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Risk Monitoring through Traceability Information Model

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***Abstract*—**This paper shows a traceability framework for supply risk monitoring, beginning with the identification, analysis, and evaluation of the supply chain risk and focusing on the supply operations of the Health Care Institutions with oncology services in Bogota, Colombia. It includes a brief presentation of the state of the art of the Supply Chain Risk Management and traceability systems in logistics operations, and it concludes with the methodology to integrate the SCRM model with the traceability system.

***Keywords*—**Supply risk, risk monitoring, supply chain risk management, cancer drugs, traceability systems.

I. Introduction

STARTING with an investigation carried out by the sepro research group of National University of Colombia, a common cause affecting the fulfillment of oncology programs goals on Bogota cancer drugs supply chain is the materialization of supply risks. The main risk factors were in each of the logistic processes, which are associated mainly with the conditions of chain agents operation, the weakness of the used technological infrastructure and the current normativity for this sector.

The study established that the main factors of supply risk associated with the relationship of the distributors (DI) and Preparation Centers (PC) with Health Care Institutions (HI) are related to absence of inventory levels information, changes in the demand and the response levels by the providers. This situation making vulnerable to the supply chain, generating ruptures in the flow of products, long times for responding to the patient, high costs of management inventory, high cost intermediation in purchase process, instability of the service levels and bad perception from patients in general.

In the development of the study, the methodology of risk management that includes the risk identification, analysis and evaluation was applied to establish handling actions. Based on the parameters of risk determined by a group of experts, we proceeded to typify the risk in accordance with the exhibition and impact level on the indexed operations. The performance indexes of the variables associated with risk factors in the SC, as were identified the basis to determine the requests and approaches in the traceability system. This paper presents the methodology, the conclusions and recommendations proposed.

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II. Supply Chain Risk

Several studies have dealt with supply chain risk. The general definition refers to the probability of occurrence of unexpected events that can cause interruptions or perturbations in the flow of materials, products and information in the supply chain. The supply chain risks have been classified mainly as internal risks (of the SC) and external risks (of the environment). In [1], five risks were established inside this typology: process risk, control risk, demand risk, supply risk and environmental risk. In another similar classification eight categories were proposed: supply risks, operative risks, demand risk, safety risk, macro risks, political risks, competitive risks and resources risks [2].

In a study presented in [3], it was noticed that 60 % of the most recurring problems that can have major influence in the SC risk, has to do with debts, availability of information, the demand known, restrictions in the deliveries and the coordination in the SC. Others, in less percentage but with incidence in the SC performance, are related to the rigidity of infrastructure, operation costs, SC integration and technology. The risk level in a SC is affected by its size, cycle and way of operation. The relations become more complex as the number of providers and links in the chain increase.

The uncertainty increases the SC risk, and the risk is a consequence of the external and internal uncertainty that affects the chain. [3]. In the large logistics cycles, the uncertainty can affect the availability time and increase the risk of inventories obsoleteness. The use of systems to respond on time and the large number of types of products may cause difficulty for maintaining stable relations in the supplying operations, mainly because of their capacities of response and the complexity in the support services.

The SC vulnerability is presented as an exhibition to the serious perturbations that can affect its performance and the propensity to the risk materialization [4]. The possible losses in which the company might incur are the result of the SC vulnerability by an interruption for different events. In accordance with [5], four vulnerability categories appear in the supply chain: financial, strategic, operational and natural disasters. In this context, there must be focused on the reduction of vulnerability that will allow for improving the general performance.

Although, novel models have been developed and policies have been implemented in the SC management on how to reduce the delivery times, minimizing the handling costs and improving the relations between the links of the chain, difficulties still appear as important in the supplying systems, [6] defines system instability that arises with the irregular but

persistent fluctuation of the production, income, and demand level, the changes of the market labor and services, the inventories, among many others, which affect all kinds of industries and have a negative effect on the economy.

This instability in the SC affects the different components of the system, from providers, producers and distributors to the final customer. Delays in the response time, excessive inventories, high costs of technology investment and services, the oversized labor and resources, the non-fulfillment to the requisites of the customer, may produce an unstable system. This instability in the SC is possible to observe from a vulnerability perspective, which is the risk that may affect the different links of the chain.

As a response to the latent risk in the different logistic operations upstream and downstream, methodologies have been developed and applied methodologies of supply chain risk management (SCRM). In [7], the SCRM is defined as the management of the external risks through a coordinated approach between the members of the SC to reduce the chain vulnerability.

The SCRM can be tackled from two dimensions; the first one deals with the operational risks and risks from the interruption in the SC and the other one, with the risk mitigation approach in the supplying, demand, products, and the information management. [8].

