MODERN APPROACHES IN LOGISTIC PROCESSES MANAGEMENT FOR PHARMACEUTICAL PRODUCTS

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ABSTRACT

The pharmaceutical products market possess tow main characteristics – is one of the oldest market in the world and the one of the most government restricted mass market of all the time.

The logistic processes associated with this market are particular and specialized in terms of flows, actors and production means and equipments.

The management of all processes involved by the way of a pharmaceutical product from the dispatch of a medicine product to the patient tends to become a very specialized sub-branch of management with rules, functions and theory that differs it from the rest of supply chain management general rules. Continuous improvement of the processes conducts to better performance of the management and knowledge based theory deployment.

Present paper main purpose is to identify the similarities and most differences of the pharmaceutical products' logistic processes, compare to the general supply management processes and also to emphasis the management particularities of the pharmaceutical products' logistic processes.

1. Specific elements of logistic processes management of pharmaceutical industry

Pharmaceutical products market is one of the oldest traditional markets in the world and its functionalities are subject of strict rules and regulations by local authorities in the whole world and also in European Union. From these reasons the supporting activities of this market presents differences comparing to similar markets from the point of view of the products, production facilities, distribution and marketing.

The rules and regulations on the pharmaceutical market are present in pricing levels – maximal prices- and markups through the whole distribution chain. In the same time there the quality parameters of the distribution activities are set by the laws and regulations. These parameters are related to the quality of the products but also to the mandatory organizational issues concerning the logistic chain, meant after all to insure the appropriate response to the patient need and the correct choice of the products.

At global level the pharmaceutical and pharmaceutical assimilated products market is comparable from the point of view of total turnover with the petroleum products market, comparison that gives a good idea of the dimensions of the processes and activities involved in this market. The economic chain of pharmaceutical products market mainly consist in producers, pre-wholesalers, wholesalers and retailers – pharmacies – each one of them with specific activities and operations.

For each single specific part of the logistic chain of production and distribution there are rules set up in laws at national or transnational level, regulations and best practice for manufacturing, storage, transportation and distribution of the pharmaceutical products.

The flow of pharmaceutical products from the producers to the final consumer – patient- is subject of logistic processes, presented and analyzed in the present paper from the management specificity of these processes.

Strict rules and regulations on the pharmaceutical products market mean that all the activities of the operators on this market are according to above mentioned regulations, with fixed price levels and markups, thing that, without any doubt will lead to a permanent concern of efficiency and competitiveness given by a better operational management activities and a better and efficient logistic processes. In the logistic chain, the wholesalers are one of the most important link in the pharmaceutical products market, being mainly specialized operators,, able to achieve the quality and efficiency conditions imposed by laws for the products and processes and also capable to have a wide portfolio of products in order to maintain a functional distribution system.

Analyzing the role of the wholesaling companies in the pharmaceutical products market, these mainly have to ensure performance in logistics through distribution chain by respecting the laws, rules and regulation and also having the optimal effectiveness of own activities. From this respect it can be consider that the wholesalers are the main logistic operators, strictly specialized on the pharmaceutical products market.

Summarized, the internal services of transport and storage on an economic chain have as objective the proper ensuring of the needed quantity from the needed goods, on the appropriate moment in time and at the specified costs, on appropriate location and with all the needed information.

The plan, start-up and go live of the activity of a wholesaler in pharmaceutical market distribution have to respect the standard principle of logistics but also the limitation given by specific regulation related to quality of products, commercial restriction given by the laws and specificity of the market that the wholesaler operates in.

Even from the beginning the activity of a wholesaler of pharmaceutical products needs to be approved by local National Drug Agency from the compliance with the regulations point of view, afterward is permanently supervised from the regulatory point of view. The quality of the pharmaceutical products and of the processes within a wholesaling company is a priority as much for the regulatory institutions as for the wholesaler itself and is subject to best practices guides at national and transnational level – *Good Distribution Practice (GDP) for pharmaceutical products distribution*.

