

Benchmarking the Dossier Preparation Process

Jessie Li, Pharm.D., Emalie J. Burks, Pharm.D., BCPP, Seema Patel, Pharm.D., Alexander P. Danyluk, Pharm.D.
Medical Communications, Ortho-McNeil Janssen Scientific Affairs, LLC, Raritan, New Jersey

REVISED ABSTRACT

The process of creating and updating dossiers is a resource-consuming responsibility of pharmaceutical companies. An electronic survey was developed to gather benchmarking data on the dossier preparation process at pharmaceutical companies in the United States. Aspects of the dossier preparation process targeted for research include the reasons for dossier creation and the process of dossier development. Ten out of the 25 companies responded to the survey. Survey results suggested that responding to the needs of health care decision makers is the most influential driver for dossier creation. Most of the companies surveyed do not create and maintain multiple dossier formats for each product; dossiers are developed following the AMCP format. For the majority of the companies, the dossier development process is coordinated by the medical information department with input from other scientific groups. While some companies work with vendors to create the original dossier, most companies use internal resources for dossier updates.

BACKGROUND

An increasingly important responsibility of medical information departments within the pharmaceutical industry is responding to requests for product dossiers from health care decision makers. In recent years, pharmaceutical companies have had to create dossiers in various formats, such as the AMCP (Academy of Managed Care Pharmacy)¹ or the DERP (Drug Effectiveness Review Project)² format, in order to meet the needs of health care decision makers. Creating and maintaining dossiers are resource-intensive processes. The goal of this research project is to collect benchmarking data from pharmaceutical companies and to identify best practices in dossier development.

OBJECTIVES

- To identify the reason(s) for dossier creation.
- To research the process of dossier development and maintenance with a focus on dossier formats and the use of internal and external resources.
- To identify methods of dossier delivery as well as other forms of product information sent to health care decision makers in response to dossier requests.

METHODS

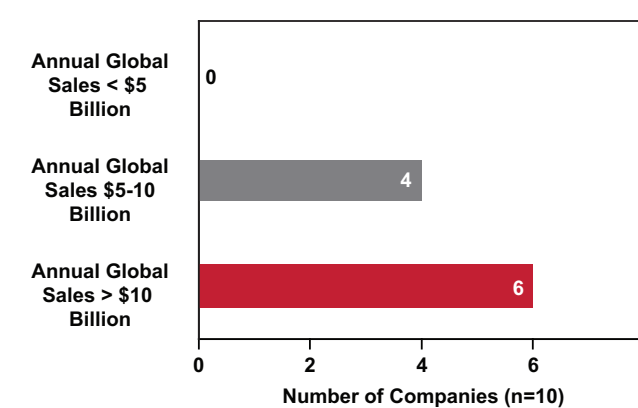
- From December 2007 to January 2008, a 14-question electronic survey was sent to the medical information departments of 25 U.S. companies with branded products.
- Recipients of the surveys were instructed to distribute surveys to the person currently involved in the decision making process for dossier creations and updates within the company.
- The first 4 questions were intended to identify the size of the companies, whether or not they prepare dossiers, and their reasons for dossier development.
- Eight questions of the survey were designed to probe the companies' processes for dossier development, such as the format(s) of dossiers the companies choose to use, the departments participating in dossier preparation, the use of internal vs. external resources for dossier writing and updates, the timing of dossier preparation relative to product launch, and the frequency of updates.
- Two questions were intended to identify the route of delivery of dossiers (paper or electronic) as well as other forms of product information sent to health care decision makers.

RESULTS

- Ten out of 25 companies responded to the survey. The relative size of the companies in annual global sales is illustrated in **Figure 1**.
- The companies' practice of dossier development for marketed products is summarized in **Figure 2**. Eight companies develop dossiers for marketed products; and of these 8 companies, 2 companies develop dossiers as standard procedure for all marketed products, while 6 companies develop dossiers for some but not all products.

