



FDA NEWS

FDA RELEASES DRAFT GUIDANCE ON COMMUNICATION BETWEEN PHARMA, PAYERS



January 19, 2017

The FDA recently released draft guidance in order to clarify regulations related to the sharing of health care economic information (HCEI) between pharmaceutical manufactures and health care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 or 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."

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INVESTIGATIONAL PRODUCTS

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

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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.

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