



Public Workshop: Ensuring Access to Effective Patient Medication Information

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Creating Effective PMI – The Roles of Manufacturers and PMI Vendors

- Outline
 - What are the objective measures and outcomes for effective PMI?
 - How could effectiveness of PMI be demonstrated and regulated?
 - Whose responsibility is it to develop PMI for generic products?
 - What are the ideal roles for manufacturers?
 - How can manufacturers promote effective distribution of PMI?
 - What are some innovative solutions to ensure patients have access to high-quality PMI?

What are the objective measures and outcomes for effective PMI?

- Consistent format, font size, use of color to enhance important information
- Include patient centered information on why medicine was prescribed, benefits and risks – KISS
- Include 1-800 number and web address of manufacturer so patient can access additional information, if necessary
- FDA approved

How could effectiveness of PMI be demonstrated and regulated?

- FDA reviewed and approved
- Test prototypes in real-life pharmacies and obtain follow-up information from patients who received PMI: what medicine are they taking, when/how often is it supposed to be taken, what are the risks in taking the medicine, what medicine(s) should not be taken while on this medicine
- As with current Medication Guides, PMI is part of labeling and should be expected to be kept up-to-date by RLD and reviewed by FDA as part of any labeling revisions

Whose responsibility is it to develop PMI for generic products?

- 21 CFR 314.94(8)(iv)
 - Labeling (including the container label, package insert, and, if applicable, Medication Guide) proposed for the drug product must be the **same as the labeling approved for the reference listed drug**, except for changes required because of differences approved under a petition filed under 314.93 or because the drug product and the reference listed drug are produced or distributed by different manufacturers.

What are the ideal roles for manufacturers?

- Manufacturers should be responsible for the content of PMI. FDA review and approval will minimize chances of PMI as direct-to-consumer advertising
- Must be kept up-to-date
- Ensure access of PMI at patient level (whether through physician or pharmacist) both in paper and electronic forms

How can manufacturers promote effective distribution of PMI?

- One printed copy accompanies product (regardless of how many units can be dispensed out of the bottle)
- Electronic availability (single repository such as DailyMed or company website)
- 1-800 number and company website on primary container label of product so patient can access additional information at their convenience

What are some innovative solutions to ensure patients have access to high-quality PMI?

- Current Medication Guides and Patient Information leaflets as PMIs
 - Tiered approach: products with REMS first, then most prescribed products
 - Due to FDA resource issues, current Med Guides and Patient Information leaflets could be reformatted for ease of FDA approval.
- Highlight new or updated information to attract readers attention

Review – Manufacturer's Perspective

- Current system of PPIs, CMIs and Med Guides has become complex
- Concerned with patient safety, education and communication
 - Availability in paper and electronic forms
 - Add manufacturer 1-800 number to PMI