RESULTS (CONTINUED)

Figure 1 – Relative Size of Companies



- For the 6 companies in which dossiers are prepared for some but not all marketed products, respondents were asked to rate the importance of various factors in influencing their decisions for dossier creations (see **Figure 3.1 – 3.6**).

Figure 3.1 – Mandated for Consideration on Formulary

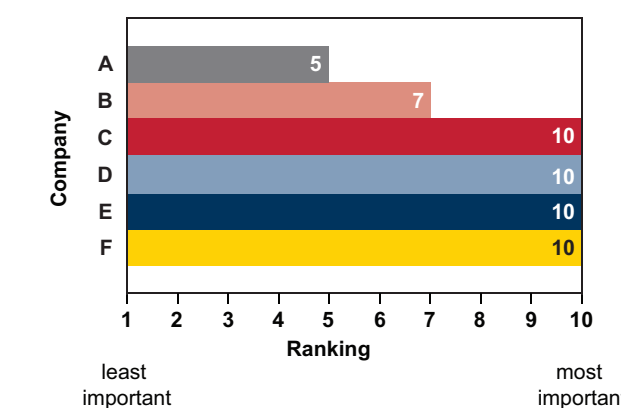


Figure 3.3 – Requests from Health Care Decision Makers

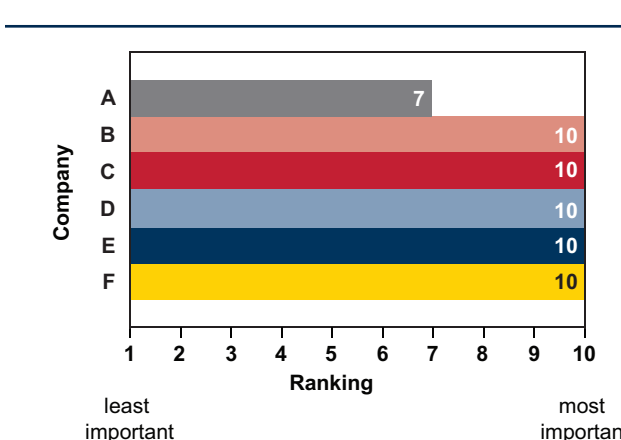
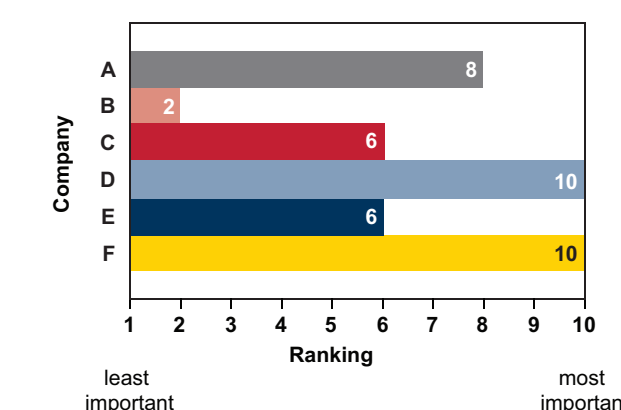


Figure 3.5 – Budget or Resources



*The relative size of companies A, B, D, E, and F: global annual sales >\$10 billion

Figure 2 – Dossier Development for Marketed Products (n = 10)

