Late Breaking News Update: June 2018

FDA Issues FINAL Guidance on, "Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities."

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On June 12, 2018 the FDA issued final guidance regarding manufacturer communication with payors, formulary committees and similar entities (Payor Guidance) which provides further context about the FDA's position on this topic. FDA published a draft version of this document in January 2017, which we previously summarized here.

In announcing the guidance, FDA Commissioner Scott Gottlieb emphasized "the importance of linking payments for drugs to their value" and "removing regulatory obstacles to value-based purchasing by payors." To achieve these goals, Commissioner Gottlieb acknowledged the need for FDA to provide "clear guidance to pharmaceutical companies about open, responsible communication with payors, formulary committees and others." Commissioner Gottlieb also remarked that FDA believes the guidance document "will provide clarity to companies as they develop communications about their medical products and help ensure that patients, providers and insurers have access to a range of relevant, truthful and non-misleading information from companies about medical products." The term "medical products" refers to both drugs and devices.

There are several major changes from the draft guidance that are summarized below:

- The final HCEI guidance is now clearly defined to include both drug **and device** manufacturers, instead of drug manufacturers only.

- The HCEI definition is expanded and further clarified by adding the statement that "HCEI pertains to the **economic consequences (including, but not limited to, monetary costs or resource utilization)** related to the clinical outcomes of treating a disease (or specific aspect of a disease) or of preventing or diagnosing a disease."

- The final guidance now includes **preapproval communication of unapproved uses of approved medical products**, in addition to investigational products not yet approved.

- The Payor Guidance restates its view that it does not apply to individual health care professionals (HCPs) who are making individual patient prescribing decisions. However, the final edition clarifies that if an HCP has multiple roles (HCP and formulary committee member) the provision of HCEI to that HCP when the HCP is acting in his or her capacity as a formulary committee member **would be** within the scope of the guidelines.

- **Compliance/Adherence** is now listed as an example in of HCEI analyses that relate to an approved indication and states that "HCEI analyses may be derived from studies assessing patient compliance/adherence with a drug for its approved indication."

- When HCEI has **material differences** from FDA labeling (e.g., new or increased risks, different dosing/use regimens, different endpoints, more limited/target patient populations, etc.,) the HCEI must present a conspicuous and prominent statement describing such differences.

The Payor Guidance also provides several new examples of appropriate or inappropriate HCEI communications.

The FDA kept its position from the draft guidance that "communication of HCEI about drugs under [section 502(a)] is promotional labeling," and thus subject to FDA postmarketing reporting requirements that apply to all promotional labeling—including submission to OPDP on FDA Form 2253 at the time of initial dissemination or initial publication.

Significant Statements

Safe Harbor for Approved Product Communications:

"If a firm disseminates to an appropriate audience HCEI that is the type of information within the scope of section 502(a) (i.e., HCEI that relates to an approved indication and is based on competent and reliable scientific evidence (CARSE), as each of these elements is described in this guidance), FDA does not intend to consider such information false or misleading. HCEI should clearly and prominently present the information discussed in Q.A.7/A.A.7 and Q.A.8/A.A.8 of this section, including study design and methodology, generalizability, limitations, sensitivity analyses, and information relevant to providing a balanced and complete presentation. If HCEI includes material differences from the FDA- approved labeling (e.g., new or increased risks, different dosing/use regimens, different endpoints, more-limited/targeted patient populations), it must present "a conspicuous and prominent statement describing any material differences between the health care economic information and the labeling approved for the drug,"22 as discussed in Q.A.7/A.A.7.

In addition, FDA does not intend to use HCEI that is disseminated consistent with this guidance as evidence of a new intended use."[1]

Safe Harbor for Pre-Approval Communications:

"When the following types of information about unapproved products (as defined in this guidance) or unapproved uses of approved/cleared/licensed products provided by firms to payors are unbiased, factual, accurate, and non-misleading, and are presented with information discussed in Q.C.2/A.C.2, FDA does not intend to object under 21 CFR 312.7(a) or 21 CFR 812.7(a) to such communications, nor to use such communications as evidence of a new intended use. FDA also does not intend to enforce any applicable postmarketing submission requirements for these materials."[2]

SUMMARY

The release of the FDA's final guidance reinforces the need for Manufacturers to update their current policies as well as their internal HCEI/Payor Strategy and ensure education on the final guidance to relevant stakeholders (Legal/Compliance, Medical Affairs, Access, Outcomes Research).

Due to the risks involved in communication with customers (not understanding the different rules of engagement between HCEI & Clinical etc.) and communication risks among the account team, Manufacturers should provide enhanced training on potential field medical and account team risks and how to deliver effective and compliant HCEI to customers. Per usual, DMH can easily help with any of your training needs.

About DMH BioPharm Advisors, LLC

DMH BioPharm Advisors is a boutique compliance-training firm with proven proficiency in creating and delivering highly effective and personally impactful compliance training curriculums and learning strategies for commercial, medical, and access employees in the biopharmaceutical and device industries. mholloway@dmhbiopharm.com | 908-246-5797 | http://www.dmhbiopharm.com | LinkedIn

Foot Notes:

[1]Federal Register (June 13, 2018) "Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities – Questions and Answers; Guidance for Industry and Review Staff."
(Page 6 Q.A. 3/A.A.3) https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm537347.pdf

[2]Ibid. (Page 18 Q.C.1/A.C.1)