Best practices for standard response letters: Creating guidelines for medical information across pharmaceutical companies

Ghazal Maghareh, PharmD1, BCPS; Rena J. Ral PharmD2; Evelyn R. Hermes-Desantis PharmD1

1Ernest Mario School of Pharmacy, Rutgers the State University of New Jersey, Piscataway, NJ

Background

❖ Pharmaceutical companies develop scientific response letters (SRLs) as a response to healthcare providers (HCPs) unsolicited requests for off-label information.
❖ Although there are requirements mandated by the Food and Drug Administration for these queries, there is a wide variety of practice standard operating procedures (SOPs) utilized by the industry and no one set standard.
❖ HCPs have been surveyed to identify key characteristics of SRLs that would be important for making clinical decisions.

Objective

❖ To adapt a rubric from surveyed data and use it to evaluate SRLs with the goal of increasing clinical transparency. Based on the assessment of the SRLs, the rubric will be modified to improve SRL practices and serve as a tool for standardization.

Method

• A rubric will be developed based on current literature of HCPs preferences for SRLs.
• The rubric will be ranked from 3 – contains all components, 2 – contains some components, and 1 – contains none of the components.
• SRLs will be collected via company MI online databases or by request as a medical information inquiry.
• The SRLs will be classified by the type of question and the rubric will be implemented to assess SRLs.

Results

❖ The questions were classified as adverse event, dosing and administration, therapeutic use, drug interaction, pregnancy and lactation, stability and compatibility, and other-allergy.
❖ When the average for each section across all seven types of questions were taken, it was found that the results/clinical data summary and methods section scored the lowest at 2.07 and 2.23 respectively.
❖ On the other hand, the sections that scored the highest across all seven type of questions was the abstract and references, at 2.55 and 2.51 respectively.

Discussion

❖ There is a lack of standardization to SRLs. There is specifically an information gap in the results/clinical data summary and methods section.
❖ This information is critical to give HCPs because it allows them to understand the process pharmaceutical companies used to gather the information presented and allows HCPs to replicate this search strategy on their own.
❖ Enforcing criteria for SRLs to meet will allow pharmaceutical companies to establish better trust with HCPs and act as a fundamental piece in the clinical decision making process.

Conclusions

❖ The most common queries were adverse event, dosing and administration, and therapeutic use, shown in the results section.
❖ A limitation that was recognized was that the questions were not standardized and this could impact the format of the SRLs and the overall results.

Author Contact Information

Ghazal Maghareh, PharmD
Postdoctoral Fellow
Ernest Mario School of Pharmacy
100 Frelinghuysen Rd
Piscataway, NJ USA 08854
ghazal.maghareh@rutgers.edu