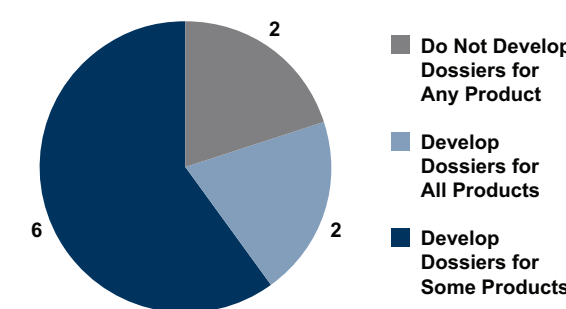


Figure 3.2 – Need for Differentiation from Competitors

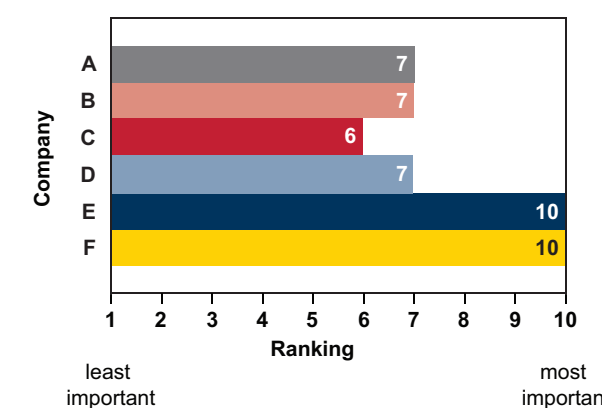


Figure 3.4 – Need for Introducing Drugs with New Mechanism of Action or Indication

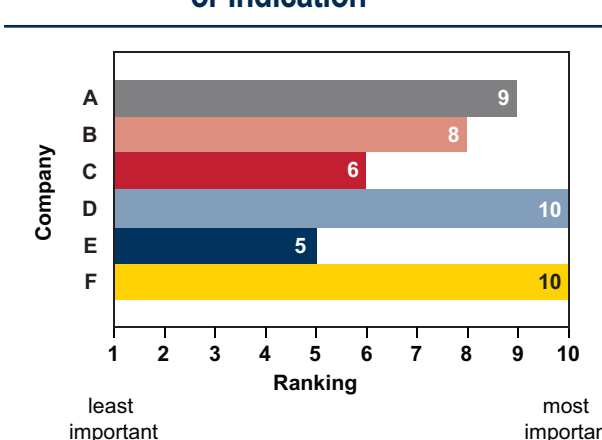
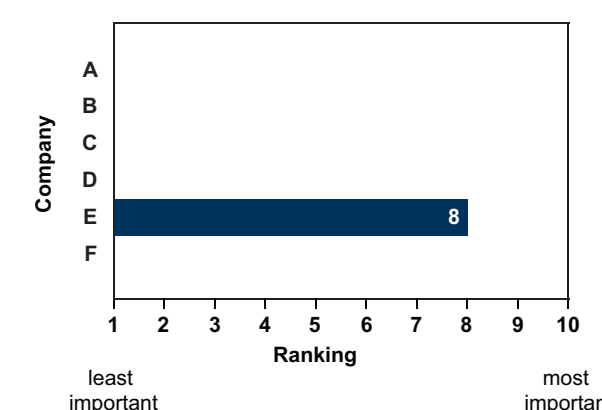


Figure 3.6 – Other



*Only one company provided a response (specified as brand team input) for other factors

- Five out of 8 companies indicated that the dossier preparation process begins prior to product launch, and the remaining 3 companies responded that the timing varies for different products.
- The departments participating in the dossier preparation process for 8 companies are summarized in **Table 1**.

Table 1 – Departments Participating in Dossier Preparation

Company	Department Coordinating Overall Dossier Development Process	Collaborating Departments
A	Varies (Medical Information or Outcome Research)	Medical Director
B	Publications Group	Medical Information, Outcomes Research, Managed Markets
C	Medical Information	Medical Writing, Outcomes Research
D	Medical Information	Medical Director, Outcomes Research
E	Medical Information	Outcomes Research
F	Outcomes Research	Medical Information, Medical, Marketing
G	Medical Information	N/A
H	Medical Information	Medical Affairs, Outcomes Research, Marketing

Abbreviation: N/A, No Answer Provided

- Five out of 8 companies indicated that only one dossier is developed following the AMCP format. For the 3 remaining companies, the following materials are provided in addition to an AMCP formatted dossier:
 - Company C - Product Monograph
 - Company D - DERP, Medicaid Version
 - Company G - DERP

- The types of resources used for dossier development and updates are summarized in **Table 2**.
- The approximate time for dossier development and frequency of dossier updates for 8 companies are summarized in **Table 3**.

