Patient Medication Information:

Perspectives from the Biotechnology Industry

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This presentation was developed on behalf of the Biotechnology Industry Organization (BIO) and in conjunction with members of BIO's Consumer Medication Information Task Force.

Disclaimer: The views presented do not necessarily represent the position[s] of Eli Lilly and Company.

Presentation Overview

I. Effective PMI

II. PMI Development

III. Standardized PMI Language

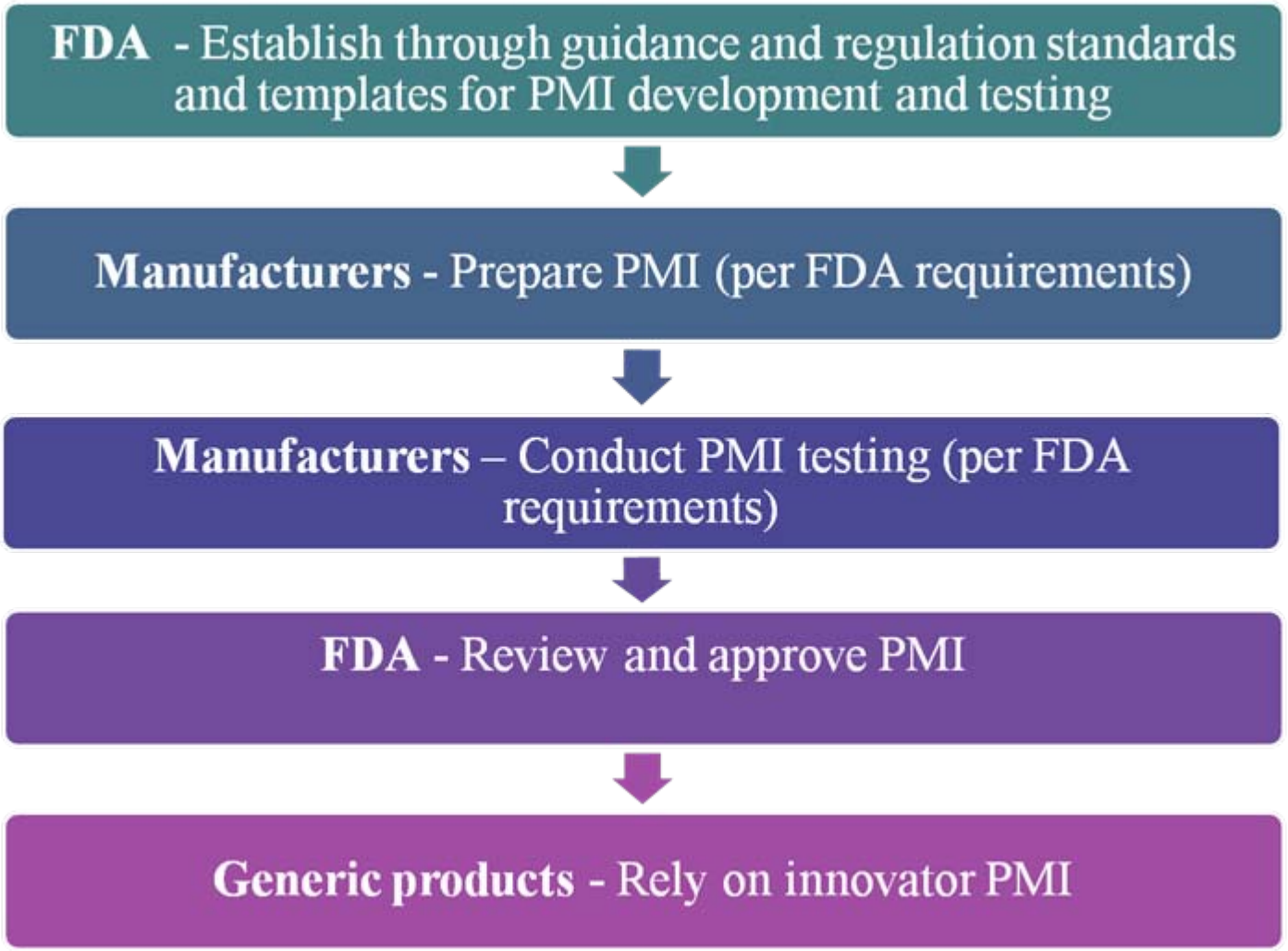
IV. Distribution of PMI

V. Implementation

I. Effective PMI

- PMI objective – improve patient outcomes
  - Reinforces communication between the patient and healthcare professionals
  - Enables
    - understanding of benefits and risks
    - safe and effective use of medication
- Patients should be able to
    - locate, interpret, and act upon information

II. PMI Development



III. Standardized PMI Language

- FDA-approved list of language to be used in PMI
  - Mapped to concepts that appear in the US Prescribing Information (USPI)
  - Lay-friendly, standardized descriptions of benefit and risk information, potential adverse reaction symptoms, and appropriate patient actions
  - Initially the list would include terms utilized for the most frequently used products and would grow over time

Standardized PMI Language *(continued)*

- The language would be created by an independent coalition to include:
  - FDA representatives
  - Medical experts
  - Patient education and communication experts
  - Pharmaceutical manufacturers
- The language would be tested by patients
- Manufacturers would be required by regulation to utilize language included in the list unaltered

Standardized PMI Language *(continued)*

Benefits would include:

- Patients would see the same terms used from product-to-product , benefiting from increased standardization that has become the norm with food and OTC product labeling today
- FDA would streamline review due to use of already approved language
- Manufacturers would streamline development of PMI content due to use of standardize language associated with concepts found in the USPI.

IV. Distribution and Dispensing of PMI

- Distribution of printed PMI by manufacturers with the product should not be required
- PMI should be posted to a centralized database, such as DailyMed
- Customization
  - Prescribing - benefits and risks focus – optional
  - Dispensing – content and format unaltered – print or electronic delivery to patient – mandatory
- Mandatory distribution by dispensers for products administered by non-healthcare professionals
- Manufacturers should NOT be held accountable for distribution or evaluation of distribution

V. Implementation

- Phased implementation, such as the 2006 Physician Labeling Rule
- Adequate piloting and validation phase
- Initially focus on approving and implementing PMI for
  - Most commonly prescribed products
  - Those that already have Medication Guides

Questions and Comments?