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# UNDERSTANDING PHARMACEUTICAL SUSTAINABLE SUPPLY CHAINS – A CASE STUDY APPLICATION

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***ABSTRACT***

*A major paradigm change is occurring in the pharmaceutical industry and an increase of returns and recalls has been seen; although this industry in known for the continuous search for quality and regulatory compliance.*

*Hence, in this paper we combine the findings of previous literature reviews conducted by the authors. Essentially, explore the links between pharmaceutical drugs quality, reverse logistics, and sustainability. A case study on a global corporation manufacturing in the area of generic drug products has been selected and correlations are done with regards to returns and recalls from hospital pharmacies, in particular. With this approach it is expected to link both parties in the application of a quality by design risk management approach as well as reduce variability and risk of noncompliance.*

**Keywords:** Recall, Reverse, Sustainability, Pharmaceutical Industry

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## 1. INTRODUCTION

This paper is motivated by the changes that the pharmaceutical industry is undergoing to cope with new challenges of the global economy. Intensive globalization processes, increased competitiveness, fast changing structure of competitors, complex strategic positioning, shrinking pipelines, expiring patents, counterfeit drugs, increased regulatory scrutiny on profits and a fight for global market share, are some of the factors giving the pharmaceutical companies new challenges (PAPAGEORGIOU et al. 2004; REUTERS, 2009; ALMOR, 2009; EDWARDS, 2010).

Complex requirements are forcing pharmaceutical manufacturers to adopt more formal business processes and stricter reporting methods (SOUZA et al. 2005); Pharmaceutical companies undergo strong regulations dictated by the FDA (Food and Drugs Administration) and EMA (European Medicines Agency), for example. Even small irregularities in product or processes can lead to the elimination of the whole production batches and in the worst case enormous civil penalties (GRAUNAEUR et al. 2009). Furthermore, as John Avellanet (2010) suggests 'as long as the industry fails to take a holistic cross-functional view of regulatory compliance, risk management and operational excellence, it will continue to see consent decrease, product recalls and tremendous waste.

The pharmaceutical industry as a whole has traditionally been very profitable. On a global scale, the total size of the global pharmaceutical market has been forecasted to experience grow 4 to 6% exceeding $825 billion. The global pharmaceutical market sale is expected to grow at a 4 to 7% rate (CAGR) through 2013. Global pharmaceutical market value is expected to expand to $975+ billion by 2013 (IMS HEALTH, 2010). Besides, total pharmaceutical sales from the top 10 companies accounted for more than 4% of the total market. Additionally, the US pharmaceutical market grew by 3.0% in 2009 to $300.3 billion with highest growth in mail services and clinics; the major five Germany, France, Italy Spain and the UK, together accounted for over 60% of all European pharmaceutical sales in 2009 (PHARMACEUTICAL MARKET TRENDS, 2010). Conversely, product recalls in the pharmaceutical industry are becoming extensive and increased radically, according to CNN (2010) in 2009 alone, the Food and Drug Administration reported more than 1,984 recalls comparing to 379 from 2008, from that more than 1,000 was from a

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contract manufacturer; with an estimated $5 billion dollars and more than $700 million in fines since 2001 and billions more in lost revenues (KUMAR et al. 2009, SOUZA et al. 2007). Industry sources have estimated the total of returns cost to be 3 to 6% of the annual pharmaceutical sales (HUNTER et al. 2005). Product recalls has increased with ranges from 5 to 10% (ABBOUD & HENSLEY, 2003) with an estimated $5 billion dollars (KUMAR et al. 2009).

Despite of the industry focus on quality, pharmaceutical manufacturing has failed to keep up with other industries in terms of efficacy and productivity. Therefore, all stages of the business value chain are affected, from development of new drugs to the management of the manufacturing and supply networks (PAPAGEORGIU et al. 2001; ALMOR 2009; EDWARDS 2010). Organizations that cannot show a clear ethical conscience in supply risk significant tend to see their customers change their preferences to rival companies over time (HOWARD & HUMBY, 2008). These drivers show how organizations are facing increasing pressures from a wider range of stakeholders to engage with social and environmental corporate responsibility activities (REUTERS, 2009).

