

Off-Label Wish List: Industry Groups Want US FDA's Guidances To Do More

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- ANALYSIS



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Executive Summary

Sponsors and payers question guidances' scope and potential audiences, and wonder if the agency couldn't just perform some retrospective audits of off-label communication to speed things up.

Maybe not surprisingly, industry groups are unhappy FDA did not do more to unleash off-label communication in its recent draft guidances.

Michelle Drozd, Pharmaceutical Research and Manufacturers of America deputy VP of policy and research, said FDA could have allowed more sponsor communication about off-label uses.

"Scope is a clear issue from our perspective," Drozd said during the recent Drug Information Association Advertising and Promotion Regulatory Affairs conference. "It's great that the guidance allows communications about patient-reported outcomes, adherence, long-term outcomes, subpopulations. Those are all things we were pleased to see. But we really think that the guidance does not go far enough because it does not allow a lot of communication related to unapproved uses."

FDA in mid-January released two draft guidances related to off-label communications. One laid out considerations for when sponsors can

disseminate information that is not included in the FDA-approved label, stating that it must be deemed "consistent" with the information that is in the label.

Patient-reported outcomes, product convenience and additional context about the mechanism of action was mentioned as likely to be considered consistent with labeling, and while the guidance lacked a lot of detail, FDA included a three-prong test that it will use to determine whether off-label information is considered consistent with the label. (Also see "[Off-Label Communication: When Does It Align With Approved Labeling?](#)" - Pink Sheet, 17 Jan, 2017.)

PhRMA has not finalized its comments on the guidance, Drozd said, but PhRMA and the Biotechnology Innovation Organization released their principles for communicating information with payers and health care professionals, primarily intended to facilitate off-label communication, in 2016. (Also see "[Off-Label Communication Principles From PhRMA, BIO Aim For Reg Changes](#)" - Pink Sheet, 27 Jul, 2016.)

Among FDA's concerns about off-label communication is the accuracy of the information presented. During a public hearing on off-label communications in late 2016, FDA raised questions about how to deal with unpublished information that was not published or subject to peer review. But PhRMA argued that the principles would govern sharing that information. (Also see "[Off-Label Communications: Industry, FDA Debate Role Of Peer Review](#)" - Pink Sheet, 9 Nov, 2016.)

Delays While Waiting For FDA Advisory Comments A Concern

FDA advisory comments on potential off-label communications also seem to have raised concerns in some parts of industry.

Soumi Saha, Academy of Managed Care Pharmacy (AMCP) assistant director of pharmacy and regulatory affairs, said during the conference that requiring pre-submission of off-label presentations could delay that information getting to the intended recipients.

"Because payers will need this information as soon as possible, any pre-submission process would slow down the release of that information," she said. "If anything, the FDA could consider some sort of retrospective audit process so that there's not a hold-up."

Agency officials have wondered whether periodic audits of off-label communication were possible. (Also see "['Who Is The Arbiter?' US FDA Asks As It Mulls Loosening Off-Label Reins](#)" - Pink Sheet, 9 Nov, 2016.)

FDA is willing and now able to accept submissions for advisory comments on whether potential off-label communication is consistent with the approved label. But the agency has warned that the reviews may be lengthy because they could require extensive reviews of study data and consults with other FDA staff.

The reviews also are new for the Center for Drug Evaluation and Research's Office of Prescription Drug Promotion, and it appears staff will be learning how best to implement the guidance along with industry. (Also see "['Off-Label Promotion Decisions Likely Made Case-by-Case, US FDA Official Says](#)" - Pink Sheet, 27 Feb, 2017.)

How Much Context Is Necessary?

Another related draft guidance on communicating health care economic information with payers and similar groups included requirements that sponsors give the context for the off-label data they present, including study methods and limitations.

Mark Gaydos, [Sanofi](#) VP of North America general medicines and established products, US advertising and promotion, global regulatory affairs, said during the conference that there is "an extensive list of contextual information that FDA's recommending accompany these communications to payers," which could be problematic.

"For any given communication, do you need to check the box on every item that's listed in the guidance for every communication with a payer?" he asked. "I would envision that's where we're going to see a lot of push-back in terms of comments and really needing clarification. Are there certain requirements for contextual elements that are really absolute musts and others that may be required in certain circumstances?"

Should The Audience Grow?

Saha also said AMCP has questions about the intended audience of the off-label communications envisioned in the guidances. She said the group has

recommended that the information be available to more than just health care decision-makers.

Drozd said PhRMA was not concerned about the intended audience for the information.

FDA's draft guidance on communicating with payers states that health care economic information should be targeted to formulary committees, drug information centers, technology assessment panels, pharmacy benefit managers and other entities making drug selections or reimbursement decisions or managing formularies. (Also see "[Industry Communications With Payers: US FDA Okays Info On Investigational Drugs](#)" - Pink Sheet, 19 Jan, 2017.)

AMCP has said that along with formulary committees, entities like accountable care organizations, those developing value frameworks and compendia, and integrated delivery networks also should receive the data, if necessary. (Also see "[Rx Economic Information-Sharing Concept Getting Renewed Push](#)" - Pink Sheet, 30 Jun, 2016.)

In contrast, some consumer and other non-industry stakeholders have argued for limitations of where sponsors can share information about off-label uses. (Also see "[Keep Limits On Off-Label Promotion, Consumers And Patients Say](#)" - Pink Sheet, 10 Nov, 2016.)

FDA is accepting comments on both draft guidances until April 19. They were part of a litany of guidances and other documents issued in the final days of the Obama Administration. (Also see "[FDA's Document Dump: Guidance Release Skyrockets Ahead Of Trump's Arrival](#)" - Pink Sheet, 22 Jan, 2017.)