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Como referenciar este artigo:

STROZZI, Vitor Hugo; GRAEML, Alexandre Reis. The pharmaceutical industry in Brazil and the use of traceability supply chain information. Proceedings of the 14th Annual International Conference of the European Operations Management Association, Ankara, 17-20 June, 2007.

THE PHARMACEUTICAL INDUSTRY IN BRAZIL AND THE USE OF TRACEABILITY SUPPLY CHAIN INFORMATION

Vitor Hugo Strozzi¹ e Alexandre Reis Graeml²

*1 – Centro Universitario Positivo (UnicenP)
e-mail: vitorhugo@strozzi.com.br*

*2 – Centro Universitario Positivo (UnicenP) / Universidade Tecnológica Federal do Parana (UTFPR)
e-mail: graeml@fulbrightweb.org*

ABSTRACT

This paper analyzes the information flow along the pharmaceutical industry's value chain, focusing on traceability data that is gathered in compliance with the country's legislation. The objective of the study was to find out how such transactional data converts into information for tactical and strategic decision making. Eight key executives were interviewed, including the president of the national association of pharmaceutical laboratories, the president of the wholesalers' association, executives of two IT companies that collect and distribute the information and market intelligence executives. Results show that the massive set of data that results from the obligation of the pharmaceutical industry tracing its products can be (and is) used to better understand the market. While the sales force uses it as an instrument to determine sales targets and objectives, marketing people have it as a tool for strategically planning future market actions.

Key-words: pharmaceutical industry, traceability, supply chain, information flow

INTRODUCTION

The pharmaceutical industry is one of the most sensitive sectors to the pressures of the population. As a result of that, a very primitive industry, which consisted on the unsophisticated production of teas and magical spills, one hundred years ago, has possibly converted into the most complex field in the chemical sector.

Due to its relevance and the need of safety for the population, the pharmaceutical industry is controlled by governments, by means of special regulatory agencies that are intended to protect and promote the citizens' health. The Brazilian Agency for Sanitary Surveillance (Anvisa) is responsible for the pharmaceutical industry's control in the country, with the intent of "protecting the population and promoting the people's health, ensuring the quality of the products and services and their availability" (ANVISA, 2006).

The pharmaceutical industry is responsible for the quality of the medicine that reaches the consumers in a pharmacy or hospital, in Brazil. That is a legal obligation, which demands pharmaceutical laboratories to keep track of their products during the whole life cycle of the product. The ability of tracking products anywhere along the supply chain is called traceability.

Traceability is a must, in order to ensure the patients' safety, but it is also a protection for the participants in the supply chain. It helps dishonest middle-men or retailers, who sell stolen or fake products, to be more easily spotted. In addition to that, it is a very rich source of information for the industry.

As a result of the legal obligation of being able to trace its products, the pharmaceutical industry records data at several points along the supply chain, which provides data on over 1.5 billion SKUs (stock keeping units) of medicine, while they are being transferred from the laboratories to wholesalers, then to retail and finally to consumers. The objective of this paper

was to find out if such data, whose primary purpose is to allow for diligent recall when a problem is found, is also used for marketing positioning and decisions on the required actions to achieve that. The authors intended to understand if that data was used for further tactical objectives (logistics efficiency and sales efforts) and for strategic purposes (marketing long run planning).

An analysis of the information flow along the pharmaceutical industry's value chain in Brazil was performed for the identification of the data management model used by the major players in that market. It was also attempted to find out if companies in the pharmaceutical industry have market intelligence departments that convert the transactional traceability data into relevant information for tactic and strategic decision making.

INFORMATION SYSTEMS AND THE PHARMACEUTICAL INDUSTRY

We currently live in a real time world, "which has as one of its main characteristics the great proximity between idea and action, between beginning a task and concluding it" (McKENNA, 1998, p. 26). The technological arsenal that is available to organizations allows them to continuously generate and collect data. The huge volume of data generated by any operation today makes it difficult, though, to convert it into useful information for decision making. In such an environment, it is more difficult to choose among the available information than obtaining it. For Graeml (2000, p. 19), "until the 1970's, significant changes were signaled by strong evidences. More recently, the amount of available information increased so much that signals became weaker and weaker, almost disappearing in the middle of so much data".

