



# Communication of Drug Safety Information

Food and Drug Administration  
Center for Drug Evaluation & Research  
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# Communication of Drug Safety Information

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# Focus of Comments

- Pharmacists' awareness, use, and perception of communication tools
- Accessibility and usability of Internet-based risk communication information



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# Risk Communication Tools

- Patient information sheets
- Healthcare information sheets
- Talk papers
- Public health advisories
- Press releases
- MedWatch listserv safety updates
- Patient safety news
- Educational campaigns
- CDER website
- Product labeling
- Patient package inserts
- Medication Guides
- Consumer Medication Information
- Dear Health Care Professional letters
- Drug Watch website



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# Challenges with Awareness & Use

- Number of communication vehicles
- Lack of a uniform communication system
  - What drives use of one tool versus another?
  - Tools to communicate drug safety also used to communicate other information



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# Challenges with Internet-Based Tools

- **FDA Website**
  - Must actively search for information
  - Can be difficult to locate
  - Lack of a central drug safety information repository
- **FDA MedWatch/CDER New Listserv**
  - Number of daily communications



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# Recommendations

- Review existing communication tools
  - Identify tools that are not needed
  - Streamline and consolidate remaining tools
- Implement a systems-based approach
  - Develop criteria to determine when to communicate risk information, to whom, and what tool to use



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# Recommendations

- Create a central drug safety center on the FDA website
  - Expand the CDER drug safety section
  - Add prominent link on FDA homepage
- Maximize the pharmacist's role
  - Work with pharmacists to communicate risk information to patients
    - Assist with information interpretation



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