



Communicating and Disseminating Drug Safety Information to the Public

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Outline

- Tools other than labeling for communicating important drug safety information
- Tactics for dissemination and public outreach

Drug Safety Communication (DSC)

- CDER’s primary tool to communicate postmarket drug safety information to the public
 - Emerging drug safety information
 - New or updated information about known or established drug risks

FDA Drug Safety Communication: FDA warns that SGLT2 inhibitors for diabetes may result in a serious condition of too much acid in the blood

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Safety Announcement	▼
Facts about Sodium-glucose Cotransporter-2 (SGLT2) Inhibitors	▼
More Info for Patients	▼
More Info for Health Care Professionals	▼
Data Summary	▼

Types of Issues Communicated by a DSC

- Issue affecting a large number of patients due to widespread use
- Potentially serious or life-threatening adverse event (regardless of widespread use of drug) discovered postmarket
- Clinically relevant information about a known adverse event
- New contraindication for a subpopulation of patients
- Previously uncharacterized drug-drug or drug-disease interaction, or medication error that may result in a serious or life-threatening adverse reaction

When to Communicate with a DSC

- An important drug safety issue is identified that:
 - May significantly alter the drug’s risk and benefit balance
 - May affect HCP’s decision to prescribe and monitor
 - May affect patient’s decision to use
 - Has measures that can be taken to prevent or ameliorate harm
- Need to balance concerns of unnecessarily alarming the public with the public’s need to know
 - Should we communicate now (earlier, potentially saving lives) with less complete information OR communicate later when we have more definitive information and recommendations?

Alerts and Statements

- Generally used to communicate more critical or urgent safety issues:
 - Product quality issues
 - Adulterated or contaminated products
 - Counterfeit products
 - Voluntary recalls
- Can be used if we want to communicate to HCPs only or to target a specific audience
- Statements are also used to communicate preliminary safety findings from clinical trials

Other Communication Tools

- Press releases
- External Q&As
- Consumer Updates
- Perspectives/commentaries in NEJM and other peer-reviewed medical journals
- Articles in trade journals
- FDA Expert Commentary and Interview Series on Medscape

Other Communication Tools (cont'd)

- Drug Info Rounds videos
- Webinars
- CDER Conversations & From Our Perspective articles
- FDA Voice blog
- Educational outreach materials (e.g., fact sheets, pamphlets, articles)

Dissemination Outlets

- Email Listservs
 - MedWatch Safety Alerts: 315K subscribers
 - Drug Info Listserv: 136K subscribers
 - Biweekly Updates for Health Professionals Newsletter (69K subscribers) & Patient Network Newsletter
- Drug Safety Podcasts
- Social Media
 - Drug Info Twitter: 178K followers
 - Facebook: 273K followers
 - YouTube
- Traditional and Trade Media

Public Outreach

- Federal Partners (VA, DOD, IHS, BOP)
- Foreign regulatory counterparts (EMA, PMDA)
- Targeted stakeholder email blasts
- Targeted stakeholder conference calls
- Media calls/interviews

In Conclusion

- We are committed to providing the public with up-to-date drug safety information
- We use a variety of communication tools and tactics for dissemination
- Our overarching goal is to ensure that the right people get the right message at the right time



Thank You