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Domain Ontology for Risks Management in Pharmaceutical Supply Chain

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Abstract

The partners of pharmaceutical supply chain need access to a set of information and knowledge distributed across several information systems to make its choices efficiently while taking into consideration all risks or events that can prevent all or part of the efficient flows in strategic, tactical or operational level. In this paper, we propose a decision support for manage these risks and events how would have negative effect and can disrupt the good function of the pharmaceutical supply chain.

Keywords: *Risks, Supply chain, Pharmaceuticals product, Decision Support.*

1. Introduction

The pharmaceutical supply chain is a set of processes and operations involved in the discovery, development and manufacturing of pharmaceuticals products. It aims to provide medicines with the good quality at the right time and the right place and customers with optimal cost to be consistent with the objectives of the health system [1]. Thus, there are risks in a pharmaceutical supply chain when unexpected events might disrupt the flow of products from initial suppliers through to final customers. Indeed, the control and management of these risks become a key issue for the overall performance of pharmaceuticals organizations.

A profound and critical analysis of the literature review [2] allows extracting and selecting twenty-five risks classified into six categories: process risks, demand-side risks, procurement risks, environmental risks, market risks and financial risks. Other risks classification is proposed by Benazzouz and al. [3]: environmental and external risks, risks related to the internal organization of each partner and risks related to the interactions between the various partners in the pharmaceutical supply chain. With the emergence of ontologies as a new paradigm of information modelling, controlling and sharing of these risks between different partners in pharmaceutical supply chain has become possible. In fact, ontologies not only allow exchange risks between systems, but they also offer the possibility of inferring new risks from already existing ones.

The aim of this paper is to present ontologies as an integrating element and as an efficient support for identifying, analyzing and sharing the risks related to the pharmaceutical supply chain and making the management of these risks explicit and common between the different partners.

2. Ontology: presentation

The ontology is a new modelling paradigm of knowledge borrowed from philosophy and developed as part of the semantic web. They define the concepts, relationships between concepts, choices and constraints that must be respected. Indeed, an ontology defines an organised whole (often in the form of taxonomy or semantic network) of usable concepts for formulating knowledge.

Ontologies specify explicitly the conceptual knowledge using a formal or semi-formal language. For the community of knowledge engineering, the ontology term is often associated with a meta-model that describes the contents of a database, its properties, it utilisation and the vocabulary and syntax provided by the representation language.

2.1 *Ontology life cycle*

Ontology has a life cycle that needs to be precise. First of all, we need to start with a needs study to know what the

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ontology is for, then build it, yet distribute it before using it (Figure 1).

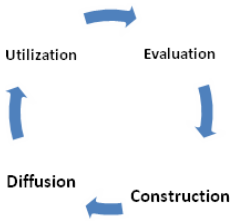

Fig. 1 Ontology life cycle

The needs identification and evaluation are the first steps in the constructing process of ontology. They serve to identify the construction objectives and future users of the ontology and to specify the application domain.
Conceptualisation allows expressing domain knowledge through two techniques: interviews with experts or/and manual or automatic analysis of documents related to the ontology domain. The result of this step is an informal conceptual model expressed in natural language. This conceptual model must subsequently construct in a semi-formal language to make ontology usable by the machines. After the ontology utilisation, the needs can be evaluated and the process of reconstruction can be triggered.
Any domain needs powerful and well-defined ontologies, for this reason several methods and methodologies of ontology construction have appeared in the ontological engineering domain.

2.2 *Types and development tools of ontology*

There are several types of ontologies and its applications are diverse. We suggest in this context the classification proposed by [4] which proposes four types of ontologies:

- Generic ontologies or upper ontologies: are independent conceptualisations of a problem or a particular area, for example: space, time, objective and event.
- Domain ontologies: describe the vocabulary related to an area such as health, industry and education. In addition, it can describe the vocabulary associated with a task such as planning, diagnosis or purchase. This type of ontology defines the necessary knowledge to solving a particular type of work.
- Application ontologies: provide concepts based on a specific task and a particular area.
- Representation ontologies: specify conceptualisations that underlie knowledge representation formalisms.

