Evaluation of Pharmaceutical Companies' Current Practices Surrounding Dossier Development

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Background

In recent years, there has been increasing emphasis on determining the total value of a drug products. This includes an evaluation of both safety and efficacy information, as well as clinical and economic value relative to other therapies. The AMCP Format approach was adopted to help streamline formulary decision making. The AMCP guidelines recommend that the submission layout include the following: information on the drug's place in therapy, related disease management strategies, unpublished studies, data on off-label indications and an economic model to estimate the product's value.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.

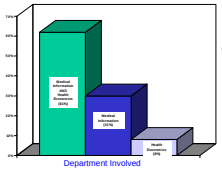
Evaluation of Survey Respondents

- Half of key contacts notified completed the survey (13/26).
- One hundred percent (N=13) of survey respondents participated in dossier development at their respective companies.
  - 77% (10/13) of respondents were from Medical Information.
  - Remaining 23% (3/13) were from health economics.
  - 85% of survey respondents' primary role in dossier development was the preparation of clinical information for submission.

Results

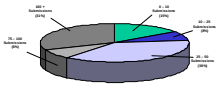
Organizational Burden

Departments Responsible for Creating and Maintaining the Dossier



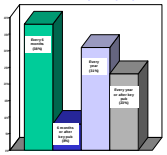
- 31% reported dossier is solely medical information responsibility, 61% collaboration between medical information and health economics

Number of Annual Dossier Submissions Varied Among Companies



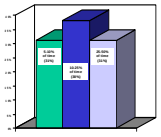
- 31% reported 100+ annual submissions for a single product

Dossiers are Frequently Updated



- 46% reported dossiers are updated at least every 6 months; 31% annually

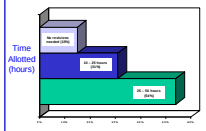
Time Allocated to Dossier Preparation



- One third of respondents reported that 25-50% of their time is allocated to the preparation and submission of dossiers.
- 15% of respondents felt it was necessary to increase head count specifically for preparation of a dossier

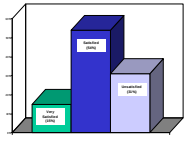
All participants reported utilizing consultants as well as in house resources for dossier development

Additional Time Allocated to Revise Outsourced Dossiers



- Nearly all (81%) of dossiers that were outsourced required revision
- 54% claimed 25-50% of dossier content required revisions, requiring an additional 25-50 hours

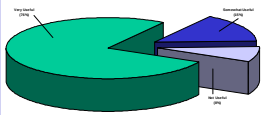
Satisfaction as Reported by Respondents



- 31% reported outsourced product as unsatisfactory

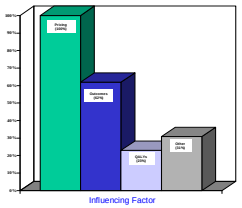
Overall Value

Perception of Dossier Value



- 76% reported the dossier as a very useful to demonstrate the value of a product to managed care organizations

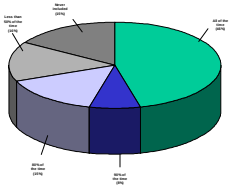
Perceived Factors that Influence Formulary Decisions



- Dossiers for company products
  - 54% had dossiers for all their company products
  - 46% had dossiers for 75% of their products
- 62% respondents reported providing presentations along with the dossier to managed care organizations 10-40% of the time
  - Presentations were given predominately by medical science liaisons (MSLs) and account managers

Economic Modeling

Inclusion of Economic Models



- Less than half of respondents 46% reported including an economic model in all of their company dossiers
- 85% reported using ISPOR guidelines in the development of economic models

Inclusion of Cost Utility Models

Inclusion of Cost Effectiveness Models

Inclusion of Budget Impact Models

- 92% included budget impact models
- 92% reported inclusion of budget impact models that were clearly presented, transparent and modifiable

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Discussion

Organizational Burden

- Majority of respondents (92%) reported that the Medical Information department has a responsibility to maintain and create dossiers with the primary role of preparing the clinical information content.
- All respondents relied on both in house and outsourced resources for dossier development. Nearly all outsourced dossiers required revision; over half of the respondents (54%) claimed that 25-50% of the outsourced dossier needed revisions requiring an additional 25-50hrs of in-house Medical Information hours.

Economic Models

- A recent article reported that only 29% of dossiers included unlocked transparent economic models.[3] Contrary to these findings, respondents from our survey perceived 92% of economic models included in dossiers to be clearly presented, transparent and modifiable.
- Majority of respondents (85%) reported including an economic models in dossiers, of which nearly half (46%) reported model inclusion in all (100%) of their dossiers.

Overall Value

- Dossiers were considered very useful in demonstrating the value of a product to a managed care organization by the majority of companies; respondents consistently reported that 75 - 100% of all company products had dossiers.
- Despite clinical efficacy and safety being the primary focus of managed care organizations, pharmaceutical companies, as reported in our survey, still believe that the driving force for formulary decisions is pricing.[2]

Limitations

- Small sample size (N=13) renders it difficult to generalize findings.
- Survey relied on respondents' recall (retrospective).
- Managed care organizations were not surveyed; therefore, we were unable to determine if pharmaceutical companies' perceptions are aligned with managed care organizations expectations.
- 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 formulary decision-making process.[2] In contrast, pharmaceutical companies perceive pricing to be the driving force of formulary 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 may potentially decrease the superfluous resources spent on dossier revisions.
- Overall, findings from this survey assess perceptions regarding the dossier and provide insight on potential process improvements.
- Discussions of the study results initiated the following topics which may warrant further investigation: headcount in Medical Information necessary for dossier development, preparation of different dossier versions created for a single product, and routes and methods of dossier requests from managed care organizations.

References

1. Academy of Managed Care Pharmacy. A format for submission of clinical and economic data in support of formulary consideration by health care systems in the United States. The AMCP Format for Formulary Submissions, Version 2.1. April 2005. Available at: http://www.amcp.org/data/AMCPFormat2_1.pdf. Accessed November 20, 2007.
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3. Spooner JJ, Gandhi PK, Connelly SB. AMCP Format dossier Requests: Manufacturer Response and Formulary Implications for One Large Health Plan. *J Manage Care Pharm*. 2007; 13(1): 37-43.