The SC resilience has been tackled by different authors, and it is possible to define it as the SC adaptation aptitude to be prepared for unexpected events, to respond to the interruptions, and to recover of these to maintain the continuity of the operations in the desired level [5]. The resilience processes are flexible and agile and they can change quickly. [9]. The agility in the SC is one of most effective ways of achieving the recovery capacity, the agile SC gives faster response to the new conditions. [10]

III. Cancer Drugs Supply Chain

The supply chain of cancer drugs, object of study of this paper, is composed by distributors (DI), Preparation Centers (PC) and health care institutions (HI). There are other agents involved in the chain, such as pharmaceutical laboratories, third-party logistics providers and medical waste treatment providers, which do not take part of this study. DI corresponds to drug suppliers, wholesalers and traders that perform activities of local purchases and importation, for distribution in different regions of the country. The HI correspond to hospitals and clinics specialized in oncology services, responsible for the treatment of patients, which is by dispensing drugs in pharmacies and through the application of chemotherapy which can be done in two different modalities: inpatient and outpatient. This will depend on condition of the patient, concomitant diseases and the type of medication to receive [12]. The PC, are infrastructures enabled by the Colombian government for the production, processing, preparation, mixing, adaptation and adjustment of dose concentrations and repacking or repackaging of chemotherapy. In some cases, vertical integration is presented in the HI, which not only performs patient care, but also prepares their own mix. The chain operates in a decentralized manner, even if business groups have organizations that perform pharmacy functions, preparation plants and specialized clinics.

IV. Drug Supply Chain Flows

The review of the operation of the drug network is focused on the flow of goods, materials and information, presented in Figure 1, which involves flows between DI, PC and HI. The model of operation in these three links is given by the interactions and functions of each type of organization.

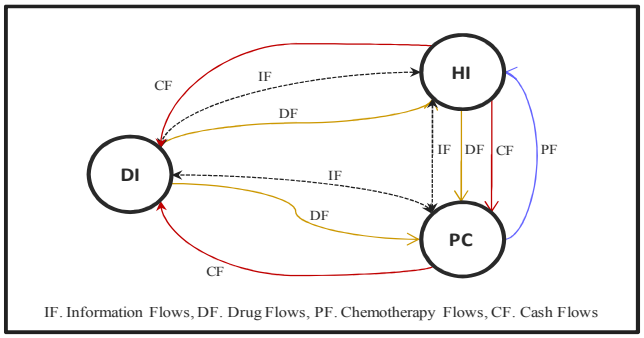

Fig. 1 Flows Supply Chain, own source

In the relationship of HI with PC, physical flows, money and information is showed according to the negotiation between these links, which defines the way of operation. The first case occurs when the HI provider contracts directly with DI the purchase of medicines, makes the reception and storage, and according to the medical program for the application of chemotherapy, presents basic medicines for the PC to develop the respective dose and return to the HI for the application of treatments. These operations generate costs in the displacements that must be done, but reduce, in most cases, the costs of intermediation in the purchase of medicines. The second case occurs when the PC purchases drugs to DI, provides storage, handling and supplies the preparations according to HI requests for application of chemotherapy. In both cases, these models have operational inefficiencies movements that affect the performance, but those are favorable to HI that lack the infrastructure necessary to mix and dose the preparation. Information flows are presented to the issuance of purchase orders, the review of inventory levels, communication of the schedule of the oncology treatment, the requests and inquiries from agents. The flow of money is not taken into account in this study.

V. Drug Supply Chain Risk

Below are the risks identified in the chain, whose evaluation resulted in significant risk and unacceptable risk, according to the evaluation table in Table I. and applying the general methodology of risk management in the supply chain.

TABLE I
RISK EVALUATION

Probability of occurrence	High	RM	RI	RE
	Medium	RT	RM	RI
	Low	RA	RT	RM
		Slight	Moderate	Catastrophic
		Impact		

RA	Acceptable Risk
RT	Tolerable Risk
RM	Moderate Risk
RI	Important risk
RE	Unacceptable risk

TABLE II
NEGOTIATION RISK

Risk factor	Risk	Variables for traceability
Negotiation conditions	R1. Increases in the purchase price of medicines	Price negotiation baseline
Unique suppliers		% of intermediation on purchase
Policies on drug pricing		Periodic price variation
Intermediation of commercialization		Suppliers Evaluation
		Negotiation capacity
		Exchange rate
		Availability of the drug in the market

TABLE III
SUPPLY RISK

Risk Factors	Risk	Variables for traceability
Responsiveness of suppliers	R2. Cuts in the supply of drugs	Purchase orders on time
Flexibility of suppliers		Availability of the drug on the market
Increased demand versus offer in the market	R3. Variations in the amount of product received	Availability of logistics services
Availability of medication		Time of shortage
Errors in forecasting demand	R4. Delays in the supply of drugs	Stock levels
		Supplier lead time
	R5. Shortages of drugs	Reliability of forecasts

TABLE IV
INFORMATION RISK

Risk Factors	Risk	Variables for traceability
Information available on the SC	R6. Asymmetries of information among the agents of the SC	State of supply operations
Lack of coordination among chain actors		State of storage operations
Absence of integrated information systems	R7. Cuts of information flow	State distribution operations
		Integration of the information systems
	R8. Uncertainty in logistics operations	

VI. INFORMATION SYSTEMS AS A TOOL FOR TRACEABILITY SYSTEM

According to [12], the supply chain defines the traceability as "the necessary information system to provide the record of products and services from the origin up to the point of sale", in such a way that the information system may be defined as a game of interrelated components that capture, store, treat and distribute the information to support the decision making process and the control of an organization [15].