The premises within a wholesaler activity is put in place have to be authorized, with specific and mandatory areas and sub-areas of activity, temperature and humidity control and supervising, hygienic and pest standards, according to the European and international standards related to pharmaceutical products. The mandatory zones within a pharmaceutical wholesaler warehouse are: Goods in, Quarantine, sellable stock area, critical stock area, Expired goods area, Damaged goods area, dispatch area. When a pharmaceutical products warehouse's areas are set there are factors to be considered: products classification from pharmaceutical point of view in order to be able to transpose the status of products in areas of the warehouse and segregation of the flows within the warehouse on all distribution flow. Inside a warehouse there are unrestricted products, cold chain products, toxics and narcotics and according to each type of product separate areas in which to store and manipulate.

When starting up a wholesaling activity warehouse for pharmaceutical products is mandatory to define and setup the areas described above ensuring the segregation of the flows of different products from goods-in area to dispatch area accordingly.

The management functions of plan and organize have to take into account the constraints given by the mandatory areas in the warehouse and have to ensure the efficiency

of economic activities within the warehouse of pharmaceutical products wholesaler. Physical delimitation of the areas both on legal criteria and on pharmaceutical criteria makes the decision related to the size of the warehouse the subject of deep and detailed analysis of the product portfolio, specificity of the purchasing, client's number and spread, existing and needed storage structures. It comes in this manner to a multi-criteria model of analysis, the result of running this model being an estimation of the needed space for each particular area so that the activity can be put in place according to regulatory conditions and best practices within the industry.

2. Organizing the logistic processes in pharmaceutical products warehouses

The basic principle of distribution of pharmaceutical products is that one given by the method First In First Out, with the difference that always is taken into account the shelf life of the product or the Expiry Date written on the secondary package of the product. It has been developed in this way a new concept defined as First Expired First Out concept which is widely used in pharmaceutical products distribution market.

On whole distribution flow a pharmaceutical product has characteristics that define it as a stock keeping unit (SKU): Commercial name of the product, concentration, Batch number, expiry date and the storage type of the product (cold chain, unrestricted, toxic and narcotic). According to these characteristics it is made a segregation of the flows within a warehouse of pharmaceutical products. The Batch number is the key element that helps in traceability of the product on whole distribution flow and is the basis for recalls, quality issues and logistic processes.

Expiry date represent the element by which inside the same type of product it can be identified products Sellable stock, critical stock or Expired stock. Critical stock represent a commercial segregation of the stock based on a certain period remained until the expired date is reached, period in which the product shall have priority in leaving the warehouse, in special condition of price and discounts.

Typology of product from storage areas point of view ensure segregation of products in terms of storage and handling having products unrestricted, cold chain products, toxic products and narcotic products.

In handling products in the deposit must be taken continuously into account the correlation between the condition of the goods and the area where they are stored and those that present a rigorous separation of non-compliance.

In the context of the above situations, the route of a product must comply with basic principles of a logistics process (reception, storage and delivery), which generates numerous handling and transfer operations from one area to another. In the particular case of the pharmaceutical products the route can often be more complex, due to two additional factors: status of the product and the FEFO principle. A pharmaceutical product can be transferred from reception to quarantine area the in storage area as sellable product, and then again in quarantine if quality non-compliance factors come up or may be transferred in the damaged area if physical damages occur.

From strictly economic point of view the stock range can be segregated by logistic criteria – easy access to stock, buffer stock storage in a separate area, the frequency of replenishment activities i.e.

All these reasons conduct to a multiplication of the handling and transfer activities within a warehouse together with an increasing complexity of the flows that comes from the need of batch number traceability all along the shelf life of the product.

Time is, nevertheless, the most important factor that determines the flows of goods in a pharmaceutical products warehouse.

Comparing with traditional logistic companies in which the main concern of management is to maintain the level of stock in terms of quantity, in the particular case of pharmaceutical products distribution the concern of the management becomes also the quality of stock, not only from the physical point of view but also from the pharmaceutical quality point of view. This specificity conduct to a detailed and permanent analysis of the stock level related to area, expiry date and batch number and as a consequence the need of using of support information system meant to ensure the fluency and coherence of the operations.

The permanent comparison between the expiry date and the actual date is one of the main concerns of the operational management of the company. Hence, to be able to respect the FEFO principle is needed also the comparison between the different expiry date and different batch number of the same product within the same storage area, meaning that only homogeneous products from the status point of view are subject of comparison.

