Conformance of AMCP Dossiers to Recommended Page Limits and Strategies Used to Streamline Presented Information

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Background and Objective

- The Academy of Managed Care Pharmacy (AMCP) advises manufacturers to provide a clear and concise review of relevant evidence and product information in dossiers to facilitate review by healthcare decision makers.[1]
- Although guidance has been provided by AMCP on the recommended length of each section of the dossier, end users have expressed dissatisfaction about the length of these documents and prefer greater concision.[1,2]
- Our objectives were to determine whether the length of various sections of AMCP dossiers complies with Version 4.0 recommendations and to describe common and unique strategies applied to streamline the presentation of information to aid timely and effective dossier review.

Methods

- AMCP dossiers created or updated since April 2016 by a global contract research organization, through contracted partnerships with pharmaceutical manufacturers, were evaluated.
- Data collected from each dossier/product included the manufacturer, drug approval date, date created or updated, therapeutic area, number of approved indications, number of clinical studies included in the product labeling at the time of development/update, number of off-label studies included, and total length of the dossier.
- For each section of the dossier where AMCP provides page count recommendations, results were collected and categorized as follows: within recommended length, above recommended length/within maximum length, or above maximum length. Please see **Table 1** for AMCP recommendations.
- Observations were made and documented as to methods used to streamline information.

Table 1. AMCP Recommendations on Lengths of Each Section[1]

Section	Recommended Length	Maximum Length
Section 1.0: Executive Summary	5 pages	8 pages
Section 2.1: Product Description	5 pages	10 pages
Section 2.2: Place of the Product in Therapy	10 pages (per indication)	15 pages (per indication)
Section 3.1: Study Summaries	2 pages (per summary)	5 pages (per summary)
Section 3.2: Evidence Tables	<1 page (per study)	2 pages (per study)
Section 4.0: Economic Value and Modeling Report	12 pages (per model)	20 pages (per model)
Section 5.0: Additional Supporting Evidence	2 pages (per source/study)	5 pages (per source/study)

Results

Search Results and Dossier Characteristics

- Data were collected from 31 dossiers across 6 pharmaceutical manufacturers.
- More dossiers were for established products (81%) than for launch products (19%), and more products were approved for one indication (68%) than for multiple indications (32%).
- These dossiers covered 10 therapeutic areas, with the most common being respiratory (n=9), immunology (n=4), and neuroscience (n=4).

Dossier Length

- Across the sample, the total dossier page count ranged from 44–345 pages (mean, 138 pages). Dossiers were grouped according to page count: 23% were ≤100 pages, 45% were 101–150 pages, 19% were 151–200 pages, and 13% were ≥201 pages (**Figure 1**).
- Dossiers were generally longer for established products vs new products (mean, 149 vs 93 pages) and for products with multiple indications vs a single indication (mean, 176 vs 120 pages).
- Some differences in overall page count were also observed when dossiers were evaluated according to manufacturer and therapeutic area (**Figure 2**).

Results (cont'd)

Figure 1. Overall Dossier Page Count by Category

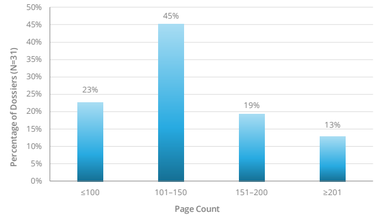
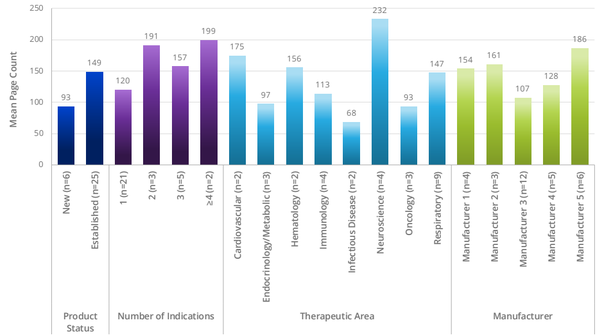


Figure 2. Dossier Page Count by Grouping



Dossier Section Length

- The sections of the dossier that most commonly exceeded maximum length were Product Description (48% of dossiers), Study Summaries (29%), and Evidence Tables (15%). See **Table 2**.
- The sections that usually met the recommended page count were Economic Value and Modeling Report (82%), Place of the Product in Therapy (71%), and Executive Summary (63%). See **Table 2**.

Strategies for Streamlining

- Considerable differences were noted in the presentation of content for the comparator table, which greatly affected page count. Use of abbreviated label statements, limiting the number of comparators, and formatting using merged rows and check marks simplified content. An example comparator table that uses many of these components is shown in **Table 3**.

