BACKGROUND

In December 2015, the PDUFA VI Agreement was signed into law along with Section 114 of the Food and Drug Administration Amendments Act (FDAAA). This section, commonly referred to as the “Ennismore Amendments,” set the stage for several anticipated changes in an effort to alleviate barriers to practitioner decision making of prescription drugs. Among the changes included increased access to post-approval healthcare economic information (HCEI).

In January 2017, the FDA issued a draft guidance titled, "Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities – Questions and Answers," to prepare industry for Industry and Review Staff (IRS). In addition to providing further information about post-approval HCEI, the FDA also defined its stance on proactive communications. The draft and final guidances permitted PIE in some cases for non-therapeutic purposes. However, the FDA also stated that the pie is a separate issue to be considered on a product-by-product basis. This is the basic rationale for the legislation, as PIE and HCEI are in different categories.

Together, the 21st Century Cures Act (Section 3037) and the FDA Draft guidance provide greater clarity regarding whether manufacturer communications of post-approval HCEI and proactively generated information are allowed. However, the extent of these efforts remains unclear.

OBJECTIVE

To understand how recent legislation and guidance has affected payers’ experiences and perceptions of post-approval HCEI communication and PIE.

METHODS

Payers were recruited through Xcenda’s market research panel and completed an online survey between December 2017 and 15/18. The 28-item survey inquired about the importance, impact, communication, and changes in frequency and quality of HCEI and PIE received by payers in the past year.

RESULTS

• Payers (N=44) largely represented managed care organizations (81%); pharmacy benefit managers (PBMs) (27%); and health plans (27%). Each respondent had access to payers’ databases, and their targets were payers with more than 10,000 lives (81%); those with 5,000–10,000 lives (22%); and those with fewer than 5,000 lives (7%).

• Nearly two-thirds (64%) of respondents perceived a gap between needed and available post-approval HCEI. Among those respondents, approximately half (41%) indicated that addressing this gap would be "very much" or "extremely" improved the frequency of proactive communication of post-approval HCEI by manufacturers, while 30% rated it "not very" or "not at all" important.

• Among those respondents who addressed the gap, 84% thought it would improve your formulary decision-making ability.

• Over half (55%) of respondents reported that post-approval HCEI was important, while 30% rated it "not very" or "not at all" important.

• Prior to January 2017, the majority of respondents (84% "usually" or "regularly") reported receiving HCEI from manufacturers while 16% reported not receiving any at all.

• Over half (59%) of survey respondents ranked important factors in communicating with manufacturers, such as importance, impact, communication, and changes in frequency and quality of HCEI and PIE received by payers in the past year.

• When respondents were asked to rate their experiences and perceptions of post-approval HCEI communication and PIE since January 2017, 82% indicated they were satisfied with the change and quality of information or the change in frequency of PIE and HCEI.

• Close to half of respondents (45%) perceived a gap between the needed and available HCEI. Among these respondents, nearly one-third (30%) indicated that addressing this gap would be "very much" or "extremely" important for improving decision-making ability, while 65% noted that it would be "satisfactory" improve decision-making (data not shown).

CONCLUSIONS

• The results suggest that PIE and HCEI are important to payer decision making.

• The results also suggest that payer decision makers may be helpful for improving formulary decision making and ultimately, treatment decisions for patients in need of therapy.

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• Further research is needed to explore the influence of the published information on the decision-making process of the payer.

LIMITATIONS

• Overall, the study has several limitations, including the sample size and the response rate. The sample size may not be representative of the entire population of payers.

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