Also, there are various ontology languages like XML, RDF(S), DAML + OIL and OWL. Many ontology tools have been developed for implementing metadata of ontology using these languages as:

- The Ontolingua server [5] located at Stanford University allows a user or group of users to view existing ontologies and cooperatively build new ontologies. A standard web browser affects access to the server.
- WebOnto [6] developed at Knowledge Media Institute at the Open University. It is a web-based tool and mainly graphic used for cooperatively build ontologies.
- ProtégéWin [7] was designed for the Department of Informatics Medical University of Stanford, especially for building ontologies. Once the ontology built, ProtégéWin automatically generates a knowledge acquisition tool for ontology instances.
- ODE [8] ontology design environment (ODE) is a construction support tool for ontology in ‘knowledge level’, which is independent of any formal language. It includes verification tools for ontology coherence.
- OWLGred [9] allows creating, editing and viewing the ontologies. It offers a comprehensive overview of OWL based on UML. OWLGred shows classes as UML classes, properties as class attributes, objects as associations and cardinality restrictions and associations between classes as UML multiplicities.

3. Domain ontology for risks in pharmaceutical supply chain

3.1 Risks in pharmaceutical supply chain

The issues related to risks in supply chains have become

an important research topic. It is therefore necessary initially to define the concept of risk in this context. Several studies focus on the aspect of risk in the pharmaceutical supply chain [2, 3, 10, 11, 12]. [3] Present a classification of the various risks and errors that can negatively affect the availability of pharmaceutical products in the public hospital by a qualitative study made in the level of the central structures involved in the pharmaceuticals supply chain, regional hospitals, provincial hospitals and university hospital centers.

In order to structure these risks in the form of a graphical representation that is easy to understand and to communicate, the Ishikawa method is used. It makes possible to prioritise, organise and analyse the major categories of all the causes identified during the study in the form of a diagram.

They have constructed a 6M diagram (Figure 2) whose causes are classified into six categories, all of which begin with the letter M: milieu, material, mind power, method, management, and money.

[2, 10] identify a table as a risk register (Table 1) that based on the literature review and reports of the Moroccan Health Ministry. This risk register classified risks related to the pharmaceutical supply chain into six categories:

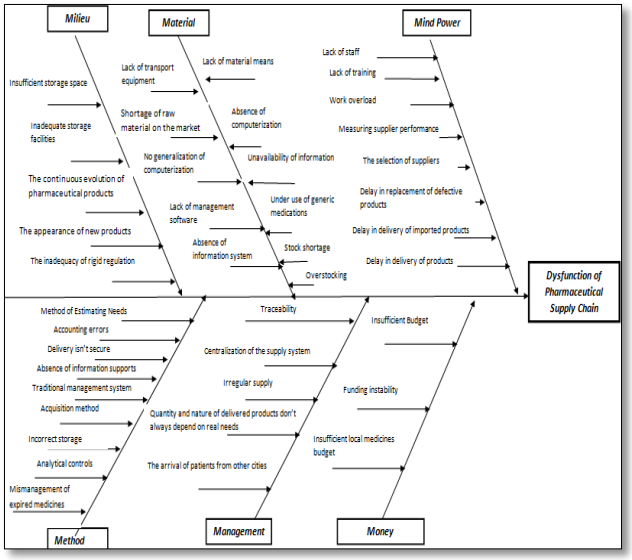

Fig. 2 Risks in pharmaceutical Supply Chain [3]

- Process risks includes six risks at operational level related to inventory management, workers skills, information flow, production and acquisition, transport, and planning and control. Outsourcing and strategy are associated to the tactical and strategic levels.
- Demand-related risks includes risk of customer demand and organisation forecasts.
- Supply-related risks: at the strategic level, supply-related risks can be associated with partnership with supplier, contract and agreements and counterfeit. At the operational level, these risks can be associated with raw material, information systems or timely delivery.
- Environmental risks: natural disasters and terrorism, political issues and waste management for suppliers; and all external events can also prevent proper operation of supply chain.
- Market risks encompass the risk of financial loss resulting from movements in market prices.
- Financial risks generally arise due to instability and losses in the financial market caused by movements in stock prices, currencies, interest rates and more.

