THE ONGOING POTENTIAL OF RFID AS AN ALTERNATIVE TO 2D BARCODE IN PHARMACEUTICAL INDUSTRY
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ABSTRACT
Pharmaceutical industry is one of the vital industries for human health and well-being and Ireland has a very strong reputation amongst other countries by hosting a great deal of global and local pharmaceutical manufacturers and producing high quality medicines. Since the industry has been suffering from counterfeit drugs besides different hurdles from both competitors and government regulations, the action of the pharmaceutical manufacturers is subject to interest in order to overcome drug trafficking. Serialization seems as a solution both for counterfeiting and the complex supply chain of pharmaceutical industry including recalls and returns. Although, there are some countries that use serialization as a legal requirement, it is still an evolving subject within the industry not just for an anti-counterfeit technology but to use supply chain and stock management more efficiently. RFID (Radio Frequency Identification) and 2D Barcode are two different data carriers that used in serialization and suggested by the US and EU authorities. Although, RFID was first introduced as a disruptive technology in late 2004 by FDA (Food and Drug Administration), 2D barcode is taking advantage of the market due to its relatively lower cost and implementation convenience. This study aims to identify the potential for RFID applications within Irish Pharmaceutical Industry, as they need to consider implementation of a serialization system. This topic has been chosen due to the researcher's professional background and personal interest in pharmaceutical industry as well as to understand the main approach in Irish market. Due to the novelty of the subject for Irish market likewise most of the countries in the world, researcher believes that it would be an opportunity to analyse the topic in that context. Considering the speciality of the topic, a group of interviews conducted with different stakeholders of the industry from regulatory body to consultancy company in order to identify the Irish pharmaceutical industry’s tendency on serialization and data carriers.

INTRODUCTION
Although highly regulated, pharmaceutical industry is very attractive for illegitimate supply chain promoters (GBI Research, 2010, p. 22) and drug trafficking due to complex nature of supply chain and counterfeiting of pharmaceuticals (Lybeck, 2008, p. 391). Counterfeit or illegal products involved in these channels threaten patients' health and safety by containing none or less active ingredient or completely different chemicals rather than the prescribed medicine (Meagher, 2004, p. 6).

Moreover, effective and efficient management for responding patient needs and market demands as quickly as possible is also required in order to recall, returns and must have stocks for special medication. Serialization of the pharmaceuticals (process for giving unique and verifiable serial number to every saleable unit (Optel Vision, 2013, p. 11) is considered as parallel line and chain of supply to avoid counterfeit products and better stock management in the supply chain which it provides tracking and tracing of every single item, Two common serialization data carriers (Power, 2008, p. 13):

- 2D Barcode: Two dimensional codes consisted of square modules requiring scanning of each item (USP, 2011, p. 9). Widely used due to lower cost and implementation flexibility.

Understanding advantages and disadvantages of both of these data carriers for further implementation in Irish pharmaceutical industry, this study intends to answer following research questions to better Irish point of view:

1) Which one of RFID and 2D Barcode is more efficient and economic?
2) Which one of RFID and 2D Barcode has more benefits for the end user?

METHODLOGY
Research Philosophy, Approach & Strategy: This study is conducted by pragmatism with an inductive approach as large empirical evidences are needed to better understand the industry whether to use RFID as an alternative to barcode technology in Ireland where grounded theory provides data analysis technique to establish the validity (Saunders and Lewis, 2011, p. 119).

Responsible person from regulatory authority (HPRA)
- Responsible person from independent standards organisation (GS1)
- Project Engineer and Senior Quality Assurance Manager in two different pharmaceutical companies
- Project Manager of a hospital (St. James’s Hospital)
- Pharmacist (Meagher’s Pharmacy)
- Senior Consultant from an engineering consultancy company

Data Analysis: Qualitative data will be used in order to analyze the interviews with sample group due to the topic specification.

RESULTS
Questions are themed in eight groups that data was analyzed:
1) Supply Chain: Fundamental issues are;
- Patient safety
- Product and API shortages in warehouses
- Manufacturing of medicines
- The level of complexity & lack of standards
- Stock management & cold chain breakages
2) Counterfeit Products: None were found in Ireland through the legitimate supply chain.
3) Recalls: Through 2013 there were 109 in total, executed within a few days (depending on the market or number of lots) when the recall decision has been made.
4) Serialization: Ireland is not playing an active role in the EU commission at the moment in order to analyze the process and reflecting the other countries’ approaches with the concern of uplift in government’s budgetary health as well as an active impact on process time. However, EU commission’s implementation of serialization deadline of 2017 is at sight.
5) Implementation: The only tracking system in place is for hemophils products in Ireland and the biggest challenge is related to the manufacturing stage.
6) Irish Pharmaceutical Industry: Only multinational companies have started developments on serialization (at least with a pilot work) while smaller companies haven’t progressed much.
7) Customer Relations: Main complaints are cost of products and drug delivery time.
8) Government: Most of the entities did not conduct a feasibility study comparing the implementation for RFID and 2D barcode due to the cost of the implementation.

DISCUSSION
During the interviews, general tendency was towards 2D barcode as it was cheaper and easier to implement. Despite, most participants said that they didn’t perform a study between two data carriers, some of them told that they didn’t conduct study due to high cost of RFID. It is also learned that after some studies for RFID implementation, most of the companies are not in favour of implementing or even testing the system due to general concerns and the negative findings of previous studies on interference with biologics or other materials.

Although, serialization definitely will bring benefits and solutions in the long term both in protecting patient health and companies’ reputation, manufacturers have to consider additional costs to their processes as they are facing different hurdles such as expensive and long product development processes, governments’ regulations on pricing and reimbursement, and patent expiration.

On the other hand, pharmaceutical counterfeiting is a rising problem which costs about $75 billion according to 2010 results (Laetus, 2014, p. 7). Furthermore, brand’s prestige is under attack, as any suspicious situation impacts their sales and share prices. At the same time, there is a decreasing trend for RFID costs as the number of tags used is increasing and the technology is developing.

Finally, there are numerous benefits of RFID for the end user such as easy tracking of patient’s medication status and history.

CONCLUSION
Both literature review and interviews showed the importance of choosing any of the data carrier and securing the pharmaceutical supply chain with the main objective of patient protection. From cost point of view, although, there is a significant drop in RFID costs during the last ten years, it is still high compared to 2D barcodes. Also, manufacturers and regulators are satisfied with 2D barcode specifications especially for inexpensive drugs.

Ultimate goal of the industry is a worldwide serialization and it is important to take a strategic decision. There would be an important evaluation which would be considered with its long term benefits rather than short term satisfaction.

REFERENCES


Figure 1. Genuine (Left) vs. Counterfeit (Right) Medicines

Figure 2. Latest Legislations Summary (Optel Vision, 2013)