Phama Co. develops manufacturers and market generic and in-licensed pharmaceutical products within three core business. The operations span 49 countries and focus on key therapeutic areas such as anti-infectives, cardiovascular, alimentary tract and central nervous system. The injectable business markets 120 branded and non-branded injectable products in 215 dosage, strengths and forms, including 7 in-licensed products. Why Pharma Co. was selected? The 2010 revenue was $731m; by region: 61% MENA, 28% from the US and for Europe and the rest of the world accounts for 10.9%. Selecting it by segment, 23.9% are generics; 21.5% injectable drug products and 54% are branded. It has more than 400 products marketed in 2010. And an operating cash flows over $140.0m. It is the second largest generic injectable supplier by volume in the US with combined market share of more than 15%. Comparing to the beginning of this introductory section, one can expect that it is a good fit of the current pharmaceutical industry scenario.

The purpose of this paper is to combine the findings of previous literature reviews conducted by the authors. In particular, explore the links between pharmaceutical drugs quality, reverse logistics, and sustainability. After introducing the group where the case study is applied, a few critical aspects are considered. The

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organization of this paper is as follows. After this introductory section, the relevant literature of Pharmaceutical applications these three main topics has been reviewed. In section 3, discussion has been presented with implications to management. Section 4 discusses limitation, conclusions and the next steps in this research.

## 2. LITERATURE REVIEW

### 2.1. Pharmaceutical Recalls

We shall first start to comprehend the process behind drug products approval. No pharmaceutical product can be placed on the market without receiving prior authorization from the regulatory authorities, upon successful completion of a lengthy procedure for evaluating the quality, safety and efficacy of the product. Moreover; regulators around the world have become more sophisticated in ensuring that drugs are safe and effective (LEVIS & PAPAGEORGIOU, 2004; SOUZA et al. 2007). The evaluation goes primarily against the drug manufacturing regulations which are based in the FDA Good Manufacturing Practices (GMP). These regulations have been improved through a management of system approach, in particular with the harmonization between risk analysis and quality systems. These changes have improved the approach to GMP compliance, marketing compliance more comprehensive, integrated, and focused on areas of the greatest impact (ICH 2011; PLUTA & POSKA, 2010; SOUZA et al. 2007).

Changes made within an operation should be made for a reason with positive business outputs, or else quality improvements would not exist (DALE, 2003). Then again, in pharmaceuticals, any change that a company wants to make is always going to be subject to the pervasive requirements of safety, efficacy, quality and cost. This approach is making some companies to remain locked into an ancient mindset that says that providing outcome meets specifications, all is well (MCCONNEL et al. 2009). However, this type of methodology has been demonstrated fallacious, and to be likely to increase deviations and recalls (MAHBOUBIAN-JONES, 2009), as demonstrated in the introduction section.

Table 1 highlights the parallels between the types of recall classification by the FDA (Food and Drug Administration) and EMA (European Medicines Agency), as can be seen high similarities can be identified.

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Table 1 – Recall classification comparison

| | FDA | EMA |
|---|---|---|
| Class I recall | A situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse consequences or death | The defect presents a life threatening or serious risk to health |
| Class II recall | A situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse consequences is remote | The defect may cause mistreating or harm to the patient or animal, but is not life threatening or serious |
| Class II recall | A situation in which use of or exposure to a violative product is not likely to cause adverse health consequences | The defect is unlikely to cause harm to the patient, and the recall is carried out for other reasons, such as non-compliance with the market authorization or specification |

Source: FDA and EMA (2011)

The decision to recall a product may be due to comprise issues related mix-ups, volume, potency, tampering, quality of dosage forms, questioned generic substitutions, labeling defects, lacking therapeutic effects, question formulations, dispenser malfunction and container defects, for example (CHEAH et al. 2007; EMA 2011; FDA 2011). A comparison of the most common incidents registered by both FDA and EMA for the 2007 period can be found in table 2.