Organizations started counting on management information systems in the 1950's, which helped structuring data (Kotler, 2000). In the 1970's, decision support systems were introduced to the market, as stressed by Alter (1983). Then, in the 1980's, it was the time of specialist systems, according to Ignizio (1991) and, close to the end of the 1980's and early 1990's, strategic information systems became available in the market, having their qualities highlighted by authors such as Porter (1987) and Mintzberg (1996).

According to those authors, the adoption of such systems is based on at least two critical elements: constant reduction of technology costs and continuous improvement of interaction languages that allow the communication between people and equipment. According to the literature, companies first only focus on control systems but, after a while, they start implementing strategic management systems.

Differently to what happens in rich countries, though, Leite's (2004, p. 84) research demonstrated that IT executives in Brazilian firms concentrate on operational objectives and are still far from strategically benefiting from it. For that author, "the executives' preference concentrates on projects that generate cost cuts. There is strong rejection to projects that intend to improve the decision making process and the strategic use of IT".

Leite (2004) also states that the scenario for investments in IT has two major components: one is quantitative and relates to the *reduction of costs* category, being used for the optimization of operational capacity. The other concerns the *expansion of operational capacity* and involves improvements in the decision process and the strategic use of data. Criteria used to justify this second category of investment tend to be subjective, which makes the figures generated to support it fragile, when exposed in an argumentation, increasing the chances of project rejection.

The pharmaceutical industry has very few alternatives to improve its profitability. According to Falk (2005, p. 130),

in order to increase profits, pharmaceutical companies could use three different strategies: increase the price, increase the volume of sales or decrease cost. The first option is unfeasible, though, because the sector is being very closely watched by the [Brazilian] government, which controls the market in a very strict way. The

alternatives that are left are to increase sales of prescription drugs and/or to control costs, eliminating operational inefficiencies.

Falk (2005, p. 130) also states that “just using computers doesn’t mean that they generate competitive advantage.” He argues that “it is very difficult to find out companies in the pharmaceutical industry that are thoroughly integrated, internally or/and externally”.

The government has imposed the obligation of traceability to the pharmaceutical sector, which has to track the products it commercializes during the whole life cycle. According to Dyer (*apud* EAN BRASIL, 2007, p. 1), traceability “is the ability to trace the history, application, use and location of each individual product [...] by means of identification numbers that are printed in the merchandize”.

Traceability is required for the patients’ safety and as a protection for the whole pharmaceutical value chain, in any place of the world. As a consequence of traceability, the Brazilian pharmaceutical industry generates data on more than 1.65 billion units of products, while they are moving along the value chain. Such data is used to allow a fast recall, when problems are found with any medicine, but they can also be used to locate fake or stolen products. These are possible operational uses of the data by the industry. But such data can also be used more strategically, for laboratories to decide their desired positioning in the market and the measures that are required to achieve that, for example. Based on the analysis of the company’s market share in a specific market, it can formulate tactics and/or strategies to improve its performance.

Rezende and Abreu (2001, p. 168) state that policies that relate to knowledge belong to the group of “strategic policies that are created by the upper management...”, which differ from those “operational policies that guide the daily routine and basic procedures in organizations. As a result of strategic policies, information policies are also created, which influence and include information systems”.

In an unfavorable analysis to the pharmaceutical industry, Falk (2005, p. 117) says that “few experiences are currently being carried out with web services, especially with respect to activities related to the companies’ core businesses”. Falk also says that the available IT alternatives for this industry focus specifically on cost reduction, but this statement is refuted by the evidence that was collected based on the current research project, as will be discussed later on, in the section that analyzes the interviews given by the specialists.

Next, the methodological procedures that were adopted are briefly presented.

