

Designing Pilot Programs to Distribute Patient Medication Information (PMI) Expert Workshop

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Content Development Issues

- **Selection of drug products:**
 - ❖ Include range of drug complexity and risk
 - ❖ Include drugs in multiple dosage forms with variations in PMI
 - ❖ Include drugs with Medication Guides and REMS
 - ❖ Include drugs from same class but different manufacturers
 - ❖ Include same drugs from different manufacturers
 - ❖ Include drug pair with inconsistent risk information



Content Development Issues

● **Creation of PMI**

- ❖ **FDA should first publish clear guidance on content and format**
- ❖ **Manufacturers should interpret guidance independently**
- ❖ **Manufacturers should develop content independently based on their own interpretation of guidance**
- ❖ **FDA should not review content in advance of distribution**



PMI Distribution Issues

● **Distribution of PMI**

- ❖ **Should test access from centralized repository**
- ❖ **Should test known issues with FDA's NDC data**
- ❖ **Should test multiple dosage forms of same drug**
- ❖ **Should test multiple manufacturers of same drug product, including generics**
- ❖ **Should test other known data-quality issues with manufacturer-controlled submission of electronic files to central repository**



Non-integrated Content Issues

● **How will pharmacy reconcile?**

- ❖ High-level drug interaction alerts from pharmacy information system (PIS) not reflected in PMI
- ❖ Counseling messages from PIS not reflected in PMI
- ❖ Other PIS alerts/content (auxiliary labels) not reflected in PMI
- ❖ Liability issues about standard of care/advice differences between pilot PMI and existing risk communication documents
- ❖ Patient confusion in comparing such documents

Comparator Content

● **What will it be?**

- ❖ **Web-based?**
- ❖ **Print-based?**
- ❖ **Combination?**

● **Medication Guides**

● **Independent drug information publishers**

- ❖ **Notify all comparator sources of drugs to be tested**
- ❖ **Allow comparator CMI to adopt new content and format standards versus Keystone CMI**

