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FIRST REPORT

FDA NEWS

FDA Releases Draft Guidance on Sharing HCEI Between Pharma, Payers

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The FDA recently released draft guidance in order to clarify regulations related to the sharing of health care economic information (HCEI) between pharmaceutical manufacturers and health care decision-makers, including payers, formulary committees, and similar entities.

According to consensus recommendations released by the Academy of Managed Care Pharmacy (AMCP) in June 2016, HCEI is crucial to payers and formulary decision-makers because it helps them “determine the ‘value’ of new medicines.” The FDA defined HCEI as “a range of information on effectiveness, safety, and cost-effectiveness of approved prescription drugs, including information from firms, to help support [payers’] drug selection, formulary management, and/or coverage and reimbursement decisions on a population basis.”

The FDA noted that HCEI often differs from the information used by the FDA to make approval decisions. Because of this, the FDA stated that “it is essential that information provided by firms to payers about their drugs be truthful and non-misleading.”

The new guidance states foremost that drugmakers are prohibited from disseminating “false or misleading” information regarding FDA-approved products. The FDA considers information to be false or misleading if it pertains to an indication not approved by the FDA. The FDA further clarified types of HCEI that fall under the scope of what is not considered to be false or misleading information, including information related to treatment duration, practice setting, burden of illness, dosing, patient subgroups, length of hospital stay, outcomes assessments, or validated surrogate endpoints. The FDA also stated that HCEI related to product persistence and comparisons of approved treatments against other treatments are also permissible.

The FDA further clarified information it does consider to be false or misleading, such as an economic analyses of disease course modifications for drugs that only treat the symptoms of a disease, and analyses outside the specifically-indicated patient population. As an example, the FDA stated that an analysis including information that broadly applies to all gene mutations of cystic fibrosis, for a drug

that is only approved for a specific cystic fibrosis gene mutation, would be considered false of misleading.

The FDA also noted that “this guidance does not apply to dissemination of HCEI to other audiences, such as health care providers who are making individual patient prescribing decisions.”

INVESTIGATIONAL PRODUCTS

The FDA also elaborated on how drugmakers should communicate with payers regarding investigational products that have not yet received FDA approval.

The guidance clarified that drugmakers should only share data related to product information, the intended indication sought, results from clinical trials (not to be interpreted or concluded on in regards to efficacy or safety), timelines for FDA approval, pricing information, marketing strategies, and patient support programs.

The FDA also stressed that drugmakers must provide a clear statement that the product is under investigation and that no safety or efficacy profile has been identified. Drugmakers must also clearly report what stage of development the investigational product is currently in.

The investigational drug guidance also recommends that drugmakers update payers if previously provided investigational drug information becomes outdated as a result of additional analyses—or if a product is determined to not be ready for approval or is denied approval.

PAYERS RESPOND

In response to the release of this new draft guidance, AMCP lauded FDA for clarifying how pharmaceutical companies and payers should communicate about FDA-approved and investigational products.

“We are very pleased with the FDA's long-awaited draft guidance that gives biopharmaceutical companies clarity on how they can proactively communicate important information with entities that make health care coverage decisions for millions of Americans,” Susan A Cantrell, RPh, CEO of AMCP, said in a press release. “Absent this guidance, existing laws had made it difficult for manufacturers to initiate sharing of any information beyond their FDA-approved labeling.”

According to Norm Smith, president of Viewpoint Consulting, Inc, and a *First Report Managed Care* Editorial Advisory Board member, payers have been expecting the release of this guidance for some time.

“This is long overdue, and a positive step by the FDA,” he said. “AMCP has done extensive work on the proper way to convey this information as part of the sales process for new products. It was an ‘unmet need’ in the marketplace.”

Mr Smith went on to explain that pharmaceutical legal departments have often labored over whether to approve HCEI data for inclusion in payer communications when the data was not part of the FDA-approved label. He noted that the new guidance should loosen up those limits and improve the flow of information between the drugmakers and the decision-makers.

According the Jeffery Dunn, PharmD, senior vice president and chief clinical officer of VRx Pharmacy Services, LLC, and *First Report Managed Care* Editorial Advisory Board member, the new guidance from the FDA will make payer decisions better informed and more substantive than they have been in the past.

“The announcement today will be welcomed by payers,” Dr Dunn said. “Payers spend a lot of time searching for data, meeting with Pharma companies’ medical personnel, performing their own modeling, etc. Historically, we have been able to request an AMCP dossier, which provides some access to economic data and off-label clinical information, but often our interactions have been

limited to labeled information due to legal, or other, interpretations. Having access to this type of data will make our comparisons for formulary discussion more robust.”

Mr Smith also stressed that HCEI is not intended for use among sales representatives.

“These data are not for use by field representatives in physician promotion, and perhaps not for use by account managers unless they are specially trained in presenting [HCEI] data,” he said “It would best be presented by those trained in health economics, and can be home-office based or field based. It is essential that the data presented is only to support approved uses for a product in populations that have been included in the study, not for any new indication.”

“This guidance goes a long way toward providing clarity,” Ms Cantrell said in the press release. “It also provides assurances around the proactive exchange of information on products prior to FDA approval. Having access to information on both marketed and pipeline products will help population health decision makers design benefits that ensure patients receive the most effective and appropriate medications possible.”

Further Guidance

The FDA also released guidance on how the industry should communicate regarding medical products that are consistent with the FDA-required labeling.

According to the FDA, the purpose of this guidance is to provide “information for firms about how FDA evaluates firms’ medical product communications, including promotional materials, that present information that is not contained in the FDA-required labeling for the product but that may be consistent with the FDA-required labeling.

The FDA outlined that it determines whether the content of communications about a product are consistent with the product’s labeling by considering the three factors.

The first factor relates to misinformation regarding a product’s indication, patient population, limitations and directions for use, and dosing. The second factor is related to whether or not the communication increases the potential for harm. For example, the FDA looks at whether or not a communication causes the likelihood of abuse or misuse of a product. Finally, the third factor looks at whether or not use of the product is communicated in a way that reflects the original FDA-approved conditions for use.

The FDA also reiterated that “if a communication alters the benefit-risk profile of a product in a way that may result in increased harm to health, this indicates that the communication is not consistent with the FDA-required labeling.”