Pre-Approval Information Exchange (PIE) In The US: Sharing The PIE

Introduction

PIE is information that manufacturers can share with healthcare decision makers (e.g., payers) prior to the FDA approval of a new product or a new indication. In 2018, 63% of manufacturers noted an increase in PIE communications between 2017 and 20181,2. In 2020, the increase in PIE communications was noted by 68% of manufacturers. According to online surveys (N=41 for 2018; N=57 for 2020), the increase in PIE communication on the manufacturer side is potentially because the percentage of manufacturers with either guidance related to PIE or a system in place to approve PIE materials increased from 37%-68% between 2018 and 2020.3,4

Methods

A targeted literature review was conducted in PubMed, Embase, and Cochrane using keywords related to the use of PIE (e.g., pre-approval, information, exchange) in the US. The search was limited to English- and Spanish-language publications from the release of the FDA Guidance on PIE in January 2017 to the passage of the PIE Act in December 2022. In addition, the ISPOR Presentations Database and the abstracts from the AMCP Annual Meeting and AMCP Nexus Conference were searched using similar strategies. Narrative review articles and editorials were excluded.

Abstracts were examined to determine which ones contained, or were likely to contain, information on PIE. Any abstracts that did not contain or were unlikely to contain information related to PIE were excluded. For abstracts that were likely to contain information on PIE, the full-text articles or posters were obtained and examined, and if they did not contain information on PIE, they were excluded.

Results

The proportion of healthcare decision makers who either requested or received PIE Increased between 2017 and 2019

Healthcare decision makers have reported an increase in PIE communications over time.5,6 In 2018, an online survey (N=44) found that an increase in PIE communication from 2017–2018 was noted by 39% of healthcare decision makers. First, an online survey (N=41 for 2018; N=57 for 2020), the increase in PIE communications.9 According to online surveys (N=41 for 2018; N=57 for 2020), the increase in PIE communication on the manufacturer side is potentially because the percentage of manufacturers with either guidance related to PIE or a system in place to approve PIE materials increased from 37%-68% between 2018 and 2020.3,4

Similarly, 63% of manufacturers also noted an increase in PIE communications between 2017 and 20181,2. In 2020, the percentage increased further, and 68% of manufacturers noted an increase in PIE communications.6,8 According to online surveys, the increase in communication on the manufacturer side is potentially because the percentage of manufacturers with either guidance related to PIE or a system in place to approve PIE materials increased from 37%-68% between 2018 and 2020.3,4

Gaps and barriers that limit PIE dissemination still exist

Healthcare decision makers have reported that information about a product’s anticipated place in therapy, pricing, clinical trial results, potential indication, and anticipated timeline for FDA approval are some of the most important types of PIE that they can receive from manufacturers (Table 1).1,5,6,10,12 In contrast, no information about which types of PIE were most important to manufacturers was identified.

Most of the published information about PIE has been shared only during conferences

Among 21 sources identified for inclusion, 18 (86%) were conference proceedings and 3 (14%) were manuscripts. Overall, 67% (14 of 21) of the conference abstracts contained authors from consultancies, 10% (2 of 21) involved authors from manufacturers, 14% (3 of 21) involved authors from both, and 10% (2 of 21) involved authors from neither. Most of the studies reported on conference proceedings for healthcare decision makers (81%; 17 of 21); fewer reported outcomes for manufacturers (10%, 2 of 21) or for both healthcare decision makers and manufacturers (10%, 2 of 21). These findings are summarized in Figure 1.1-12

Figure 1. Sources identified for inclusion, publication type, authorship, and population examined.a,b

References


Conclusions

US healthcare decision makers and manufacturers have engaged in PIE discussions more frequently during the past few years. Because most of the information has been shared only during conferences, this has perhaps limited the ability of interested parties to gain knowledge on PIE. Future studies that include non-conference-based and/or examination of outcomes of PIE discussions during conferences may have the potential to examine the importance of different perspectives on PIE.

Limitations

Some of the conference posters and oral presentations could not be obtained.

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Table 1. Types of PIE that are either very important or extremely important to healthcare decision makers

<table>
<thead>
<tr>
<th>Type of PIE</th>
<th>Web-based survey</th>
<th>Online survey</th>
<th>Online survey (N=44)</th>
<th>Online survey (N=57)</th>
<th>Web-based survey (N=41)</th>
<th>Web-based survey (N=57)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Place of the product in therapy</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Pricing information</td>
<td>88%</td>
<td>86%</td>
<td>86%</td>
<td>86%</td>
<td>86%</td>
<td>86%</td>
</tr>
<tr>
<td>Proposed indication</td>
<td>82%</td>
<td>82%</td>
<td>82%</td>
<td>82%</td>
<td>82%</td>
<td>82%</td>
</tr>
<tr>
<td>Clinical trial results</td>
<td>53%-82%</td>
<td>84%</td>
<td>80%</td>
<td>82%</td>
<td>80%</td>
<td>82%</td>
</tr>
<tr>
<td>Anticipated timeline for FDA approval</td>
<td>82%</td>
<td>80%</td>
<td>80%</td>
<td>80%</td>
<td>80%</td>
<td>80%</td>
</tr>
</tbody>
</table>

Authors from Consultancies, Authors from Manufacturers, Authors from Both, Authors from Neither

aIn this study, healthcare decision makers ranked which type of PIE was most important.

bFor the study, healthcare decision makers ranked which type of PIE was most important. PIE = pre-approval information exchange.