Assessment of Standard Response Database Management for Mature Brands by U.S. Medical Information Departments of Pharmaceutical Manufacturers

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Background
The Medical Information (MI) department in a pharmaceutical company is generally responsible for writing responses to unsolicited requests from Healthcare Providers (HCPs) and collaborating with Medical Science Liaisons (MSLs) in real-time customer engagement. Standard Response Document (SRD) creation and maintenance is an ongoing task that ensures responses to HCPs include up-to-date clinical data. As a company’s drug portfolio expands, mature lifecycle products may have a lower priority and less MI support and visibility. This project seeks to evaluate the current practices of MI departments for their mature brands (legacy product) and the amount of support given towards these products.

Objective
To identify similarities and differences in which medical information departments currently answer unsolicited requests on mature products and manage their MI databases to include up-to-date clinical data.

Methods
To assess the management of SRD databases, an electronic survey was delivered via email to target professionals who are currently employed in U.S. MI departments at top pharmaceutical companies based on 2016 global sales. A survey was used to collect information on the overall practices within their department without specifically targeting a specific company, product, or process. Results were compiled to identify commonalities and gaps within practice that can be improved upon as an industry.

Results
Upon review of the data collected from the distribution of our survey, a total of 76 responses were received from personnel who worked in any pharmaceutical company. Out of these 76 individuals surveyed, 44 individuals currently work in a MI or medical communications department within a pharmaceutical company. Of these 44 individuals, 36 stated that their respective company currently supports mature legacy products, and therefore, maintains a database of SRDs for these products (Figure 1). The other individuals either did not support a mature brand or did not work in MI or communications.

Of those surveyed, 63.3% reported that the mature products in their portfolio, the number of active SRDs retained within their database ranged from 5-25 responses (Figure 2). Based on responses for actively promoted products, the amount of active SRDs generally ranged from less than 20 to greater than 100. In comparison to actively promoted products, our results indicate that the process for updating SRDs for mature products differs in that there is less periodic review, content updating timelines become less stringent, and a more reactive approach is used versus a proactive approach when updating SRD content.

Our results indicate that the product's package insert is predominantly provided to address questions for mature brands, in many cases customized literature searches were conducted for specific questions. Dissemination of the most up-to-date version of a SRD was done 74% of the time, while customized literature search results were disseminated 48% of the time. The amount of time dedicated to updating and maintaining a database for mature products.

Results also show that efficiencies have already been made on the following matter and are further discussed in the Conclusions section.

Conclusions
As a company’s overall drug portfolio expands, it can be concluded that mature lifecycle products become a larger portion than actively promoted brands, and thus, are provided less support by the MI/Communications departments. Actively promoted brands generally have 11-100 SRDs which are proactively updated, in contrast to a mature brand that may only have 11-23 SRDs reactively updated. Important considerations for the number of up-to-date mature brands SRDs include the amount of time (per year) that the mature drug has been on the market and has been used in clinical practice which can increase SRD familiarity with the product and decrease the updates. Consequently the number of SRDs necessary to maintain up-to-date SRDs. This reactive approach to MI/Communications stops when MI/Communications stop updating their mature brand SRDs due to lack of MI support regardless of the number of inquiries and only provide the latest version with the date of last review.

Our results indicate that the product's package insert is predominantly provided to address questions submitted by healthcare professionals for mature brands, in many cases customized literature searches were conducted and responses were tied to address product specific questions. Although, workflow time usage reported to be minimally impacted by these products (Figure 3). Prominent aspects of current practice, 50% of participants believe their current workflow for updating a mature brand SRD was adequate. Efficiencies brought up by survey participants include reflecting clinical practice which may increase HCP familiarity with the product and decrease the number of clinical questions they have. These factors can impact the amount of inquiries and stops the update and review process is not common to all pharmaceutical companies as some companies will consequently the number of SRDs necessary to maintain up-to-date SRDs. This reactive approach to MI/Communications stops when MI/Communications stop updating their mature brand SRDs due to lack of MI support regardless of the number of inquiries and only provide the latest version with the date of last review.

We can conclude from these results that more time allocated to updating and maintaining the SRD database for mature brands adds value to the workflow and can provide the latest version with the date of last review.

Disclosure
Author(s) of this manuscript 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:

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