

PhRMA Paperless Labeling Initiative



Overview

- Lessons to be learned from PhRMA assessment on electronic distribution of PIs
- Translating these lessons to the distribution of ePMI



Lessons learned from PhRMA assessment on paperless labeling

PhRMA Paperless Labeling Initiative

- Pharmaceutical Research and Manufacturers of America (PhRMA) has long supported the systematic approach to reduce the use of paper prescribing information at dispensing sites
- Electronic distribution of prescribing information will enhance patient safety by having the most recent prescribing information available

PhRMA Paperless Labeling Initiative

- Since 1998, PhRMA has collaborated with external stakeholders from the pharmacy and healthcare provider communities to ensure that the perspectives of dispensers were considered.
 - 2 Field Trials conducted [2002, 2004]
 - Pharmacy Technology Assessment conducted [2008]

Use DailyMed

- PhRMA proposes that NLM's DailyMed be the singular database of current labeling:
 - FDA approved labeling pushed to NLM daily
 - Ensures that all are accessing the same current electronic labeling for each product.

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- **Subsequent Enhancements to DailyMed:**

- Seachability of DailyMed by NDC code.
- Link the DailyMed database to standard bar code technology (UPC) using the product's NDC number.

Still Desired:

- Develop additional SPL stylesheet to enable the prescribing information to be printed in a smaller, but readable, font size directly from the DailyMed website, where needed.

Features of the Desired System

- **Cost neutral to dispensing sites**
- **Available at all dispensing sites**
- Readily accessible
- Timely (information current, updates pushed)
- Comprehensive (complete PI)
- Standardized format
- Printable (where needed to be printed)
- Text cannot be edited by dispenser
- Virus protected
- Exploit bar coding technologies for rapid access
- **Provided via existing pharmacy systems (minimize interference to existing workflow)**

PhRMA Paperless Labeling – Revision

- Project Revised based on 11/16/10 Stakeholder Meeting with PhRMA member companies, GPHA, NLM, Vanderbilt University, FDA (Randi Levin), Pharmacy Organizations (APHA, NCPA, NCPDP):
 - Paperless labeling pilot using DailyMed will not be conducted with pharmacies as originally planned
 - An assessment of the state of readiness for a paperless labeling pilot among a nationally representative sample of pharmacies including chain and independent retail pharmacies, hospitals, and other dispensing sites (both urban and rural) will be conducted instead.
 - Issues will be identified and feasibility of potential solutions will be explored.
 - The project will be conducted by Vanderbilt University with Dr. Kevin Johnson as Principal Investigator

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- **Identify Opportunities to Collaborate:**
 - Educate stakeholders to increase awareness of DailyMed (e.g., Physicians, Pharmacists).
 - Ensure labeling is available for all prescription drug and therapeutic biological products approved for use in the United States.
 - Phased-in Approach

Assessment Timeline

Milestone	Jan	Feb	March	April	May	June
Complete semi-structured interview questions	X					
Conduct interviews/Focus Groups	X	X				
Survey development		X				
APhA Distribution utilizing			X	X	X	
Data analysis					X	
Prepare final report						X

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Translating these lessons to the distribution of e-PMI

ePMI

- Understand the variety of intended audiences (many cohorts)
- Define very specific objectives for delivery of ePMI (e.g., increase access, readership, verified readership, comprehension, compliance, etc.)
- Carefully consider the current state of technology, how it is used by intended audiences, and where it is trending

Thank You!

