■ Achieving Balance with the AMCP Format for Formulary Submissions, Version 4.0: A Dossier Producer's Perspective

We applaud the AMCP Format Executive Committee for updating the *AMCP Format for Formulary Submissions* in response to the evolving health care landscape. During our 20-year history of developing dossiers, the 1 consistency we have observed is the struggle to achieve balance between efficacy and safety, evidence and aspiration, and access and cost. As Lee et al. (2016) describes,¹ the primary stakeholders in the *AMCP Format* (manufacturers and health care decision makers [HCDMs]) often have different goals for using the *Format*.

We feel that the new version of the *Format* makes great strides towards achieving this balance, providing the necessary elements for sound evidence-based formulary decisions while not being overly prescriptive. While the new *Format* may require some “rethinking” of the current Table of Contents, it will result in a succinct dossier that provides clarity for a new technology's comparative clinical and economic value. We would like to call attention to 3 specific points with regards to the new *Format*.

First, the *Format* should not be a data repository for all clinical data—the relevance of evidence for the HCDM audience should be weighed before inclusion. Version 4.0 has updated the page recommendations and added suggested maximum limits.² Having heard from HCDMs that they are often overwhelmed with the data in the dossier and the review time required,³ we feel that this will help balance the needs of both groups. The page recommendations are such that the dossier length may range from 45 pages to 90 pages for an “average” new product with a single indication and typical FDA submission package. This range permits the manufacturer to provide any additional evidence needed to support a product's value.

Second, interpretation and consideration of which evidence should be provided will still be required of the manufacturer. Version 4.0 provides clarity on the evidence that HCDMs want to see and guidance as to inclusion in the *Format*; however, specifics are left to the discretion of the manufacturer and should be informed by the product/technology, disease state, and other individualized elements. For example, pharmacoeconomic data (exclusive of the model report in Section 4.0) may be handled in several ways. A retrospective claims analysis of 2 therapeutic options in multiple sclerosis may demonstrate clinical impact (number of relapses) and economic impact (direct medical costs) and thus be considered for either Section 3.0 or 5.0. While this is an operational issue, manufacturers should still carefully consider the type of evidence to include.

Version 4.0 also states that manufacturers should provide justification or rationale for the selection of the evidence, from product comparators to clinical guidelines to clinical studies. This is the first time that the rationale for selection of evidence will be explicitly described in the dossier and should help ease concerns raised by HCDMs regarding bias or “cherry-picking” of data.

Third, in addition to fostering an open dialogue between manufacturers and HCDMs, the dossier should be received and reviewed with an open mind. We, too, have often heard the criticism that manufacturer-provided dossiers are “biased.”³ We hope that providing transparency into the thought process of the evidence presented will help to alleviate some of these concerns. The vast majority of manufacturers genuinely seek to provide the evidence that is needed and requested in order to support evidence-based formulary decision making.

All of these changes move towards open and ongoing communication between manufacturers and HCDMs. As dossier producers, we often see the chasm that exists between the 2 disparate stakeholders. We welcome Version 4.0 as the bridge to cross this gap and look forward to its implementation.

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DISCLOSURES

Both authors are employed by Xcenda and develop AMCP *Format* dossiers.

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2. AMCP Format Executive Committee. A format for submission of clinical and economic evidence of pharmaceuticals in support of formulary consideration: the AMCP *Format for Formulary Submissions*. Version 4.0. April 2016.
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