wp-content/uploads/2020/10/PDSA-QA-Document-on-Dispenser-Requirements_Final-1.pdf
Why it is important to comply with DSCSA?

Because failure to comply can result in penalties: imprisonment and/or fines

SEC. 206. PENALTIES.
(a) PROHIBITED ACT.—Section 301(t) (21 U.S.C. 331(t)), is amended—
   (1) by striking “or” after “the requirements of section 503(d),”;
   (2) by inserting “, failure to comply with the requirements under section 582, the failure to comply with the requirements under section 584, as applicable,” after “in violation of section 503(e)”;
(b) MISBRANDING.—Section 502 (21 U.S.C. 352), as amended by section 103, is further amended by adding at the end the following:
Check out FDA’s DSCSA website

Be vigilant.
Be diligent.
Be ready.
For our patients.
Thank you!!!

ILISA BG BERNSTEIN, PharmD, JD, FAPhA
Senior Vice President, Pharmacy Practice and Government Affairs
ibernstein@aphanet.org

KARIN BOLTE, JD
Director, Health Policy
kbolte@aphanet.org