Table 2. Percentage of Dossiers that Met or Did Not Meet AMCP Recommendations on Section Length

Section	n	Page Count Compared With AMCP Recommendations: Within Recommended	Above Recommended/ Within Maximum	Above Maximum
Section 1.0: Executive Summary*	30[†]	63%	23%	13%
Section 2.1: Product Description	31	23%	29%	48%
Section 2.2: Place of the Product in Therapy	31	71%	29%	0
Section 3.1: Study Summaries	31	6%	65%	29%
Section 3.2: Evidence Tables	27[†]	15%	70%	15%
Section 4.0: Economic Value and Modeling Report*	22[†]	82%	14%	5%
Section 5.0: Additional Supporting Evidence	25[†]	56%	44%	0

*Due to rounding, total exceeds 100%. [†]Section not contained in all dossiers.

Table 3. Streamlined Product Comparison Table (Sample)

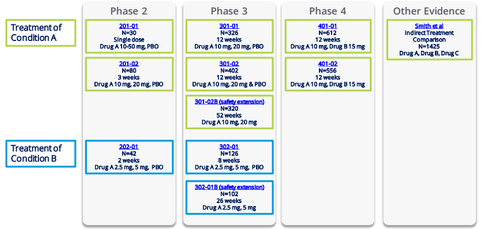
	Primary Drug (Generic)	Comparator Drug A Brand Name (Generic)	Comparator Drug B Brand Name (Generic)	Comparator Drug C Brand Name (Generic)
How Supplied	Tablets: 5 mg, 10 mg, 20 mg, 40 mg Solution: 1 mg/mL	Tablets: 3 mg, 6 mg, 12 mg	Tablets: 5 mg, 10 mg, 15 mg Oral Disintegrating Tablets: 10 mg, 15 mg	Capsules, Extended-Release: 50 mg, 100 mg, 200 mg, 300 mg, 400 mg
Indication	Treatment of Condition A in adults, adolescents, and children ≥6 years of age	Treatment of Condition A in adults	Treatment of Condition A in adults and adolescents ≥12 years of age	Treatment of Condition A in adults
Dosage Frequency	Twice daily	Twice daily	Twice daily	Once daily
Boxed Warning				
Abuse and Dependence	Class Warning: This medication class has a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy.			
Contraindications				
Renal impairment	✓ (CrCl <30 mL/min)	✓ (CrCl <30 mL/min)	—	✓ (CrCl <50 mL/min)
Known hypersensitivity to the product or any of its components	✓	✓	✓	✓
Warnings/Precautions				
Agitation and hallucinations have been reported in patients with renal disease or those who received higher than recommended doses	✓	✓	✓	✓
Acute renal failure may occur in elderly patients	✓	✓	✓	✓
Hemolytic uremic syndrome has been reported	—	✓	✓	—
Avoid use during pregnancy	Use only if potential benefits justify risks	Use only if potential benefits justify risks	Use only if potential benefits justify risks	✓ (especially during third trimester) ✓ (late pregnancy)

Abbreviation: CrCl=creatinine clearance. Note: These are not actual products. Content developed for example only.

Strategies for Streamlining (cont'd)

- Some dossiers used a figure to provide a high-level overview of the available evidence included in the dossier and allowed for easy navigation to the studies via hyperlinks (see **Figure 3**). Use of graphics to concisely summarize complex study designs or communicate results was also an effective strategy.
- To avoid repeating information in the Clinical Evidence section, many dossiers presented replicate studies together, used hyperlinking within and outside of the dossier, and presented data through a study summary or an evidence table (but not both).
- For some dossiers, the length and/or format (summary, evidence table, bibliography) of the study content was modified according to the importance and/or relevance of the evidence and whether it was on- or off-label.
- Manufacturer preferences regarding content to be included, style/formatting, and page limit targets were also noted to contribute to differences in overall page count.

Figure 3. Overview of Studies Summarized in a Dossier (Sample)



Abbreviation: PBO=placebo.

Limitations

- This evaluation included a small sample of dossiers from a limited number of manufacturers. Furthermore, most dossiers were for established products and not all therapeutic areas were represented. A larger sample of dossiers would have provided for a more robust assessment.

Conclusions

- Overall, the dossiers that were evaluated met the recommended number of pages for each section; however, there were certain sections, such as Product Description, where improvement is needed.
- Certain factors influence the total page count of a dossier, such as number of indications, therapeutic area, and product status (new or established); these factors are primarily driven by the amount of evidence available for the product.
- To improve end user satisfaction, manufacturers should apply streamlining strategies to succinctly display information in AMCP dossiers.

References

1. Academy of Managed Care Pharmacy. (2016). The AMCP *Format* for Formulary Submissions. V4.0. [online] Available at: http://www.amcp.org/formatv4/ [Accessed 16 Jan 2019].
2. Dymaxium. (2018). Pre- and post-approval dossiers: making all evidence count. [online] Available at: http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=23830 [Accessed 23 Jan 2019].

Disclosures

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation: K.Hughes, T.Murry, K.Kovalycsik, K.Murphy, and S.Saini are all employed by Evidera. Corresponding author email: kendra.hughes@evidera.com.

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