The high complexity of portfolio of products represented by trade name and concentration of the active substance and strict deadlines for the expiry implies the need to use new approaches and tools which will allow decisions about the rational and prompt handling of products in the deposits of pharmaceuticals

In order to answer to all these needs it has been developed Dedicated system of Information and communications technology, systems that contain economic models and algorithms on which the whole activity base and which are also decisions support tools for the management and workers for such complex multi-criteria processes.

It is to mention that the management of supply and demand for pharmaceutical products and also the permanent stock level monitoring on products and batch number in order to determine the optimum level for replenishment orders become a very complex activity due to the involvement of quality factors in setting the optimum stock level. There are frequent situations in which a stock level, apparently enough from the quantitative point of view, on a deeper analysis is proven to be non compliant from the qualitative point of view that conduct to an out-of-stock situation.

Operational management has to ensure availability of the internal resources for handling products according to their status and their distribution within the warehouse, the level activity given by the number of customers' orders.

All these operations can be carried out promptly and accurately only if it is been used Modern and Performant Information Systems, whose core will be represented by the organization's integrated information system (ERP) and ensures the efficient matching of resources at any time, respecting delivery requirements.

In conclusion, the qualitative aspects of product flows in a deposit of pharmaceuticals should be carefully monitored by qualified persons in terms of specific pharmaceuticals, from reception to delivery. In this specific way it can be realized the inclusion within the decision system of the qualitative aspects and be modeled by the Integrated Information System, management decisions being directly and permanently linked to the qualitative issues related to products.

The approaches to be considered by the management of a pharmaceutical products wholesaler warehouse are strictly connected with the dynamic of the stock level in the respect of frequently change of the status caused by criteria other then economics, and a permanent concern in rationalization and optimization elementary process of handling and transfer being in the same time compliant with the regulations and having the needed flexibility to fulfill the strategic needs of the company.

Considering the two main constraints existing in the pharmaceutical products distribution and the need to connect and coordinate them it comes to the development and implementation of a dedicated and integrated software solution – Warehouse Management System – considered to be in present an adequate tool that ensure efficient informational support for operational decisions and automatization of the basic logistic operations – handling and transfer.

3. Considerations on ERP –WMS systems

The use of Enterprise Resource Planning (ERP) applications becomes more popular in the latest years, the decision of an ERP implementation being taken by the management due to several factors among which can be identified: the increasing complexity of the activities, the needs of standardization and benchmarking, transfer of know-how, the speed and accuracy of information given by an integrated information system.

Developed initially as an Information systems that integrate at a relational database level the financial and industrial flows the software solutions become in time more flexible and much dedicated to specific functions of the enterprise as Warehouse management systems, that emulate and handle flows, processes and structures in a warehouse and which represent the decision making and operational support of the modern logistic management.

The specificity and complexity of pharmaceutical products distribution lead to the need of develop and implement tailor made economic models within Warehouse Management Systems. The fundament of these models consist in principles of working of the logistic processes inside a pharmaceutical product distribution warehouse and shall be connected to the company ERP in which are managed the financial and commercial flows and also linked to the warehouse automatization systems in a three tire integrated management information system.

In present, efficient activity of a pharmaceutical products warehouse, respecting the legal regulations and economic effectiveness implies the need of implementing of such information applications.

The operational management will thus be able to create the framework for efficient activity by using software application incorporating the optimized models of processes; the use of information systems also creates the premises for a better organization and becomes the main decision making support.

4. Final conclusions

The efficiency of modern logistics consist in the efficiency of designing the flows of goods, the flows of information, the reasonable reducing of service time and costs by integrating logistics in the whole company as a system.

The logistics and the processes of the logistics of supply chains have the same goals and principles of efficiency but the means of reaching these goals might be sometimes different and the overall efficiency and satisfaction depends on the capacity of the management to understand the business that they are in and they run and on the daily actions and decision of the management.

A modern and performant management of the logistic processes in pharmaceutical products distributions can not be reached without real understanding of the topics related to

quality criteria and use of and integrated approach together with the modern and appropriate tools and instruments IT&C adjusted to the specificity of the sector.

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