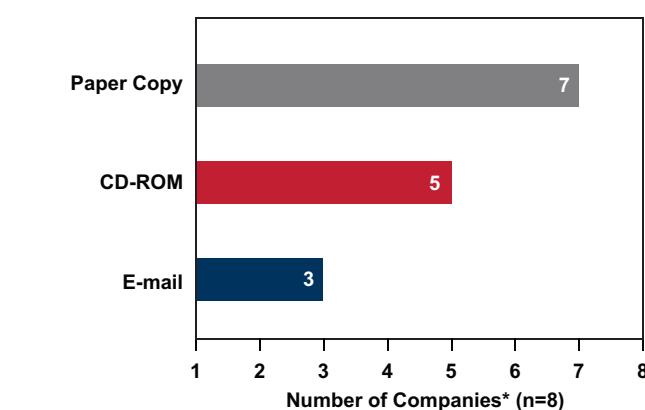
Table 2 – Use of Internal Resources vs. Outsourcing for Dossier Creation and Updates

Company	Resources Used for Original Dossier writing	Resources Used for Dossier Updates
A	I	I
B	P	I
C*	I	I
D	O	O
E*	I	I
F	O	I
G	O	I
H	O	I

Abbreviations: I, Completed Internally; O, Outsourced; P, Partially Outsourced
*These companies do not generally outsource service to persons outside of the company

- The methods through which dossiers are delivered to health care decision makers are summarized in **Figure 4**.
- Companies were also asked to describe the types of materials they provide to health care decision makers if no dossier is available (see **Figure 5**).

Figure 4 – How Dossiers Are Supplied to Health Care Decision Makers



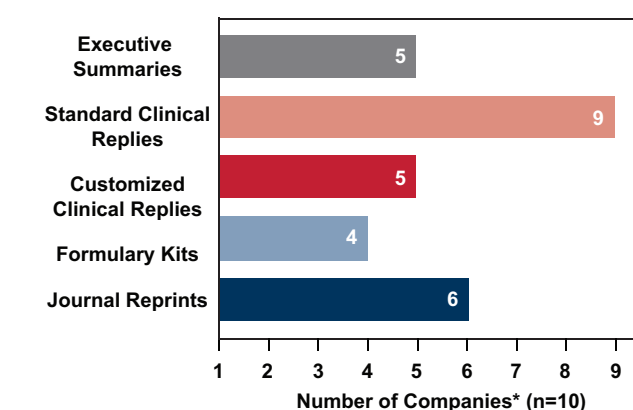
* One company may select multiple answers
Note: None of the respondents chose website as an answer

Table 3 – Dossier Preparation Time and Frequency of Updates

Company	Approximate Time for Dossier Development	Frequency of Updates
A	4 – 6 months	Periodically
B	4 – 6 months	PRN
C	0 – 3 months	Every 12 – 18 months
D	> 12 months	PRN
E	0 – 3 months	PRN
F	4 – 6 months	Every 6 months
G	7 – 12 months	Every 12 months
H	0 – 3 months	PRN

