18th Annual Pharmaceutical and Medical Device Compliance Congress

Mini Summit XV: Recent FDA Guidance on Off-Label Manufacturer Communications

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Disclaimer

- The views and opinions expressed in this presentation are those of the presenters and do not necessarily reflect the views or positions of their employers.

For what type of organization do you work?

Biopharmaceutical company

Medical device company

Contract research or manufacturing organization (CRO or CMO)

Health plan, health system, or physician organization

Law or consulting firm

Bank or venture capital company

Other

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...r organization have a policy or procedure in ...nications to payers, formulary committees, an... entities?

Yes

No

Not yet, but are currently developing one

I don't know

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rganization, who is communicating medical ation to payers, formulary committees, and entities?

Managed Markets / Managed Access staff

Sales Force

Medical Affairs staff

Dedicated Managed Markets MSL staff

Other staff within my organization

My organization does not communicate with payers or formulary committees / not applicable

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organization, to whom do you communicate product information?

To healthcare providers (HCPs) who prescribe our product(s)

To payers and other managed care audiences

To patients

All of the above

HCPs and managed care audiences only

My organization does not communicate medical product information / not applicable

I don't know

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t type of medical product information does y organization communicate?

On-label information only

General disease state and/or clinical trial data only

On-label information and clinical trial data

On-label information, clinical trial data, and healthcare economic information

None of the above

I don't know

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ur organization, who approves presentation healthcare economic information (HCEI)?

Promotional review committee

Medical review committee

Both promotional and medical review committee

No approval required

My organization does not communicate healthcare economic information / not applicable

I don't know

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FDA's Current Thinking on Off-Label Communications – January 2017 Draft Guidances for Industry and Memorandum

- **Today's Objective: Discuss considerations for the application of FDA guidance documents released in January 2017**

- Two draft Guidance for Industry documents on:
  - Manufacturers' communication of health care economic information (HCEI) about approved drugs and information about investigational products to payers, formulary committees, and similar organizations
  - Medical product communications that include data and information that are not contained in a product's FDA-required labeling, but that are consistent with the FDA-required labeling of the product
- Memorandum on "Public Health Interests and First Amendment Considerations Related to Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products"
  - Additional background on FDA's views regarding manufacturers' communications about unapproved uses of approved or cleared medical products

Summary of Documents

- Communications must be consistent with the labeling
- 3 factors to determine whether communications are consistent with FDA-approved label:
  - Related to indication, patient population, and dosing/administration instructions as per approved or cleared label, and not inconsistent with any use limitation or direction for handling or using the product
  - Must not increase potential for patient harm or adversely impact risk/benefit profile
  - Under conditions represented in the communication, directions for use in FDA-approved or cleared labeling must enable product to be safely and effectively used
- Once a communication is deemed "consistent with the labeling," consider whether appropriately substantiated
  - Grounded in fact and science and presented with appropriate context
  - Scientifically appropriate and statistically sound
  - Accurately characterized, including limitations of the strength of the evidence and the conclusions that can be drawn from it

Summary of Documents (continued)

Payer Communications:

- Healthcare Economic Information (HCEI) may be provided to payers, formulary committees, and similar entities if the information relates to drug's approved indication and is based on competent and reliable scientific evidence
  - FDA does not object to HCEI being disseminated to payers and formulary decision-makers prior to FDA approval if communications are "unbiased, factual, accurate, and non-misleading"
  - HCEI in approved indication post-approval considered promotional; subject to existing FDA guidance on post-approval communications and submitted on Form FDA 2253
- Drug and device manufacturers may provide certain information about investigational products to payers, including, e.g., factual presentations from clinical studies, anticipated timeline for approval/clearance, targeting/marketing strategies

Summary of Documents (continued)

- Questions about communication on medical products still need to be addressed; these include:
  - Ability to communicate appropriate information about investigational uses of unapproved drugs
  - More clarity regarding the definition of "relates to," for example, to accommodate real-world evidence
- FDA's stance on commercial speech and the First Amendment continues to be unclear
  - Scott Gottleib stated in a speech held at the RAPS 2017 Regulatory Conference in September that FDA's regulations "cannot be in conflict with the courts," noting that the FDA is currently "in a period of ambiguity"

Case Study
Scenario 1

- A pharmaceutical company plans on using real-world evidence from a prescription claims database to support comparative safety and efficacy claims against a competitor product.
  - Is this approach compliant and permissible under current guidance?
  - What aspects does the company need to take into consideration when evaluating whether or not to communicate such data to healthcare providers? To payers and formulary committees?

Case Study
Scenario 2

- A medical device company plans on communicating data from a clinical study to their payer audience prior to approval of a product by the FDA.
  - What should the company take into consideration when preparing to communicate pre-approval study data?
  - Does it make difference whether the product is an investigational product or a new intended use of an already marketed product? If yes, in which way?

Case Study
Scenario 3

- A pharmaceutical company plans to communicate data from a pivotal clinical trial, including data from:
  - The comparator arm of the trial
  - A secondary endpoint
  - A subanalysis of the trial data
  - Patient-reported outcome (PRO) data

- Can these data be communicated and, if yes, what should be taken into consideration during their dissemination?

Key Takeaways to Operationalize Key Learnings

- **Who** is **communicating** medical product information?
  - **Different** considerations for communications by **Managed Markets, Commercial, and Medical Affairs staff**
  - The government is **more concerned with the content of the message** rather than the messenger
- **Who** is the **audience** for the medical product information?
  - Regulatory requirements for communications with a payer and other Managed Care audiences differ from communications with healthcare providers (HCPs)/prescribers or with patients
  - **The audience matters!**
- **What** medical product information is being communicated?
  - Depends on the type of information being shared – for example, communication on general disease state vs. on a marketed product or clinical trial data vs. healthcare economic data

Key Takeaways to Operationalize Key Learnings (continued)

- **Where** is medical product information is being communicated?
  - Depends on where information is being communicated – for example, in-person meetings with payers or HCPs vs. branded print or digital materials vs. clinical data presentations or publications
- **When** is the medical product information being communicated?
  - Timing depends on the type of information being shared – requirements around sharing certain **healthcare economic information** have been carved out specifically by statute

- **The timing of medical product communication is significant from a regulatory standpoint, both in regard to a product's life cycle, as well as the proactive or reactive nature of the communication**

Questions?

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