Table 2 - Reported Drug Quality Defects

| CDER | | EMA | |
|---|---|---|---|
| **Category** | **Incidence (%)** | **Category** | **Incidence (%)** |
| Product Defects | 27% | Product defects | 15% |
| Formulation/ Substitution | 24% | Deviation from Manufacturing Authorization | 15% |
| Labeling | 13% | Product information literature | 23% |
| Packaging | 6% | Packaging material | 14% |
| Fill Problem | 5% | Ancillary materials | 14% |
| Delivery | 13% | OOS | 12% |
| Other | 12% | GMP findings | 7% |

Source: CDER (FDA), 2007 & EMA, 2007

Although increasing, the recall or removal from the market of pharmaceutical products is not a regular event. When the product involved is a drug which is being dispensed to hospital patients, a product recall has to be carried out quickly and effectively (AUTRY, 2005; BOWERSOX & CLOSS, 1996; RITCHIE et al. 2000), the replacement with a new one should also be done promptly. Ritchie et al. (2000) also state that due to the potential severity of using expired or ineffective drugs, it is

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critical that pharmaceutical companies get the reverse logistics right from the beginning. Companies must react quickly to problems, as well as clear the supply chain of non-conforming material, so that an appropriate supply chain can be reissued to those waiting for their medications (KUMAR et al. 2009).

Summing up, no effective medicine is without risk and the benefits of a medicinal product always needs to be weighted up against its risks. The challenge to regulators is to find the right balance between timely availability of new medicines and the fact that knowledge on the safety profile is limited at the time of marketing authorization (EMA, 2011). The next section will discuss the best approaches when dealing with returns of recalled pharmaceutical products.

### 2.2. Pharmaceutical Reverse Logistic

Nowadays, pharmaceutical companies are multi-product, multi-purpose and multi-site facilities operating in different countries and dealing with a global-wide international clientele. It is very often the case that multi-national companies operate in many geographically distributed manufacturing facilities while dealing with an international business located in different customer zones. Therefore, the issues related to the trading structure of the company have to be taken into account when deciding on the optimal multi-site investment strategy of the company (LEVIS & PAPAGEORGIOU, 2004); consequently, the return of the drug products can be very complex. Returns from the pharmaceutical industry are mainly, end of shelf life drugs and recalls.

When dealing with a recalled product, the same system as a forward logistic cannot be applied, as the reverse supply chain is not a symmetrical image of the forward supply chain, due to the difference in the flows of materials and information demanded by either of them as stated by de la Fuente (2008). Plus, forecasting and planning in reverse logistics also differ from that of the forward supply chain mostly because of the high level of uncertainty concerning returned products and waste materials. With this in mind, companies who work in collaboration, become more effective and efficient with the integration within the supply chain. Graphic 1, illustrates a general pharmaceutical supply chain, highlighted are the items where our case study is reflected.

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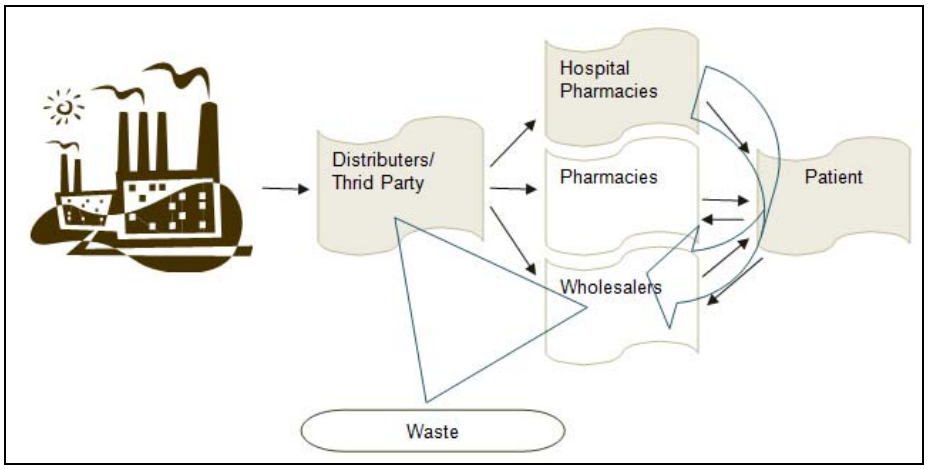


Graphic 1 – Reverse logistic for a pharmaceutical drug product

It is possible to reduce the possible transportation costs of returned materials by taking possession when delivering newly manufactured products in the area or to the same client. In this case, it is convenient to design transport to facilitate the delivery of the new products with collection of used materials and products to recover; in this case the coexistence between forward and reverse materials is possible, moreover the incorporation of reverse logistics in the existing supply chain means benefits the manufacturing company, both with regards to quality, by improving customer assistance and product delivers and collection with regard to quantity (DE LA FUENTE et al. 2008; STOCK, 1998).