Abbreviation: PRN, As needed per label change or new data

Figure 5 – Materials Provided When No Dossiers Available



* One company may select multiple answers

DISCUSSION

- The majority of the companies surveyed (8 out of 10) indicated that they do develop dossiers for marketed products. Although factors such as budget and resources, the need for introducing drugs with new mechanism of action or indication, and the need for differentiation from competitors appear to have an impact on the ultimate decision for dossier creation, companies consistently ranked the following 2 factors with the highest level of importance: requests from health care decision makers and mandated for consideration on formulary. These responses reflect the commitment of the pharmaceutical industry to the needs of healthcare decision makers.
- Survey responses indicate that dossier preparation is often coordinated by medical information departments, with input from outcomes research and an additional medical group. Most companies create and maintain one dossier for each product following the AMCP format, but a few companies also create additional documents/ formats, such as specialty monographs, DERP formats, and Medicaid versions.
- For the majority of the companies, dossier preparation begins prior to product launch. Approximately half of the respondents indicated that the original dossier writing of dossiers is outsourced, and the remaining companies create dossiers using internal resources. Dossier updates, however, are completed internally in 7 out of 8 companies. Most companies are able to develop dossiers from start to finish within 6 months; out of 8 respondents, 3 companies were able to finish the dossier in 0 to 3 months and 3 companies in 4 to 6 months. There is no indication that developing the dossier internally or externally has an effect on the length of preparation time. Approximately half of the companies indicated that the dossiers are updated as need for label changes or new data, while others update dossiers periodically (frequency varies from every 6 to 18 months).
- Survey results suggest that the most common forms of dossier delivery offered by pharmaceutical companies remain to be paper copies and CD-ROMs; only a few companies provide for electronic means of obtaining the dossier. Standard clinical replies seem to be the most common form of product information distributed to health care decision makers when dossiers are not available. Companies also provide journal reprints, customized replies, executive summaries, and formulary kits in response to dossier requests.

CONCLUSIONS

- Many companies remain committed to the responsibility of creating and updating dossiers to meet the demands of health care decision makers.
- Most companies delegate the responsibility of coordinating the dossier preparation process to the medical information department; other internal collaborating departments include outcomes research and various medical groups. The AMCP format remains to be the standard for dossier development. Some companies prefer to outsource the original dossier writing to vendors, but dossier updates are almost always completed internally. Most companies begin the dossier development process prior to product launch, but the approximate time for dossier development and the frequency of dossier updates vary slightly from company to company.
- The most common method of dossier delivery remains to be paper copies. Standard clinical replies are the most common form of product information sent to health care decision makers when no updated dossier is available.

REFERENCES

- The AMCP Format for Formulary Submissions, Version 2.1, April 2005. Available at http://www.fmcenet.org/data/resource/Format-Version_2_1-Final_Final.pdf. Accessed February 11, 2008.
- The Drug Effectiveness Review Project Dossier Submission Protocol: A Format for Submission of a Dossier of Clinical Evidence for Systematic Evidence-Based Reviews of Drug Classes. The Center for Evidence-Based Policy, Oregon Health & Science University, Version 2.0, July 2007. A available at <http://www.ohsu.edu/drugeffectiveness/pharma/FINAL%20Submission%20Protocol%20Version%202.0.pdf>. Accessed February 26, 2008.

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ORTHO-McNEIL JANSEN
SCIENTIFIC AFFAIRS, LLC

RUTGERS
Ernest Mario School
of Pharmacy

RESULTS (CONTINUED)

Figure 1 – Relative Size of Companies

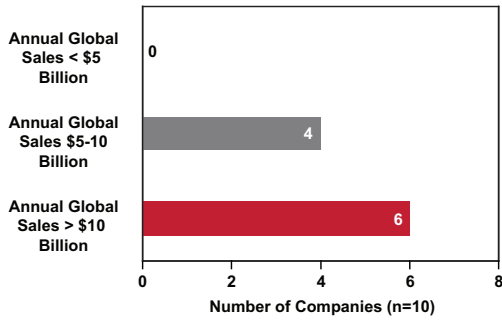
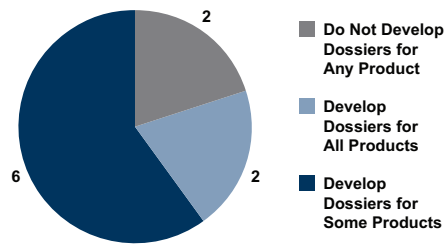


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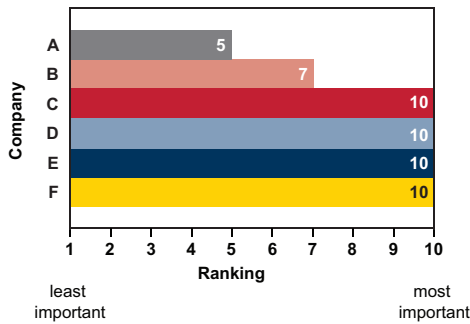