Table1.Risks register

Categories		Sub-Categories		Description
Process Risks	R1	1.1	Inventory management	The stock's rupture
				Overage
				Limited Capacity
				Poor storage conditions
				Absence of a software inventory management
				Error in the calculation of the security stock
		1.2	Workers skills	Lack of skills
		1.3	Information flow	Problem of information exchanges between the various actors
				Problem of traceability in the different steps of the management cycle
				Poor data quality
		1.4	Production and acquisition	Defect related to the manufacturer's production capacity
		1.5	Transport	Transport doesn't meet the standards
				Means not adapted to the various types of pharmaceuticals.
				Annual cost allocated to transport is very high
				Limited Capacity
		1.6	Planning and Control	Planning doesn't take into account the real needs of services
				Lack of control and use monitoring of pharmaceutical products in services
		1.7	The Outsourcing	Outsourcing transport can cause problems at delivery
		1.8	The strategies	The strategy adopted by SD for the purchase and storage is centralized who generates stock outs and overstocks
		1.9	Human Resources	Lack of human resources
Demand-related risks	R2		Customer Needs	Poor estimate of needs
Supply-related risks	R3	3.1	Partnership with the supplier	Failure to respect specifications (Delivery)
				Monopoly
		3.2	Supply and Supplier Outcome	Delay in the supply
				Poor tender management
		3.3	Raw material quality	Poor quality of raw materials can produce defective products
		3.4	Contract & Agreements	No contract enforcement
		3.5	Flexibility of supplier	Poor flexibility in the relations between SD-supplier and SD-hospital center
		3.6	Delivery reliability	Low capacity to deliver the quantity demanded of a product to the desired date
		3.7	Information systems	Absence of an information system
		3.8	Flexibility in product variety	Poor flexibility of suppliers
		3.9	Quality Management System	Absence of a system that can manage the quality
		3.10	Quality Management System	Failure to respect delivery times for suppliers
		3.11	Counterfeit	Diversion of products and the quality problems
		3.12	Raw materials	Unavailability of raw materials at suppliers
		3.13	Manufacture	Manufactured pharmaceutical products may declare non-compliant
				Complexity of manufacturing process

Table1.Risks register (The following)

Categories		Sub-Categories		Description
Environmental Risks	R4	4.1	Natural disasters & terrorism	
		4.2	Political issues	
		4.3	Waste management for suppliers	
Risks related to the Market	R5			Increasing the size of government procurement, which pose new risks
				Raw materials prices
				Interest rates
Financial risks	R6			The purchase of pharmaceutical products doesn't depend on the needs expressed by the various hospital centers but on the notified budget

3.2 Domain ontology (DO)

The proposed DO is a shared vocabulary between different partners of the pharmaceuticals supply chain in Morocco. A first job is to build a corpus, which includes the definition and classification of risk and the relationship between partners.

This DO aims primarily to "assemble and unify the terms related to risk management." In addition, it provides a vocabulary of concepts used in the domain with their definition, similar concepts, related concepts, etc. The conception of this ontology was made in the unified modelling language (UML) [10]. It is a simple formalism that facilitates the process of the ontology constitution.

UML profiles used to specialise a UML model. They can be used in all models without modifying their structure. Moreover, it should be noted that such reasoning, although it is possible, is not exploitable by a machine because UML profiles do not allow any form of automatic semantic processing. In effect, the DO modelling by UML must turn into formal ontology. It can then be edited in protected and enriched environment.

For this reason [10] and [12] suggest OWLGred tool to automatically switch the conceptual model; expressed as a UML class diagram; to the formal semantic ontology represented by OWL (Figure 3).