In summary, product recalls are generally viewed unfavorably by investors, and a failure to their systems quality (CHEAH et al. 2007; KRUMWIEDE et al. 2002). In the same line, product returns can present a significant challenge for manufacturing firms whose primary objective is usually geared towards producing and selling products to customers. The impact of returns is sometimes disregarded, or at least, not well-understood in most firms. In others, returns are often considered just a necessary cost-of-doing business (MOLLENKOPF et al. 2011), like the pharmaceutical. During a drug product recall the company must rely on the distributors or wholesalers distribution information (KUMAR et al. 2009), such as customer service, depot repair, end-of-life manufacturing, IT management, recycling, refurbishing/screening, replacement management, returns authorization, spare parts management, transportation, warehousing and warranty management (KUMAR & PUTMAN, 2008). In addition, reverse logistics leads to an increase of customer satisfaction and recovery of value; as well as reduces pharmacy costs, maximizing

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manufacturer credit benefits and/ or reduce cycle times (FASSOULA, 2005; BIEDERMAN, 2010).

### 2.3. Pharmaceutical Sustainability

Pharmaceutical companies are being accounted as more responsible towards sustainability. As the industry experiences an increasing pressure from regulation markets in the demand for more sustainable products, the need to become more sustainable increases, and the responsibility of its activities should be expanded from the production site to the whole product chain (JORGENSEN, 2008; LINTON et al. 2007).

Pharmaceutical companies are using the Global Reporting Initiative (GRI) as a way to implement and measure their level of sustainability. The GRI guidelines have been developed and revised through a process involving various stakeholders (GRI, 2011). As part of the standard sustainability report, the GRI guidelines suggest the use of indicators to measure an organization performance in environmental, social and economic areas. They list over 100 possible indicators for companies to use, both generally applicable and organization-specific, such as total water used and recycle material for example. The GRI guidelines act as an educational vehicle and promote corporate social responsibility reporting for integrating environmental, social and economic aspects, and promote transparency and improved dialogue between business and stakeholders (VELEVA & ELLENBECKER, 2001). In addition, due to the fact that financial and social criteria are crucial parts, these truly differentiate ‘sustainability’ reporting from straight environmental reporting (MORHARDT & FREEDMAN, 2002).

The sustainability Report from 2009 for the pharmaceutical industry revealed the PSI scores (Pacific Sustainability Index (PSI) which uses two systemic questionnaires: one base questionnaire for reports across sectors and a sector specific questionnaire for companies within the same sector) for 26 largest pharmaceutical companied in the world. The findings of the reports include:

- Companies in the pharmaceuticals sector place varying importance on sustainability reporting transparency;
- As in many sectors, environmental performance was the most underreported section. Fewer than half of the sector’s companies reported using

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environmental accounting, green purchasing and chemistry, or concern for biodiversity, and fewer than 60% of the companies mentioned climate change;

- Across the sector, social reporting scores were generally better than scores for environmental reporting;
- The pharmaceutical sector certainly should continue to address social issues on which it has a direct effect, such as health disparities, as well as the important environmental challenges all corporations face;
- Many pharmaceutical companies have room for extensive improvements in their sustainability reporting, although there are some leaders in the sector setting a 'stellar' example. Ten of the 26 companies in the sample were GRI reporters, all of which finished in the top half of the reports 'Overall Grade' list (Sustainability Report 2009).

Summing up, expectations on safety and health are increasingly, more and more due to globalization. Firms in the pharmaceutical industry are now expected to be responsible to economic, societal and environmental needs. Moreover; environmental protection and sustainability cannot only be used to improve the public perception of the manufacturing efficiency as costs for input and output resources (STEGEMANN, 2010). The adoption of sustainable practices helps business to distinguish them from competition through the reduction of unnecessary risks, generation of waste, increasing efficiency of materials and energy, innovating by new and environmental friendly products and services as well as gaining operating licenses from local communities (SZÉKELY & KNIRSCH, 2005), and as soon as any harm is discovered and brought to the stakeholders attention, its root causes are identified and properly rectified (CAMPBELL, 2007). This type of approach leads to the increase business performance and profitability, sustaining their activities longer (LINTON et al. 2007). From the exposed above, one may see that very little literature merging pharmaceutical supply chains and sustainability could be found. The adoption of sustainable practices helps business to distinguish them from competition through the reduction of unnecessary risks, generation of waste, increasing efficiency of materials and energy, innovating by new and environmental friendly products and services as well as gaining operating licenses from local communities (SZÉKELY & KNIRSCH, 2005), and as soon as any harm is discovered and brought to the

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stakeholders attention, its root causes are identified and properly rectified (CAMPBELL 2007). This type of approach leads to the increase business performance and profitability, sustaining their activities longer (LINTON et al. 2007).

