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FGV would like to thank all of them.

The representatives of the pharmaceutical supply chain who contributed to the study are:

ASSOCIATIONS
- Brazilian National Association of Cargo Transport and Logistics (NTC&Logística)
- Union of the Pharmaceutical Industry in the State of Sao Paulo (Sindusfarma)

TRANSPORTATION COMPANIES
- Ativa Logística
- Atlas Transportes e Logística
- Expresso Jundiaí
- Linex – Tecnologia e Transporte
- Luft Logistics
- RV Ímola
- Shuttle

During the development of this research, two of the transportation companies, Expresso Jundiaí and Atlas Transportes e Logística were purchased by a third one, FEMSA Logística, who has also contributed to the study.

LABORATORIES
- Bayer
- EMS
- Eurofarma
- Hypermarcas
- Medley
- Novartis
- Pfizer
- Sanofi

PHARMACY CHAINS
- Drogasil
- Drogaria São Paulo
- Pague Menos

PHARMACEUTICALS’ DISTRIBUTORS
- Panpharma

INSURANCE COMPANIES
- Disconal Corretora de Seguros
- Grupo Apisul
## SUMMARY

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Conducted by FGV Projetos for NTC&Logistica, this study presents an important overview of the pharmaceuticals’ transportation in Brazil, that counted with the contribution of representatives from each one of the sectors of the pharmaceutical supply chain. This was an initiative of the Pharmaceuticals’ Transportation Technical Board of NTC&Logistica (CTFARMA).

This publication summarises the impact of the changes in the sector, its current competitive scenario and its future prospects. The study highlights the importance of the pharmaceutical sector for the country and its international representation. It also shows the significant transformations occurred in the recent years affecting the pharmaceuticals’ transportation in Brazil and points out the need to expand and improve the relationship among the diverse actors of the pharmaceutical supply chain. In 2015, the pharmaceutical industry spent R$ 765 million (estimated by FGV) with pharmaceuticals’ transportation and generated more than 18 thousand direct and indirect jobs.

One of the main difficulties for the development of the pharmaceuticals’ transportation in the country, especially regarding logistics, are the deficiencies of the Brazilian transportation infrastructure. Despite this fact, the federal investments destined to its improvement are heavily decreasing. In 1975, the transportation infrastructure received 1.84% of the Brazilian GDP in investments, whereas in 2014 this amount was reduced to only 0.29% of GDP.

Furthermore, the logistics’ infrastructure in Brazil suffers from strong regional disparities, with great access difficulties in certain regions, especially in the North and Northeast. This can damage the quality of the drugs, since products take longer to be transported and are, thus, exposed to temperature variations, that can provoke instabilities of the active ingredients and impair the drugs’ effectiveness.

That situation is further aggravated by the lack of precision in the norms regulating the pharmaceuticals’ transportation and the inability of the official institutions to run a rigid and comprehensive inspection system. Another critical point is the vagueness around the characterisation of the types of vehicles required to transport pharmaceutical products over long distances. Insulated vehicles, for example, are unsuitable because they can only maintain cold temperatures for a limited period of time, and they also retain heat, which can be detrimental to the drugs’ conservation. Thus, for longer distances, the ideal solution is to use refrigerated vehicles.

The lack of an adequate set wage for truck drivers is another sensitive issue in the sector because it contributes to the employment of low or non-qualified workers. Nevertheless, it is important to point out that the personnel expenditures of the transportation companies participating in this study has increased, from 26% to 32% of total spending. Those expenditures have increased a 6% as a proportion of the companies’ net income, while others have only increased by 3%.

The research conducted has also shown that the pharmaceuticals’ transportation companies have a fleet with an average age of six years, four years below the average of the transportation sector as a whole, and eleven years below the average of self-employed drivers. Thus, the research shows that the fleet is being adequately renewed, although not necessarily with the right kind of vehicles. In this context, it should be reminded that the pharmaceuticals’ transportation companies are subject to a rigid regulation that requires specific investments in qualified personnel, infrastructure and equipment, which increases the transport costs.
In terms of the future prospects expected for the pharmaceutical supply chain, this publication has sought to highlight the challenges posed by the public sector, mainly due to the regulations, and especially those targeting the transportation companies. The aim of the study was also to point out, on the one hand, the need for greater integration and dialogue across the pharmaceutical supply chain. On the other hand, there are the impacts of possible changes in legislation on the transportation companies, mainly on the quality of their services, their competitive structure and their finances.