The basic idea of traceability is to create and to maintain a "track of information" that continues to a certain extent the way taken a physical product happened in a process of production. According to [13], the information that a company provides allows reaching the visibility in the supply chain and therefore, the traceability. An integrated information system is needed consequently and developed in order to obtain the traceability [16]. The reliability of the traceability depends on whether the information is real or not [17].

The traceability systems provide to the companies the aptitude to trace the necessary information from the beginning to the end [18]. Therefore, every company must develop the scope and precision of its system to allow the strategic and operational needs to meet the production process, the specific product needs and the targets of traceability.

According to[17], current investigations on traceability system from an information administration perspective, define a traceability system, in essence, as an information control instrument that is only useful if the information is excellent, reliable, and easily accessible [14].

An efficient traceability implies that the information administration is precise, which means to know the exact position, the record of the product many place of the supply chain [17]. Some advantages, that the reliability of the information, are the following:

- The traceability system assures the transparence of the distribution route.
- The system could provide the information to all the agents of the chain of a prompt and active way.

One of the targets is to reduce the critical risk points of the supply chain, which might diminish according to [19] after the implementation of the traceability information system.

To diminish the uncertainty in the supply chain risk, it is necessary to establish a culture of cooperation between the agents of the chain. The traceability system plays a very

important role to define the structure of the information and communication between the agents of the supply chain. According to [20], the information systems facilitate the unequivocal change of information between the supply chain agents.

Finally, the information models describe the information systems of an organization [20]. Two important components of information models are business process and associate information resources. The information models can be used in three ways: (1) identification of information system, (2) the standardization for information system development, and (3) the information system for different organizational functions.

VII. Traceability Model Integrated with Supply Chain Risk Model

The integration of the traceability model with the SCRM has a systemic approach and is a fundamental component to reduce and to handle the risk in every part of the supply chain.

The traceability model focused on the risk factors of SC shown in the tables 2, 3 and 4, included monitoring permanently the risk generators. The information system that is adopted must have the aptitude to measure in real-time these factors and risk indicators, across the integration of the software and databases to the chain agents. The information repository will allow evaluation factor state and current risks.

The identification, analysis and evaluation of risk, will establish the reduction, mitigation, transference, elimination or acceptance actions, necessary to maintain the performance of the SC.

The actions of recovery after the presented events will be established under stages previously planned, which will make the chain to be resilient and to develop agile adoption capacities in accordance with the dynamics of internal conditions and the environment.

The results of this cycle will guide the addressing of the SC by means of a systemic approach endorsed with real-time information of the state of the main SC components. Finally, it has to be guaranteed that all the knowledge of this process is managed and incorporated as part of the growth and the obtained experiences.

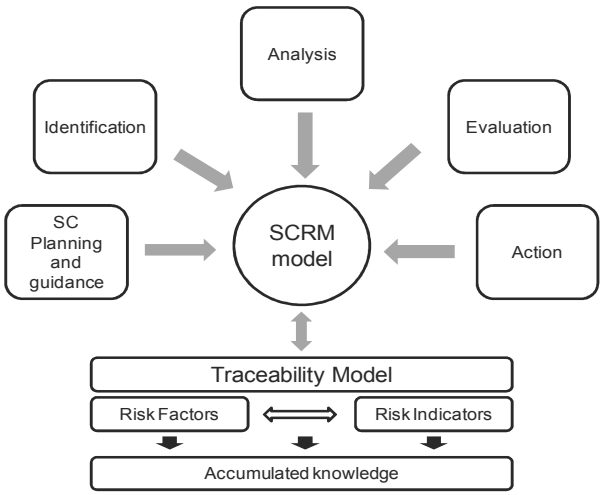

Fig. 2 Traceability model integrated with SCRM model

VIII. Conclusion

Uncertainty and risk can cause significant impact in the SC affecting the patient's health. Through a traceability model, the risk can be predicted and monitored. The risk indicators are the basis for determining the level of risk. Knowing status of the risk factors, will determine the degree of exposure on the activities of the SC. In this sense the planning and guidance stage is essential to reduce vulnerability and decision-making on SCRM.

It is then possible to improve the performance of the supply chain, through the monitoring of the risk with a traceability system, enabling to reduce levels of uncertainty in the logistical operation of the SC.

This model is the starting point to implement an information traceability system to manage risk in the SC of cancer drugs in Bogota, which allows improving the chain performance, reduce its vulnerability to risk and generate adaptation capacity to adverse situations.

The main reason to take info systems into account is because they allow obtaining information in a faster and more effective way.

IX. Future Research

This model allows establishing the base for future research, for developing methodologies and systems to implement SCRM programs, involving traceability and tracking components, with the design and quantification of indicators, for anticipating undesired situations and develop technologies for feedback of operational status of the SC.

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