Chapter 4
Information Quality Issues in the Identification and Tracking of Drugs within the Pharmaceutical Industry

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ABSTRACT

This contribution examines solutions how Information Quality (IQ) dimensions as a framework along with Radio Frequency Identification (RFID) and the Electronic Product Code Information System (EPCIS) as tools may improve needed drug trackability and traceability capabilities in the pharmaceutical industry (PI). For years counterfeit drugs have been impacting the industry and putting patients' health in danger. We analyze applications, methods and practices in the improvement of the quality of drug tracking and tracing. The potential of IQ, RFID, EPCIS and related applications and technologies suggest and design corresponding information and materials flows. This research presents examinations, reviews and recommendations and utilizes two theoretical frameworks: Transaction Cost Theory and Collective Action Theory. This setting may be viewed as a large, complex and international web of corporations, legislation, regulatory efforts, compliance regimes, manufacturers, wholesalers, pharmacies, importers as well as rapidly advancing technologies and applications.

INTRODUCTION

Information Quality (IQ) as a discipline is applicable to and encompasses any form of organization. The pharmaceutical industry, the focal setting of this research, is no exception. Since the pharmaceutical industry is an information-intensive industry utilizing extensively both structured and unstructured data to create, sell and distribute drugs, IQ is of paramount importance in determining the identity and

DOI: 10.4018/978-1-5225-0248-7.ch004

authenticity of drugs and their ingredients. For all parties involved, the safety of drugs is often taken for granted when visiting the pharmacy to purchase medicine that cures our various ills. However, the problem of counterfeit drugs and drug ingredients has made and is continuing to make its way into the U.S. drug supply chain at an alarming and ever increasing rate. We explore drug counterfeit Information Quality-related issues in the pharmaceutical industry and how they can be, at least partially, addressed by embracing Radio Frequency Identification (RFID) and related technologies and applications together with various regulatory schemes addressing this dilemma.

Information Quality as a field offers important dimensions that make information resources useful for planning and decision-making. For this chapter, the focus of our research setting is the pharmaceutical industry. Many IQ dimensions are crucial to numerous industries, but counterfeiting in the pharmaceutical industry is cheating and defrauding this industry by engaging in unauthorized manufacturing, packaging or the illicit commercialization of drugs being protected by trademarks, patents or copyrights.

The pharmaceutical industry has been continually fighting battles on many fronts including the adoption of pricy new technology in order to reduce drug counterfeiting or to improve supply chains. Counterfeit products, expired products that are re-entering the distribution chain as well as costs to guard for these illicit practices have been among the battles the pharmaceutical industry has been fighting for many years. Moreover, the industry is faced with patient safety issues as well as packaging practices being designed for the market rather than patients' use.

LITERATURE REVIEW

This literature review addresses several bodies of literature. They include identity management and authentication, dimensions of Information Quality, various technologies and applications such as RFID, counterfeiting in general, as well as the practice of counterfeiting in the pharmaceutical industry.

In the following section we provide an overview of identity management.

Identity Management

Identity management is simply a tool to help identify a person, place, or thing (Millet & Holden, 2003). It can be used within multiple areas, including technology and security. Confirming the identity of a person is a common event, such as showing an ID when attempting to cash a check at the bank. For many products, identities are not as essential. For example, the manufacturer of nails does not necessarily care where the metal comes from. But, the beef industry needs to know the origin of a cow. These examples show how identity management can come in multiple forms, but its importance depends on the field in which it is utilized.

Along with identity management, authentication is a means of confirming something or someone to be authentic (Millet & Holden, 2003). It can also confirm the identity of a person or tracing the path of an item back to its origin. To authenticate an item, its attributes are compared with known characteristics of its creator. For example, a painting from Picasso can be authenticated by art experts by examining the attributes of the work. If they match known patterns, such as style, time of creation, etc., then the painting can be called authentic.

Identity management is a key concern when dealing with authenticity of a drug or drug component. The dilemma with counterfeit drugs and drug components is that they look authentic, i.e. their identity