The working method involved extensive research, consultation of available public databases and over twenty interviews with representatives from each one of the sectors of the pharmaceutical supply chain, including two industry associations, seven transporters, eight laboratories, three pharmacy chains, one pharmaceutical distributor and two insurance companies. Additionally, an interview was conducted with Nelson Libbos, consultant and executive working in the pharmaceutical sector, available at the beginning of this publication, in order to guide the reader in the nuances and particularities of the Brazilian pharmaceuticals’ transportation sector.
PRESENTATION OF NTC&LOGÍSTICA

Founded in 1963, the Brazilian National Association of Cargo Transport and Logistics (Associação Nacional do Transporte de Cargas e Logística - NTC) is the non-profit class association that represents more than 3,500 companies in Brazil and other countries in South America.

The NTC, leader of a representation system with the companies specialised in freight road transport—the majority of the membership—congregates logistics operators, freight forwarders, product and service suppliers targeted to the sector. It also gathers more than eighty employer class organisations, between federations, unions and civil associations.

To offer more subsidies to their associates and in order to achieve further development of the transports market, the association has an important department composed of engineers, economists, lawyers, administrators and social communication’ specialists, capable of conducting studies of unquestionably high technical accuracy.

The association also has its disposal sectors specialised in international freight transport, dangerous products, property security, legal matters and others. This enable the existence of business chambers aimed to research and the continuous search of solutions for specific matters. Given the large geographic reach of the membership, the NTC developed a communication system involving printed media, in-person events and remote activities through the Internet portal, the online newsletter and a WEB TV channel.

Based in the city of São Paulo, the association also has offices in Brasilia, where it has an advisory capable of monitoring in depth all the proceedings in the sectors’ interest taking place in the federal sphere.

There are twelve technical chambers, among which is the Technical Chamber of Pharmaceutical Products’ Transport (Câmara Técnica de Transporte de Produtos Farmacêuticos - CTFARMA). This chamber’s objective is to promote discussions and research related to pharmaceutical products, aiming to subsidise the entity’s decisions and to guide its associates in order to look for solutions with the sector’s control organs. In this context, the CTFARMA requested a study about The Impact of the Market Conditions on the Performance of the Pharmaceutical Products Transport Companies to FGV Projetos, which results are presented in this publication.

This is a pioneering work that shall bring substantial benefits to the sector, enabling a better understanding of the problems associated with the transport of pharmaceutical products, regarding all the activities of the value chain.
In this interview, Nelson Libbos addresses the Brazilian pharmaceutical industry scenario, highlighting the advances made, the existing challenges and the future perspectives, especially regarding the pharmaceuticals’ transportation. Nelson Libbos is now a business consultant in the healthcare sector, after being president of six of the largest pharmaceutical companies in Brazil. He has also directed several entities such as the Brazilian Federation of the Pharmaceutical Industry (FEBRAFARMA), the Pharmaceutical Research Association (INTERFARMA), the Union of the Pharmaceutical Industry in the State of Sao Paulo (Sindusfarma) and the Brazilian Association of the Non-Prescription Drugs Industry (ABIMIP).
THE PRODUCT SOLD IN THE PHARMACY MUST HAVE THE
SAME QUALITY THAT IT HAD WHEN IT EXIT THE FACTORY

WHAT IS YOUR VIEW ON THE PHARMACEUTICAL SECTOR TODAY IN BRAZIL?

NELSON LIBBOS: The Brazilian pharmaceutical sector is a thriving sector with an internal market that occupies the sixth or seventh position at the international level, depending on the exchange rate. The main breakthrough in the sector was the creation of the National Health Inspection Agency (ANVISA) in 1999, which has contributed for the increase of the quality levels and the international recognition of the Brazilian pharmaceutical industry. There have been cases of industries approved by FDE (Federal Drug Enforcement Agency), from the United States, that were reproved by ANVISA, explaining the reasons for it. The implementation of the Patent Law and the generic drugs’ regulation followed the strictest legislation existing around the world. Nowadays, a generic drug produced in the country has the same quality standards required by regulators in Europe and the United States.

The pharmaceutical industries operating in Brazil today, national and multinational, have a very good level. What is missing is a greater control in the final stages of the supply chain. The country has about 70,000 points of sale which are not adequately inspected. The government assumes that it is sufficient to control about 70 laboratories, responsible for 80% of production, but when it comes to human drugs quality cannot be ignored. We cannot tell someone to take a better or worse quality drug because we are talking about human lives. The same quality standard must be observed for all products.

The pharmaceutical market has evolved considerably, and from the regulatory point of view, Brazil is recognised as a market next to the European and the Canadian regarding the manufacturing and the registration of products. Moreover, we have to remember that we are a continental country, which size poses major challenges to the distribution of these drugs.

WHAT IS THE IMPORTANCE OF LOGISTICS IN THE PHARMACEUTICAL SECTOR?