## 3. METHODOLOGY

In studying the dynamic, complex and context-dependent problems, it is imperative that researchers explore wider methodology options (CHASE, 1998; TRIM & LEE, 2004; KIRIDENA et al., 2009). Theory-building research in operation management often requires in-depth analysis of data from real-world situations because the knowledge base has not yet sufficiently developed to allow the use of hypothetic-deductive approaches. In this study, both quantitative and qualitative approaches have been used. There were also other issues, such time and resource constrains as well as access to data that needed to be taken into account.

Case study research can provide rich insights into complex phenomena, leading towards an understanding of their deeper structures within naturalistic settings (YIN, 1994). The contribution of these insights, particularly in the early exploratory phase, to theory building is indispensable. However, the findings of case-study research often challenged on the basis of their reliance on retrospective accounts (internal validity), individual bias (construct validity and reliability), and the idiosyncrasy (external validity) of findings (EISENHART, 1989; MEREDITH, 1998; YIN, 1994). By comparison the later versions of the grounded theory approach (STRAUSS & CORBIN, 1994; GOULDING, 2002) have some inherent strength that can effectively negate most of these limitations, but are faced with the difficulties associated with the operationalization of the methodology.

For example, entering the field with no pre-conceived ideas, achieving theoretical saturation and the level of creativity and theoretical sensitivity expected of the researcher – have all been challenges for many researchers (SUDDABY, 2006). However, in terms of overall credibility, the grounded theory approach is strongly guarded by its relatively structured and rigorous process of data collection, analysis and theory generation. As such, this study decided of a combined “grounded theory – case study” approach, informed by the interpretivist school of thought, for studying the link between pharmaceutical industry and hospital concerns towards quality issues. The methodological approach adopted is consistent with the objective of the study.

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Towards the understanding of the major complaints of the organization, semi-structure interviews were applied not only to the company in question, in the main injectable manufacturing and distribution sites, but also to several hospital pharmacies in different countries of action. With this approach it is expected to link both parties in the application of a Quality by Design (QbD) which is a "systematic, scientific, risk-based, holistic and proactive approach to pharmaceutical development that begins with predefined objective and emphases product and processes understanding and process control" (YU, 2008), risk management approach as well as reduce variability and risk of noncompliance. Subsequently, a more sustainable pharmaceutical supply chain is expected to flourish, reducing waste, and increasing corporate social responsibility.

Product complaints were evaluated from 2006 until 2011 and patterns were identified and grouped in categories. The selected categories underlined the two main regulatory agencies in the world: the USFDA and EMA. The drug product quality defects reported by the two agencies shown in Table 2 are now compared with the ones observed in Pharma Co. (table 3), in this table the identified groups of Pharma Co. are also included and a correlation can be done.

Table 3 - Reported Drug Quality Defects and correlation with Pharma Co.

| **CDER**[1] | | **EMA**[1] | | **Pharma Co.** | |
|---|---|---|---|---|---|
| **Category** | **Incidence (%)** | **Category** | **Incidence (%)** | **Category** | **Incidence (%)** |
| Product Defects | 27% | Product defects | 15% | Container closure | 6% |
| Formulation/ Substitution | 24% | Deviation from Manufacturing Authorization | 15% | Formulation (color/ dissolution/ particles) | 34% |
| Labeling | 13% | Product information literature | 23% | Labeling/packaging | 11% |
| Packaging | 6% | Packaging material | 14% | Delivery | 2% |
| Fill Problem | 5% | Ancillary materials | 14% | Fill volume | 4% |
| Delivery | 13% | OOS | 12% | ADE | 11% |
| Other | 12% | GMP findings | 7% | Other | <1% |

[1]Source: CDER (FDA), 2011 & EMA, 2007

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The principal method of data collection was semi-structured interviews (KVALE, 1996; SEIDMAN, 1998), drawing participants from different hierarchical levels of the organization was backed up by a limited document analysis. The key players for the semi-structure interviews were selected in a three step process. First, the analysis of the five years of complaints received by the pilot site and the identification of the key issues rose. Second, the identification from which main distribution countries those came from. Third, from where the complaints were reported.