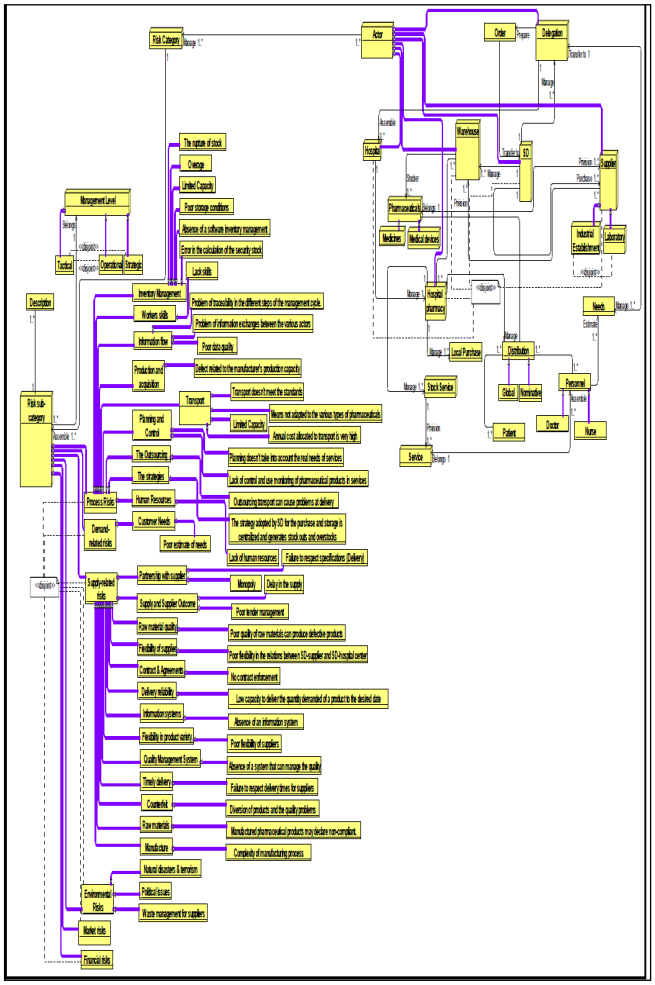

Fig. 3 Domain ontology for risks management in the pharmaceutical supply chain [12]

The proposed OD provides three functions: identifying risks in the pharmaceutical supply chain at the level of the public hospitals, semantic description of each risk category and risk management by the various partners in the chain.

- Risks identification in the pharmaceutical supply chain at the level of the public hospitals: the system users can identify the different risks that may prevent access to medicines and classify them according to three levels of management (strategic, tactical and operational) (Figure 4).
- Semantic description of each risk category: from errors and problems description in the pharmaceutical supply chain presented in the first part of this paper, the users can classify the risk to subcategories (Figure 4).
- Risk management by the various partners in the pharmaceutical supply chain: to complete the identification, the users may need information about other chain partners. The reasoning by ontologies enables the sharing of different risks, information and knowledge related to the domain of medicines supply in the public hospitals (Figure 5).

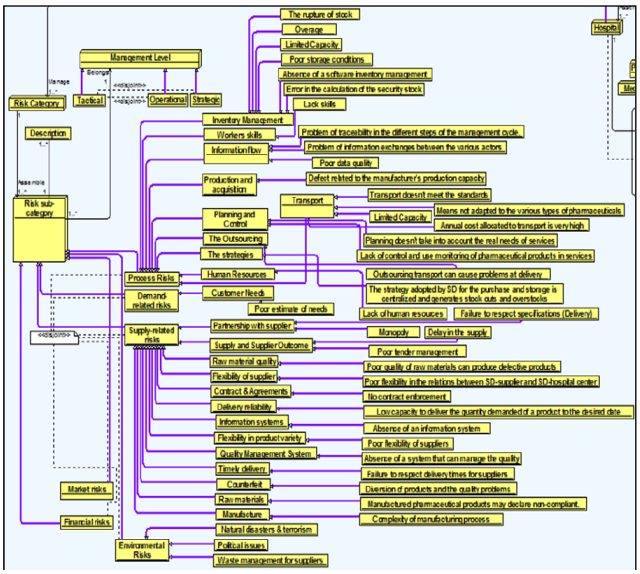

Fig. 4 OD for risk management in pharmaceutical supply chain

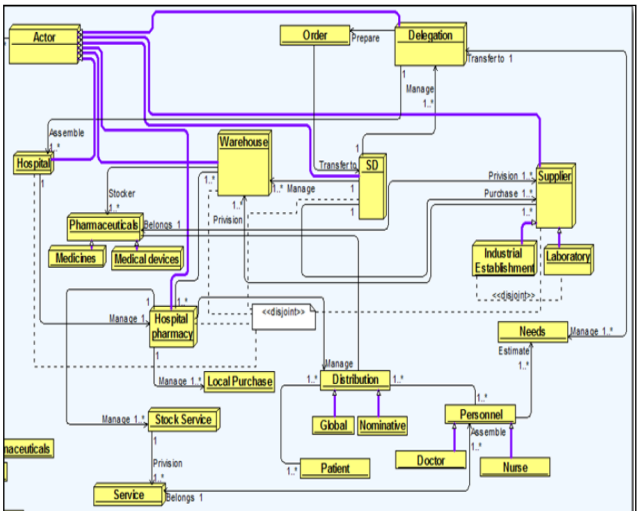

Fig. 5 The partners OD for the pharmaceutical supply chain

4. Conclusions

This paper presents a decision support system (DO) that identifies and manages the risks in the pharmaceutical supply chain. A classification of the works that have already addressed this problem is made in relation to categories, sub-categories and levels. This classification has guided us to describe the system of supply, storage and distribution for the pharmaceutical products. By determining the different partners involved in this supply chain. The proposed system provides three functions: identifying risks in the medicines supply chain at the level of the public hospitals (except University Hospital Center), semantic description of each risk category and risk management by the various partners in the chain. To develop this work, the OD proposed will be validated in a larger context with the final users.

Notes on contributors

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