METHODOLOGICAL APPROACH

Empirical data was obtained by means of semi-structured interviews that were carried out with key executives from the pharmaceutical industry, companies that gather and provide the industry with the required information for traceability, representatives of associations of laboratories and wholesalers and other specialists. The following people were interviewed:

- participant 1 – president of Interfarma (Association of the Research Pharmaceutical Industry), an association that congregates more than 90% of the pharmaceutical laboratories that commercialize patented products and more than 60% of brand medicine in Brazil;
- participant 2 – president of Abafarma (Brazilian Association of Pharmaceutical Wholesalers), an association that represents a group of ca. 20 companies that distribute more than 60% of the medicine (number of units) sold in Brazil;
- participants 3, 4 and 5 – directors of companies that provide the technological means for the data/documentation flow among the pharmaceutical value chain, i.e., Value Added Network (VAN) service providers – the authors interviewed executives of two of the three companies that perform that kind of service in Brazil (Tivit and Genexis) and an

executive of a third company that intends to enter the market in the second semester of 2007;

- participants 6, 7 and 8 – executives working in the pharmaceutical laboratories' intelligence area, who asked to keep discretion about their companies' and their own identities.

The authors chose to use a qualitative research tool – semi-structured interview – because the number of participants (specialists in the field) was small and the flexibility provided by the method would allow additional questions to the participants to be included, when the interviewer considered that suitable.

The information that resulted from those interviews was confronted with the literature. In some cases, it supported the ideas of other researchers and, in other circumstances, it conflicted with their conclusions.

ANALYSIS OF THE USE OF THE TRACEABILITY DATA BY THE PHARMACEUTICAL INDUSTRY IN BRASIL

The pharmaceutical industry's income in the period from February 2006 to February 2007 was approximately 11 billion dollars, which resulted from sales of 1.65 billion units of medicine, according to Febrafarma (2007). Table 1, below, which was extracted from Febrafarma's (Brazilian Federation of the Pharmaceutical Industry) web site, shows the sales of the industry for the last 10 years.

Table 1 – Sales of the Brazilian pharmaceutical market

Year	Sales in US\$ 1000	% variation	Base index: 1997=100	Sales in 1000 units	% variation	Base index: 1997=100
1997	8,537,436	-	100	1,854,094	-	100
1998	8,660,434	1.44%	101.4	1,814,337	-2.14%	97.9
1999	6,537,763	-24.51%	76.6	1,778,800	-1.96%	95.9
2000	6,705,678	2.57%	78.5	1,697,822	-4.55%	91.6
2001	5,685,430	-15.21%	66.6	1,640,251	-3.39%	88.5
2002	5,200,494	-8.53%	60.9	1,614,825	-1.55%	87.1
2003	5,589,133	7.47%	65.5	1,497,883	-7.24%	80.8
2004	6,818,295	21.99%	79.9	1,652,125	10.30%	89.1
2005	9,214,189	35.14%	107.9	1,613,828	-2.32%	87
2006	10,891,621	18.20%	127.6	1,664,272	3.13%	89.8

Note: the data for 2003, 2004 and 2005 were rectified by Grupemef.

Source: Febrafarma (2007)

According to Febrafarma, Brazilian laboratories hold 39% of the pharmaceutical industry's income in the country, while the other 61% relate to foreign companies that also play in the local market. In Brazil, the average price (per unit) of medicine is US\$6.50, when it leaves the laboratory, but it reaches the consumer costing US\$9.40. Prices and profit margins are controlled by Anvisa, by delegation of a Council of Ministers, which was created specifically in order to authorize price increases, involving the country's Minister of Treasury, the Minister of Health and the Minister Chief of Staff.

Figure 1 reflects the information and material flow in the pharmaceutical value chain. Examining it, one realizes that the 1.65 billion units of medicine spread through more than 110,000 points of sale, including pharmacies, bars and warehouses, in some situations.

There are more than 100 thousand points of sale that purchase medicine from wholesalers and distributors, in the Brazilian pharmaceutical market, 45 thousand of which are pharmacies or drugstores. Medicine is also sold by the pharmaceutical laboratories directly to large pharmacy chains, which are responsible for more than 4 thousand points of sale in the country. Hospitals represent 2 thousand points of sale. The federal, state and local governments are also

intermediaries in this supply chain. The pharmaceutical laboratories have to keep track of products that they sell to all those customers, in order to be able to quickly recall products that present any potential risk to the population. The traceability effort generates a lot of data that is used for the operational purposes it was originally intended to, but also offers important information that can be used for tactic and strategic decision making, which is the major concern of this research project.