Semi structured Interviews were conducted with management staff representing quality assurance, regulatory affairs, and quality compliance, from the industry side and procurement from hospitals. Each interview took about 45 to 90 min duration. Where allowed, all semi structured interviews were recorded and transcribed into text. The action of interviewing, compiling and analyzing data took around 3 months to accomplish. Participant-observer study also took place during the data collection. The use of multiple sources of evidence in case studies allows an investigator to address a broader range of historical and behavioral issues, but most importantly the developing of covering lines of inquiry, a process of triangulation and corroboration (YIN, 2009).

## 4. DISCUSSION

Even though is well known what type of returns the pharmaceutical industry receives, like end of shelf life drugs, and recalls, pharmaceutical companies need to identify the product attributes that most affect quality so that operation managers can tap internal resources, including sales, marketing, product development and technical staff. Integration of QA (Quality Assurance) processes is also a critical success factor.

The other option could be the type of policy companies are making business, in particular the use of more risk management approaches through the application of techniques such as pharmaceutical Quality by Design (QbD), for example. Part of this should involve the joint development and maintaining of performance metrics between the service provider and their business partners.

Building performance metrics into the service agreement should also be given consideration, with on-going measurement of results taking place (SARTORI, 2011),

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as global, green and social capital, can have in a firms overall economic security. In addition, direct interaction with supply chain partners can enable a company to reduce total inquiry levels, decrease product obsolescence, lower transaction costs, react more quickly to changes in the market, and respond more promptly to customer requests.

Managers can improve their materials management performance by first understanding how their decisions affect the purchasing, storage, handling, and asset recovery activities throughout their organization (MARKEY & DAVIS, 2007). From the exposed analysis, one could see that, the major paradigm change the industry is facing, i.e. the increase of recalls, is making companies to understand their process better, from the research and development phase by designing the products beyond compliance regulations until the end user, in this particular case the hospital patient. With this approach it is expected that drug product recalls and returns will decrease. It is also expected the reduction of wasted revenues in reverse logistic operations and an improvement of more sustainable pharmaceutical supply chains.

The impact of returns is ignored, or at minimum, not well-understood in many firms. In others, returns are often considered just a necessary cost-of-doing business (BLACKBURN et al. 2004). With such perspective, firms focus on cost minimization at an operational level, missing opportunities to recapture value for themselves and their customers, and build customer loyalty (MOLLENKOPFT et al. 2007). Managing costs as well as customer relationships highlights the strategic role that both marketing and operations functions can perform in returns management. Effective returns processing can contribute to customer's perception of value in dealing with a supplier firm.

Much of the value created through these activities relates to the physical flow of returned product, and the timeliness and accuracy of the operations group in processing such products. Linked to the operational processing is the ability to the accounting group to reconcile physical flows with financial and information flows in order to issue credit in a timely and accurate manner (STOCK & MULKI 2009). On the reverse logistics side, if the company performing the returns function on behalf of the manufacturer has adopted the right systems and technology to perform those tasks, there are a number of efficiencies that can be gained. Moreover, firms that

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effectively manage the reverse flow of goods benefit through decreased resource investment levels and cost reduction. It has been predicted that firms that choose to formalize their reverse logistics programs may be rewarded in two ways, via improved management of liberally following returns and subsequently, increases in overall reverse logistics effectiveness (AUTRY, 2005).

Product quality can affect a customer's sense of value in multiple ways. Ultimately, consumers or end users will evaluate the value they receive from the use of a product, and will evaluate cost/benefits associated with the price paid (BOWMAN & AMBROSINI, 2000; GRONROOS 2008). Poor quality products will create excessive return situations for retailers, creating operational and profitability concerns for them. Similarly poor packaging quality can induce transit damage or product degradation when in storage or on the retail shelf. Retailers may perceive customer value through supplier efforts to certify product quality and to ensure compliance with industry or regulatory standards (MOLLENKOPF et al. 2011).

