A Root Cause Analysis of Stock-outs in the Pharmaceutical Industry

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Summary: Pharmaceutical stock-outs exert huge influence not only on the revenue or customer satisfaction for drug companies, but also on human health, due to the nature of the product. As a leading global healthcare company, PharCo (an assumed name) is facing increasing stock-out challenges in their pharmaceutical business. They suspected that manufacturing quality defects were a major cause of stock-outs, reducing the production yield and preventing the company from meeting customer demand. To help test this hypothesis and address the stock-out challenge, our research diagnosed the root causes of stock-outs at PharCo using a customized Root Cause Analysis model. The analysis revealed that, instead of manufacturing quality defects, regulatory issues were a major cause for stock-outs at PharCo. Regulatory challenges associated with developments such as new product launches and formulation modifications need to be addressed for PharCo to reduce their stock-out level.

Problem and Research Area

As a leading global healthcare company, PharCo is facing stock-out challenges consistently in their pharmaceutical business. This has become more evident while they are expanding globally with the surge of product demand. In order to reduce the stock-out level and deliver robust products to customers in a timely manner, PharCo decided to initiate a Root Cause Analysis to determine the major factors causing stock-outs and address those factors. In particular, they suspected manufacturing quality defects as probably the main cause of stock-outs. To help test this hypothesis, our research analyzed the causality between manufacturing quality and stock-outs with a customized Root Cause Analysis model. We further identified primary causes of stock-outs at PharCo and suggested proactive actions to address those causes.

Methodology

To address the problem, we used a mixed methods approach that combines qualitative and quantitative methods for data analysis. First, we selected a specific
Root Cause Analysis framework to guide our research process. Then, we used linear and categorical coding on the text of each stock-out incident's comments to categorize them by cause. Finally, we developed two nominal logistic regression models to quantify the influence of each cause on stock-outs.

**Step1: Root Cause Analysis Framework**

To solve the identified problem in a logic and effective manner, we selected a customized root cause analysis framework, the “DO IT” Root Cause Analysis, to guide our research process. This framework breaks down the problem with creative thinking on both the convergent level (define problem, collect data, analyze data, and select solutions) and the divergent level (understand process, identify possible causes, and identify possible solutions). It also provides a project management phase to recommend a solution, implementing this solution, and maintaining the improvement and related knowledge.

**Step2: Qualitative Data Analysis**

The dataset provided by PharCo contains stock-out incidents and the comments regarding the cause of each incident. Those comments were categorized by PharCo users under default system categories that are vague and difficult to understand. To better describe the stock-out causes and facilitate the statistical analysis, we utilized a qualitative data coding method to translate the comments into new defined, meaningful categories.

**Step3: Quantitative Data Analysis**

The influence of any cause on incidents can be measured by two criteria: the “frequency” and the “predictability”. For stock-out causes at PharCo, their “frequency” can be quantified by the sum of each stock-out cause reported in PharCo’s stock-out management system. In order to quantify the other criterion “predictability”, we developed logistic regression models to generate the odds ratio of each cause, which can be used to determine how each cause predicts stock-out incidents. Finally, we plotted the predictability (as the x-coordinate) and frequency (as the y-coordinate) of each stock-out cause into a two-dimensional Root Cause Assessment matrix to evaluate their influences on stock-outs (Figure 2). A root cause is then defined as one with both odds ratio and frequency above the median values.

**Data Analysis and Results**

1. **Data Cleaning and Evaluation**

PharCo provided three reports of 16,383 stock-out incidents. To analyze the data from a global perspective, we combined three reports into one dataset and deleted all errors, resulting 11,501 entries of stock-out incidents with 35 stock-out cause categories defined by PharCo. To facilitate the statistical analysis, we also converted the stock-out categories (independent variable) and stock-out results (dependent variable) into binaries, i.e. true (1) and false (0).

2. **Logistic Model**

In order to quantify the “predictability” on stock-outs for each stock-out cause category, we developed two logistic regression models using JMP software to get their odds ratios. We created model LR1 for PharCo's default categories and model LR2 for new defined categories.

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1 Stock-out incidents and the comments of their causes were provided by PharCo.
Model LR1: All 35 default stock-out causes in LR1 have p-value around 1.00, much greater than PharCo’s standard rejection level 0.05. This means that none of the default stock-out causes contributes significantly to the model fit. Therefore, it is worthwhile to reduce the number of stock-out categories into a handful of significant clusters. Using the qualitative data coding method, we manually coded the stock-out comments into 12 new defined stock-out cluster categories.

Model LR2: There is an obvious improvement compared to LR1. Among 12 new defined cluster categories, 9 of them have p-value under 0.05 (the rejection level set by PharCo), indicating that they contribute significantly to the model fit and should be included in the model. To gain the best fit of the model, we iteratively excluded categories with p-value greater than 0.05 until all remaining variables have p-value less than 0.05. There were 8 categories left in the final version of LR2 and we calculated the odds ratio for all of them using JMP.

3. Results
Since all remaining categories are significant, we can determine their influence on stock-outs using their odds ratio and frequency (Table 1). We plotted the odds ratio

![Figure 2 - Quantitative Root Cause Assessment Matrix for PharCo’s Stock-outs](image)

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2 Statistical significance (p-value) is measured by the Prob>ChiSq value in JMP software. PharCo’s rejection level is set as Prob>ChiSq = 0.05
(as the x-coordinate) and frequency (as the y-coordinate) into a two-dimensional Root Cause Assessment matrix and generated the stock-out root cause map as shown in Figure 2.

As indicated in Figure 2, there are four stock-out cause quadrants divided by two median lines. The top right quadrant above both median values is considered as the root cause quadrant. There is only one stock-out category, regulatory issues\(^3\), with both odds ratio (i.e. predictability) and frequency above the median values. Since we define a root cause as one with both odds ratio and frequency above the median values, ‘Regulatory Issues’ associated with developments such as new product launches and formulation modifications is considered a strong root cause for the stock-outs at PharCo.

**Conclusions and Recommendations**

Although PharCo had a strong suspicion that manufacturing quality may have been a major cause of stock-outs within the organization, through an in-depth analysis, we concluded that this hypothesis is not supported by the data. A strong root cause, with ~60 odds ratio and a relatively high frequency, is the category of regulatory issues.

Because of the complexity involved in regulatory issues, especially the various regulations in different countries, it is difficult to develop a simple strategy to handle this issue. We recommend a further research to fully investigate factors that underlie regulatory challenges. Upon further research, PharCo may have to invent new procedures to address regulatory issues and reduce their stock-out level. Meanwhile, there are other factors such as forecast error and distribution issues that are not as critical as regulatory issues but still contribute to a large number of stock-outs. These factors can be addressed by optimizing PharCo’s operations with specialized tools or models. In addition, we suggest PharCo take proactive actions to address low frequency but high predictability stock-out causes as they have a high possibility of causing stock-outs and could bear serious consequences.

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\(^3\) "Regulatory issues” refers to the lack of governmental regulatory approval to release products.