Pharmaceutical Product Complaint Handling: Evolution of A Systematic Mechanism

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ABSTRACT

The customer complaint is considered an expression of dissatisfaction against the quality of the product or information associated with them. An effective mechanism for product complaint handling is one of the essential business requirements of the pharmaceutical industry. The customer complaints have the potential to jeopardize the firm’s reputation and trigger regulatory action. This study shows that the prevailing complaint handling practices in the pharmaceutical sector follow a random and independent approach without synchronizing the strategy with the gross interest of stakeholders. The study explores the dearth of study for overall mitigation of adverse impacts on business due to patient’s risk, impending legal and regulatory actions. The existing system to handle pharmaceutical complaints is handled with a technical perspective, without effective involvement of the distribution personnel. This study has produced a unique pathway to redress pharmaceutical product complaints effectively.

KEYWORDS

Customer Complaint Resolution, Pharmaceutical Customers, Pharmaceutical Industry, Pharmaceutical Quality, Pharmacy Practices

INTRODUCTION

Medicinal product industry is such a sector where all stakeholders give quality and efficacy prime importance. There are numerous cases when the product complaints have given rise to a critical turning point in the pharmaceutical business due to regulatory actions. The regulatory agencies have issued technical guidance for industry to handle complaints. However, the management’s approach must be aligned with the regulator’s expectations failing which the industry is liable to face the consequences like warning and business ban. The regulatory agency of the United States, FDA has issued several warning letters to drugs manufacturers, thereby causing qualms to their approach for handling customer’s complaints. Inadequate understanding of complaints and the organization’s strategy to deal with them may trigger the business implications.

In the pharmaceutical sector, a complaint is considered a verbal or written communication that a product out of manufacturing plant is not as per the laws and regulations under the purview of drugs regulatory administrations or not in accordance to the stated quality specifications. The quality of
medicinal products is not only the need of customers, as well as this is an ultimate prerequisite of corporates (Kumar et al., 2016c). The customer issues may prompt stern actions like:

1. Impaired goodwill and reputation of drug manufacturer
2. Drug regulator’s actions (e.g., sales ban, import alert, etc.)
3. Forced return of distributed medicines from the market

As per provisions laid down in the code of federal regulations (FDA CGMP, 2017), there should be a complaint file with each pharmaceutical manufacturer. Numerous regulatory observations and letters are issued by drug administration against poor customer complaint management by the pharmaceutical manufacturers. During the year 2012, the four percent (4%) of the total deficiencies observed by USFDA, were related to customer complaints (Chris, 2017). The most frequent causes of these observations are inadequate practice for receiving, registering and evaluating complaints. There are few other observations related to deficient procedures that do not include provisions for adequate closures of the complaints. The integrated manufacturing and supply chain management framework should consider the impact of a customer complaint on a broad scale that includes vast spanning arena of medicinal products and pharmaceutical business (Sung et al., 2016). Relevant references for handling customer complaint handling such as:

1. The United States 21 Code of Federal Regulation part 211.198
2. European Union Good Manufacturing Practices-EudraLex, 8.2
3. Indian Drugs & Cosmetics Act, Schedule M

European Commission has published the EU Guidelines for GMP wherein customer complaints handling has been addressed adequately as compared to other regulatory guidance papers (EudraLex, 2009).

LITERATURE STUDY

There are numerous cases of a drug product recall from the market and stringent regulatory actions across the globe due to the defective quality system. The inspection reports have reported several cases of inadequate customer complaint handling practices adopted by the pharmaceutical industry.

The way of handling requirements of becomes important because products of different quality levels compete in the marketplace (Mehmet, 2016). Furthermore, in differentiation studies, it has been found that quality is considered at a higher level of some attribute. The that pharmaceutical firms must spend resource to settle cases for inferior quality products (Shishir, 2016). Healthcare provision and observed that technology has made substantial progress over time and is continually improving (Stegemann, 2016). There is enormous growth in chemical and pharmaceutical business in countries like the United Kingdom (Elliott, 2015) and hence there are opportunities for the simultaneous increase in its distribution. The research in pharmaceutical manufacturing operations are aligned to promise inclusive reception into the healthcare sector. The drug regulatory investigators cited that Polydrug never bothered to address the customer complaints which finally resulted in a warning letter against the firm (FDA, 2016c).

After critical review by United States Federal Drugs Administration (USFDA), the investigators found that Cadila Pharma has failed to follow adequate written procedures addressing the customer’s concern (FDA, 2015c). The regulatory investigators mentioned in its warning letter that the firm did not adequately investigate and address consumer complaints on multiple occasions. In another report, USFDA expressed grave concern against one Chinese drug substance manufacturer Zhejiang Hisun Pharmaceutical concerns about the deletion of data related to customer complaints (FDA, 2015a).
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