As can be seen in Figure 1, the industry has complete control of products destination, when they leave the laboratories. According to participant 2 (Abafarma), whose associates are responsible for 90% of the medicine distribution in Brazil, all invoices, except those issued by pharmacies and pharmacy chains, include each medicine's batch number. That happens when products flow from the laboratories to the wholesalers and other agents, but also from the wholesalers to drugstores.

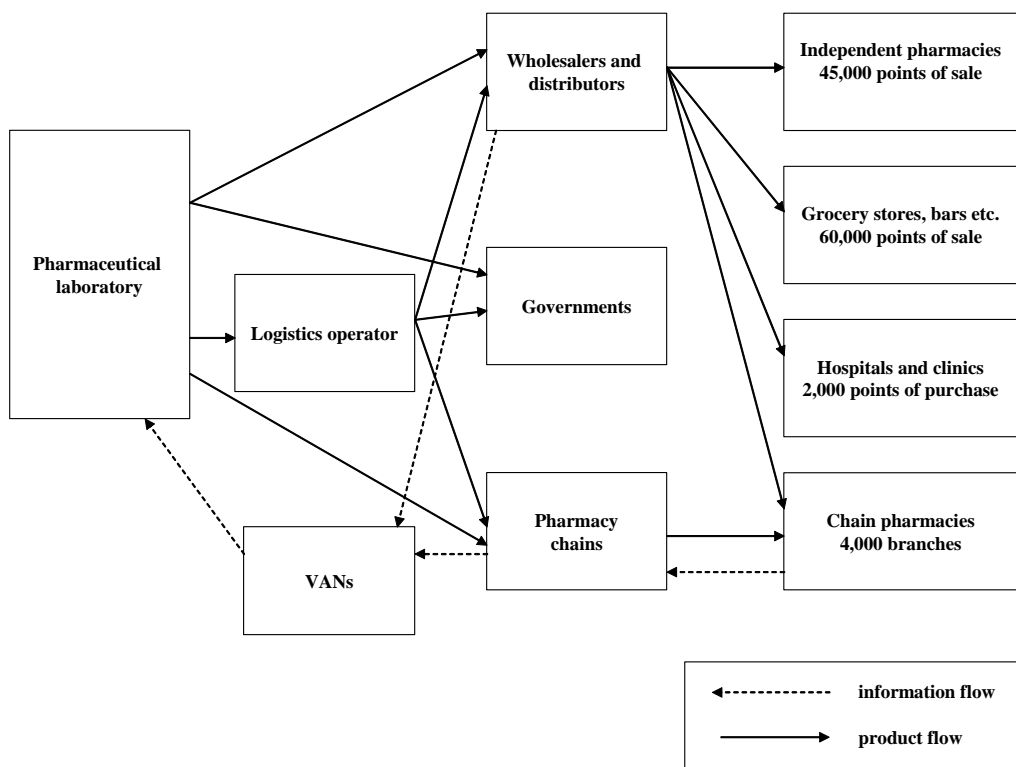


Figure 1 – Pharmaceutical industry value chain

Source: elaborated by the authors of this paper, based on information provided by the interviewed specialists.

Value added networks (VANs) operating the information flow in the Brazilian pharmaceutical industry
 Since the 1970's, there are companies that collect data from the market for the pharmaceutical industry, in Brazil. According to participant 5 (VAN executive), the first of those companies to operate in Brazil was IMS Health, an affiliate of Dun & Bradstreet. In the 1990's, Servix was founded, which later became Genexis. At last, Proceda created a division (Tivit) to collect, process and organize such data, so that it could be converted into information for its customers' decision making.

The opportunity that existed for the last two companies mentioned above (Genexis and Tivit), still according to participant 5, related to the fact that IMS was slow in collecting and validating data, with delays of over 90 days from collection to the day the information was made available to the industry. Another discouraging factor, with respect to the services offered by IMS, was its high cost. Servix started offering the same data, just two days after collection

and by means of on-line processing. Then, Proceda, which was interested in the EDI orders' business, entered the business, providing services compatible with those offered by Servix.