Organizations of any size increasingly stress their efforts at cost reduction and continuous improvement of customer satisfaction, which are the main parameters of competiveness. Cost of quality, although it is not established as a component of the final cost and is separately measured in all organizations, is a metric reflecting the overall performance of an organization in relation to both those parameters and it can be used as a progress indicator. Reverse logistics management can provide a continuing and proactive commitment to delivering value for money, by eliminating waste without in any way diminishing the quality level (Ritchie et al. 2000). Through the reduction of unnecessary risks, generation of waste, increasing efficiency of materials and energy, innovating by new and environmental friendly products and service, as well as, gaining operating licenses from local communities (SZÉKELY & KNIRSCH, 2005). As soon as any harm is discovered and brought to the stakeholder's attention, its root causes are identified and properly rectified (CAMPBELL, 2007). This leads to the increase business performance and profitability, sustaining their activities longer (LINTON et al. 2007).

No questions asked, sustainability is of relevant interest, research in this subject has been dedicated on financial impacts of environmental behaviors (MARKEY & DAVIS, 2007). Markey and Davis (2007) also refer that little work has been made addressing the impact that a sustainable supply chain, has on the

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protection of global, green and social capital, can have in a firms overall economic security; as well as the potential development of a competitive advantage using a sustainable supply chain as a base and securing stakeholder approval (HART, 1997). Moreover, Hart (2003) states that it is of increase importance for firms to evaluate the impact that a sustainable supply chain strategy has on the triple bottom line (3BL), due to the challenging global economy, in particular companies should begin to evaluate not only their supply chains impact on their traditional financial bottom line, but also on their social/ethical and environmental performance.

Companies have been developing and using environmental sustainability indicators (VELEVA & ELLENBECKER, 2000), as a manner to improve a company's public image gaining competitive advantage through product/service differentiation (PORTER, 1998, MAHLER, 2007). In addition, direct interaction with supply chain partners can enable a company to reduce total inquiry levels, decrease product obsolescence, lower transaction costs, react more quickly to changes in the market, and respond more promptly to customer requests. Managers can improve their materials management performance by fist understanding how their decisions affect the purchasing, storage, handling, and asset recovery activities throughout their organization (MARKEY & DAVIS 2007).

To sum up, the strategic importance of effectively managing returns is evident as firms seek to maximize the value they create for themselves and for customers. When firms view returns as just a cost center or a regulatory compliance issue, they miss potential value that can be created for themselves and their customers. Mollenkopf and Closs (2005) point out this value can only be created by understanding the multi-functional components of marketing, logistics, operations and finance/ accounting functions which actively engage in managing return products (MOLLENKOPF et al. 2007, SKINNER et al. 2008). This is also in line with Souza et al. (2007) regarding the necessity for pharmaceutical companies to identify the product attributes that most affect quality so that operation managers can tap internal sources, including sales, marketing, product development and technical staff. Integration of QA processes is also a critical success factor. Part of this should involve the joint development and maintaining of performance metrics between the service provider and their business partners. Building performance metrics into the service agreement should also be given consideration, with on-going measurement

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of results taking place on a quarterly or yearly basis (SARTORI, 2011). No effective medicine is without risk and the benefits of a medicinal product always need to be weighted up against its risks. The challenge to regulators is to find the right balance between timely availability of new medicines and the fact that knowledge on the safety profile is limited at the time of marketing authorization (EMA 2011).

## 5. CONCLUSION

The goal of this paper was to merge finding from previous work developed by the authors in areas like pharmaceutical recalls, retains and sustainable practices, challenges that the industry is facing not only to be accounted as responsible, but also to keep up with other industries.

The change in paradigm is obliging companies to gain more knowledge of their process better from the research and development phase (R&D), by designing drug products, generics or branded, beyond compliance to regulations until the end user, in this particular case the hospital patient. As well as adding more value to their products. This could be observed from the exposed analysis.

With the application of a Quality-by-Design (QbD) Risk Management approach it is expected a substantial decrease in drug product recalls and pharmaceutical returns. Leading to a reduction of wasted revenues in reverse logistic operations and an improvement of more sustainable pharmaceutical supply chains as well as the increase of value added to all parties involved.

From this study a country comparison can be done with regards to the health system in place in each of the selected countries of this study. Moreover, a cause-effect, action-reaction type relationship (ARA methodology Activities-Relations-Actions) can be applied which is the next step of our research project, identifying the patters and action taking with some causal understanding (to make meaning of the observed patterns).

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