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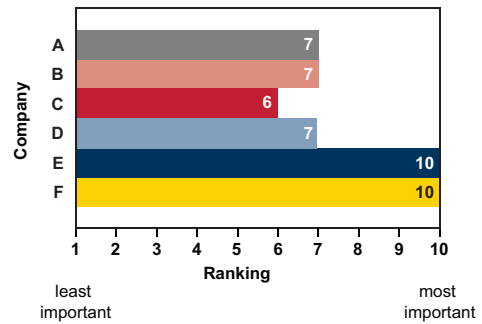


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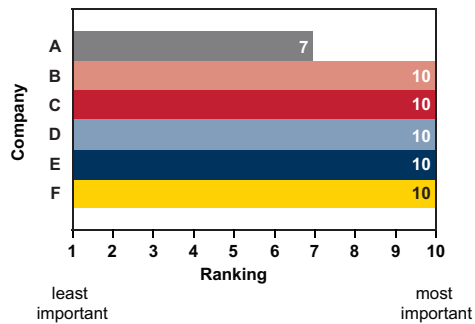


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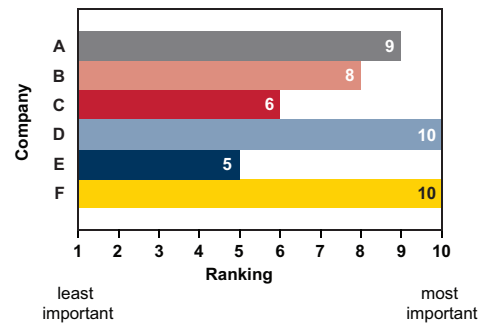


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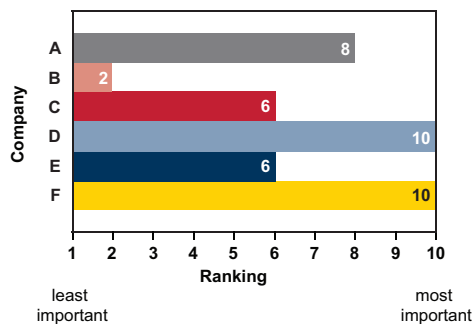
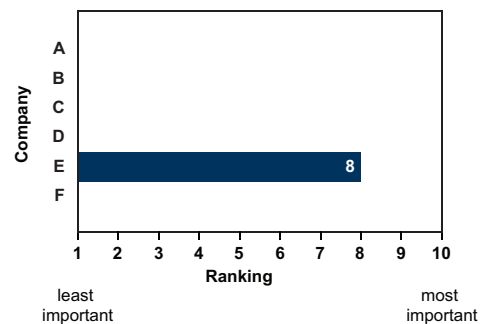


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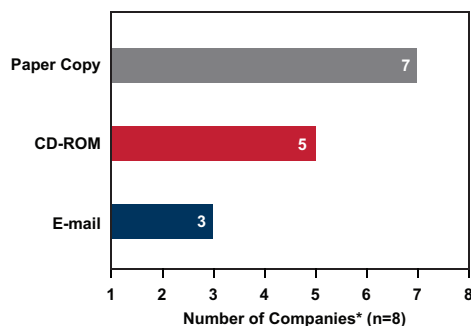
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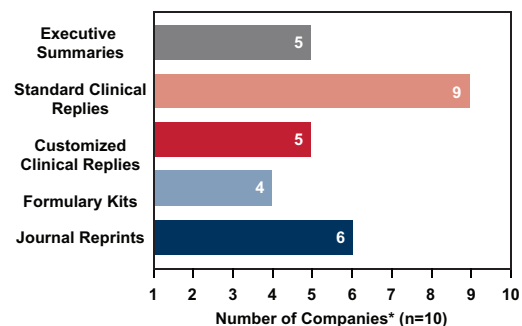
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