In spite of the poorer service and higher price of IMS, most multinational laboratories buy that service due to headquarters' imposition, as that company operates in many markets and the information it provides is internationally acknowledged, being used for global benchmarking. But many also buy the information provided by Genexis or Tivit, because it is much more update (in August 2006, Genexis was purchased by IMS).

According to participant 6 (marketing intelligence executive), prior to Genexis' acquisition, Tivit had 19 customers and Genexis had 20.

For participant 2 (Abafarma), the above mentioned companies trace all prescription drugs sold by large laboratories in the country, as well as all over the counter (OTC) products, also known as free sale products. On the other hand, the control on generic medicine (traditional formulations sold without the support of a strong brand) is not so sharp, because manufacturers many times sell straight to distributors and/or pharmacies and that is not traced by the VANs. Also according to participant 2, the commercial policy of those laboratories generally involves great discounts and bonuses that they prefer to keep as a commercial secret, which would be lost if the information were available to the VANs.

Participant 3 (VAN executive), one of the executives of the EDI (electronic data interchange) service provider states that the company works for more than 40 laboratories, which use the system to receive orders. This connectivity model has been used in Brazil since the 1990's and, although criticized due to the inflexibility of the data transfer format, which doesn't allow for negotiations order by order, its use is increasing at fast pace by laboratories that have more than 70% of the market share.

Orders are collected in electronic mail boxes that are kept by the laboratories with the VANs, which authorize them to be invoiced by warehouses of logistic service providers. Still according to participant 3, the rule is not to require any human contact with orders and invoices, except when credit problems occur or when there are not enough products available to meet the demand.

Wholesalers, distributors and pharmacy chains are demanded to identify each product, form of presentation and batch in the invoice. Thus, the box that was delivered by the laboratory (secondary packing) is opened, products are separated according to the unit of sale and re-labeled with a code created by the distributor, which can be read by electronic means, allowing for automation. Such operation, which is carried out in order to meet legislation requirements, may generate errors during warehouse handling and jeopardize the whole system, according to participant 8 (marketing intelligence executive).

Participant 1 (Interfarma) didn't consider the possibility of mistakes introduced in the re-labeling process to be a great concern. But he revealed that during 2007 the system will be replaced by a more sophisticated one, which addresses safety issues. By means of the new system, each unit of product will leave the manufacturer with the batch number physically assigned to it (printed in the box) and not as a bundle.

When the wholesalers and the warehouses of large chains send products to the various destinations they support, they generate invoices that include a great amount of data. They contain information on the customer, such as name and address, the number of units of each product that was sold, the way such products are bundled, manufacturing batches, prices and other less relevant data. Such data can be very useful, when collected in a systematic way, for the involved parties to formulate and implement more solid marketing strategies.

Information flow in the pharmaceutical industry and decision making

According to participant 2 (Abafarma), data is sent by the wholesalers to VANs, on a daily basis. Pharmacy chains sometimes transmit data once a day, other times, once a week. Such

data is processed and made available to the parties in the mail boxes the VANs make available in their web sites.

After it is available in the mail boxes, the data can be accessed by the marketing intelligence departments of the several players in the market. They start mining the data and interpreting it, according to participant 4 (VAN executive). Figures start gaining meaning, as they directly relate to a certain context, which can be analyzed from several different perspectives (time, geography, product etc.). That information allows for tactical actions, because it is update and relevant to field executives, who can react to it. However, more detailed and global analyses help product or marketing executives to use the information to modify or consolidate strategic moves.

