Evaluation of Pharmaceutical Companies’ Current Practices Surrounding Dossier Development

Background

In recent years, there has been increasing emphasis on determining the total value of a drug product. This includes an evaluation of both safety and efficacy information, as well as clinical and economic value relative to other therapies. The ANCP Formularies recommended that the submission layout include the following information: on the drug’s place in therapy, related disease management strategies, unpublished studies, data on all-labeled indications and an economic model to estimate the product’s value. A prevalent concern among pharmaceutical companies is the organizational and financial burden necessary to meet expectations of managed care organizations. This study assesses the organizational burden, inclusion of economic models as well as the overall value of dossiers, with an aim to benchmark current practices surrounding dossier development.

Objective

To assess aspects of dossier development between pharmaceutical companies, specifically organizational burden, economic models, and perception of overall value.

Methodology

Design

A thirty question web based survey was distributed electronically via Zoomerang to twenty six different pharmaceutical companies. Of the 26 companies, ½ were partners of the Rutgers University Fellowship program (including several of the top ten global companies) and the latter half were identified as key medical information contacts at other major pharmaceutical companies. Contacts were invited to either participate in a web based survey to evaluate dossier development or forward the survey to an individual who makes decisions regarding dossier creation. Participants were allotted two weeks to complete the survey. The survey was structured to assess the differences in dossier development with a focus on economic modeling, company burden and overall value. A third of the survey questions were structured to gauge the opinion of pharmaceutical companies regarding economic model inclusion, and the remaining two thirds were tailored to assess differing views related to dossier value and company burden. The majority of the questions were multiple choice; however, due to the nature and context of the questions, eleven were either left open ended or provided room for additional comments. All responses were kept anonymous.

Evaluation of Survey Respondents

- Half of key contacts responded to complete the survey (15/26).
- One hundred percent (96%) of survey respondents participated in dossier development at their respective companies.
- 7% (10/13) of respondents were from Medical Information.
- Remaining 23% (313) were from health economics.
- 65% of survey respondents’ primary role in dossier development was the preparation of clinical information for submission.

Results

Organizational Burden

- Days required to submit medical information: 35% (10/13) of respondents reported an average of 10-20 days to submit medical information.
- Days required to submit economics: 15% (10/13) of respondents reported an average of 10-20 days to submit economics.

Number of Annual Dossier Submissions

- 31% reported only 100+ annual submissions for a single product.
- 61% collaborated between medical information and health economics to develop the dossier.

Time Required to Prepare Dossier

- 31% reported 60%+ annual submissions for a single product.
- 16% of respondents reported that 25-50% of their headcount is necessary to prepare and submit a dossier.
- 15% of respondents felt it was necessary to increase headcount specifically for preparation of a dossier.

Overall Value

- 70% reported the dossier as a very useful tool to demonstrate the value of a product to managed care organizations.
- 30% reported the dossier as a useful tool to demonstrate the value of a product to managed care organizations.

Economic Modeling

- Percentage of respondents that included an economic model in their dossier: 85%
- Perception of economic modeling in dossier development: 85%

Discussion

Organizational Burden

- Majority of respondents (96%) reported that the dossier is solely medical information, 61% collaborated between medical information and health economics.
- 35% reported 100+ annual submissions for a single product.
- Days required to submit medical information: 35% (10/13) of respondents reported an average of 10-20 days to submit medical information.
- Days required to submit economics: 15% (10/13) of respondents reported an average of 10-20 days to submit economics.

Limitations

- Small sample size (96%) renders it difficult to generalize findings.
- Survey relied on respondents’ recall (retrospective).
- Limited clinical experience.
- Survey respondents were pharmaceutical organizations.
- Survey respondents were from pharmaceutical companies of various sizes. Organization size may influence company views on dossiers.

Conclusions

- Medical Information plays an integral role in the development of dossiers, especially with respect to providing safety and efficacy data. This has been stated in a recent article as being the primary focus of managed care organizations in the formulation decision-making process. In contrast, pharmaceutical companies perceive pricing to be the driving force of formulation decisions, thus illustrating a disconnect between pharmaceutical companies and managed care organizations.
- Additionally, these findings underscore the need for increased communication between vendors and pharmaceutical companies to ensure similar expectations of outcomes for the final dossier product; this reportedly may increase the superficial resource spent on dossier revisions.
- Overall, findings from this survey assess perceptions regarding the dossier and provide insight on potential process improvements.

References