The industry is currently working with information that is only one or two days old, which allows it to act with operational precision on specific markets or clusters that did not respond as expected to previous sales or marketing efforts. Any situation for which the results are different to expected can be quickly analyzed, so that the required measures can be taken. Several of the executives that were interviewed (participants 1, 3, 6, 7 and 8) said that the information made available by the VANs is used by regional and district managers of the pharmaceutical companies to check the performance of the territories and customers they are in charge of. Based on that, they can tactically act, because they are in the field. In fact, many times they check their performance from their notebook computers, on the go. Taking measures with the purpose of increasing sales is an expected consequence of having the information in the hands of managers who understand particularities of the specific markets with which they are involved, in their daily routine. However, according to participant 4 (VAN executive), the industry lacks on professionals capable of suitably treating the data in order to do what is really necessary, in real time, but with a broader view of the overall market in mind and a longer run perspective.

All participants agree that large pharmaceutical companies formulate their strategies based on the data that is collected along the value chain and on their analysts' conclusions about it. Many stress the fact that different departments have access to the data when they plan and formulate their budgets.

Participant 1 (Interfarma) highlighted the fact that the main users of the data during the year are marketing managers and directors and, in some companies, the so called product managers. Those executives are the major formulators of strategies for products or lines of products.

However, the model is criticized by participants 2 (Abafarma) and 5 (VAN executive), who consider that:

1. the sales data refer to the retail agent, i.e., the pharmacy, hospital, clinic or other intermediary that deals with the end customer. Ideally, it would be better if the information related to the consumer, at least when s/he accepted to be identified;
2. analysts capable of generating relevant information directly from the raw data collected from the transactions along the value chain are scarce. In addition, and as a result of that, turn-over is high, as such professionals are disputed by the market. The number of companies interested in that kind of analysis grows faster than the number of professionals with sensibility for field problems and prepared to carry out sophisticated analysis based on transactional data from the industry.

The criticism contained in item 1 proceeds. The data that the wholesalers provide only identifies the retailers: pharmacies, hospitals or even a grocery shop. In the United States, there are companies called *pharmacy benefit managers* (PBM), according to Falk (2005), which manage the information on patients. Those companies provide service to insurers, clinics and the pharmaceutical laboratories, mainly because they are responsible for dealing with refunds, which provides them with data on patients and their relationship with the insurance companies. According to participant 5 (VAN executive), this model will eventually be implanted in Brazil,

in the future, but it is difficult to determine when, because the insurance industry is still expanding and, for the moment, it has other more important concerns. The pharmaceutical industry, on its own, will not go any further in that direction because it already has other mechanisms that supply it with the required information to improve customer fidelity. There are specialized service providers that collect such information and make it available to the industry, among which E-Pharma and Prev-Saude deserve mention for using CRM (*Customer Relationship Management*) technologies for that intent.

The second complaint is difficult to solve, in the unanimous opinion of the participants, because the market intelligence analyst is a very complete professional, who needs to understand the data, on its own, but also take it into consideration within the context, which makes him/her very difficult to find in the market. The competence of the market intelligence analyst goes far beyond the ability to just interpret the data using statistical tools. His/her evaluation depends on contrasting the data with specific characteristics of the market that are only known to those who have dedicated years of work experience to the field, such as the consumers' purchase power, relevance of government action, isolated movements of the competition, performance of the retailers and wholesalers, and so on. Competence in that area also results from the professional's ability to "infer market moves", as mentioned by participant 7 (marketing intelligence executive).

Another interesting issue is that, as shown in Figure 1, the government demands all players to trace products in the pharmaceutical value chain, but the government itself doesn't do it, itself, when it distributes pharmaceutical products to public hospitals and other assisted organizations. That is the cause of mistakes and excesses, which are frequently denounced by the press. We weren't able to find out, in this study, what the reasons are for the government not to participate in the traceability effort performed so efficiently by the private pharmaceutical system.

Falk (2005) criticizes the pharmaceutical industry value chain, stating that "the level of competition among wholesalers is so intense that it doesn't contribute to the emergence of orchestrating companies".

This is a very complex issue. Falk (2005) suggests that a model similar to that adopted in other countries could be successfully implanted. But he forgets some important characteristics of the Brazilian pharmaceutical distribution market. According to participant 2 (Abafarma), there are more than 300 distributors and wholesalers of pharmaceutical products in Brazil, but only 20 of them, plus 25 pharmacy chains, respond for 90% of the prescription drugs sold in the country.

The North-American distribution model locks in pharmacies and hospitals, by means of permanent contracts and consistent partnerships, according to participant 7 (marketing intelligence executive), differently to the Brazilian model, in which competition prevails. That situation makes it less interesting for buyers to sign an exclusivity contract that imply having to always buy from the same source. Laboratories do not guarantee exclusiveness to their wholesalers, upstream, neither are drugstores exclusive, downstream. Facing pressure from both ends, it is difficult for the wholesaler to act as an "orchestrator" for the value chain, as intended by Falk (2005). Therefore, laboratories keep control of the value chain as they traditionally have.

CONCLUSION

The analysis of the information flow along the pharmaceutical industry, based on the interviews that were carried out with key professionals in this sector, shows that those who consider that the traceability information is poorly used for decision making are mistaken. The pharmaceutical industry created a sophisticated data network, which provided it with an important and very sophisticated data source for tactical and strategic decision making, even

before the government determined that drugs needed to be traced during their entire life cycle. The availability of such information to all interested parties along the value chain improves operational and strategic coordination of efforts among those that manufacture (laboratories), those that are involved with the logistics (logistics operators, wholesalers, distributors, pharmacy chains and government) and those that sell or make products available to consumers (independent pharmacies, chain pharmacies, grocery stores, hospitals and clinics). In fact, no other industry in the country has so much information about where, when and which products are selling, in such level of detail and so quickly available, to the authors of this paper's knowledge.

Traceability could have converted into an additional burden to the pharmaceutical industry by government imposition, if the infrastructure for the collection and handling of such information needed to be built from scrap. However, it was already in place and the collected information was broadly used to support sales all along the value chain much before the approval of medicine traceability and the creation of Anvisa, which happened just a few years ago. Therefore, the legislation only enforced something that was already a regular market practice and universalized its use by all laboratories, increasing safety in case of recalls or fraud, allowing products to be quickly withdrawn from the market, when necessary.

The data generated for traceability purposes can be (and is) organized for other uses. The specialists that were interviewed during the preparation of this paper were not unanimous with respect to the uses companies make of the information they have in hands. The majority of them say that operational and strategic decisions are taken based on such information. One of the participants, however, alerted to the fact that analysts that can make good use of the information for strategic reasons are scarce in the market. In his opinion, use is still primarily tactic (sales support focusing local/specific markets).

VANs are used as data warehouses, which provide data and technology used by market players to evaluate and determine their course of action. In spite of the lack of agreement about the extent to which such information is used for strategic decision making, it became clear that pharmaceutical companies do use traceability data as a tool to refine their sales actions and other promotional activities in specific locations, which is a tactical application of such information by sales departments, but also have it as an input to their marketing strategic thinking, when their market intelligence people try to depict and understand data patterns in order to plan for the long run.

The evidence that was collected here conflicts with two of Falk's (2005) findings. First, that author describes the pharmaceutical industry's supply-chain as poorly structured and little intensive in the use of IT. He argues that there is little use of information as a key element for strategic decision. After the current study the impression is exactly the opposite.

The pharmaceutical industry molded the market to a format that helps it to take tactic and strategic decisions. Based on the information withdrawn from the wholesalers' invoices and internal transfer bills (in case of pharmacy chains), collected by the VANs and made available to the whole industry, companies only need to put in some analytical effort to convert data into information for their decision making.

Falk's (2005) second statement that is not supported by the findings of the current research is that informatization in the pharmaceutical industry focuses on peripheral issues and is only concerned with cost reductions. That is not what one concludes from the interviews with key professionals in the pharmaceutical industry that were performed now. Participants were unanimous when they said that collected information is used for strategic decisions, in spite of the disagreement with respect to the quality of the analysis that is made of the available data.

Confirming McKenna's (1998) perceptions, companies seem to be converting into real time enterprises. Information is readily available and organizations have the chance of responding to changes in the environment straight away. Those that take that chance and develop internal

skills to quickly analyze the signals that come from the market will develop offers that are better suited to the market's needs and, therefore build a competitive advantage that will be difficult for others to match.

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