NL: Considering the size of Brazil, I believe there is still a lack of adequate legislation for the pharmaceutical’s transportation and this is the incongruity of the sector. That is, we certify the product registration process, we control the quality of supplies imported by the industry and we certify the production process, but we do not have the same level of control over the final product shipped to the pharmacies. When we say that the industry produced and sold to a retailer, we must know that the distributor, located in Sao Paulo (where is located 80% of the industry), will have to send that drug to every corner of the country. The logistics of the pharmaceutical industry is not as well-regulated as the other stages of the supply chain. It is difficult to control 70,000 points of sale, but retailers need to feel that such control from the regulatory agencies exists. States and Municipalities are responsible for the inspection of the points of sale, but the state agencies do not have the capacity for it. Being a continental tropical country, there are situations in which the goods remain inside the truck during four or five days, exposed to temperatures higher than 50 degrees. This means the deterioration of the active ingredients inside the product, which leads to the reduction or the loss of the drug’s efficacy. According to the region in which the product
will be sold, there is a classification and control criterion to ensure the product’s stability. Brazil, for example, is in zone 4 (the tropics area). Thus, for a product developed in the United States to be manufactured and sold in the country, the industry will have to comply with specific production criteria because the drug may be exposed to the Brazilian average temperatures, ranging from 28 to 32 degrees Celsius. Faced with this dynamic, what good is so much control if the products will later be exposed to temperatures higher than recommended?

There is a risk too, after the distributor’s delivery, of the product not being stored under the adequate conditions, leading again to the risk of damaging the drug properties. Hence, we purchase a product from a large company, that complied with all the production quality requirements, but does not have the same efficiency it had when it left the factory. At this point, it is pertinent to ask: is the blame on the pharmaceutical industry? Not necessarily, but the industry will be responsible in the case someone accuses the product for not having and adequate quality.

And it is the State’s function to implement such supervision. Facing the risk of selling a drug of inadequate quality, it is everyone’s loss: we are applying the best in the world in the control of the production, import and transportation of the raw material and we are using the best processes in the production and the quality control of the drugs. However, when the product walks through the factory’s door, we lose control. And it is the final consumer who pays for the consequences.

I often say that the control of the production should not be the responsibility of the States or, in some cases, of the municipalities. It should the federal agencies’ responsibility. Let’s imagine a large pharmaceutical industry installed in a small municipality. This company has dominated local labour and is significantly important for the municipal economy. The inspection criteria may be different from an inspection done in São Paulo. Unfortunately, we do not use the same criteria in the state inspections. The inspections done in São Paulo are probably stricter than in other cities in Brazil.

What we also see are conflicting state regulations. It is possible to see, in the Northeast for example, a pharmacy selling food with legal authorisation. In São Paulo there is no such situation.

Today, there is great concern from the part of ANVISA about product traceability, when they should be more concerned with the quality of the pharmaceutical products across the supply chain. Traceability is very important, but it is also necessary to improve the regulation of the drugs’ logistic process, which is also a part of traceability. Brazil needs to establish new logistics’ standards, in terms of quality control of the specific load being transported.

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“What’s the responsibility of the pharmaceutical industry in this process?

NL: The laboratories have great control over refrigerated products (the ones that cannot be exposed to temperatures higher than 8 degrees Celsius). The industry stores its products adequately and requires the transporters to do the same. The problem is that the industry’s control does not reach the retail sector. If we take care of the productive stage, someone should take care of the transportation and storage stages, at least by sampling.
There are strong regulations and control systems over the main drugstore chains and distributors, but the inspection in small pharmacies is the municipality’s responsibility, in other words, the rules are different. One more time, it is wrong that industry inspections are done by states and municipalities, because it should be the responsibility of the regulatory agency (ANVISA). This would be the only way to ensure that the same criteria are applied to every factory.

WHAT WAS THE VIEW OF PHARMACEUTICAL LABORATORIES ABOUT DRUG TRANSPORTATION AND HOW HAS IT EVOLVED?

NL: From the perspective of product quality, the industry does everything to ensure that the drug production and storage comply with the pre-established conditions. From an economic point of view, transportation is a significant cost item, because the drug’s final price is government controlled and must be the same across the country. In a huge country like ours, considering the different freight costs and distances, the profit margins vary considerably. But I think the concept is correct: provide the same drug for the same price to all consumers in Brazil.

INCREASED TRANSPORT REGULATION, AS IT HAS BEEN DEFENDED, EXPANDS THE COSTS AND PRESSURES THE PROFIT MARGINS?

NL: We have to increase regulation, even if it means higher costs, to ensure drug quality in pharmacies and hospitals. What cost is better for the Government: treating a hypertensive individual with the appropriate drug or pretend we are delivering a product that works, at the risk of this patient develop chronic kidney disease and turning to the public healthcare, which is overloaded? There is no such thing as a free lunch.

WHAT IS THE TRANSPORTERS’ TAKE ON THIS AND HOW DO THEY PERCEIVE THE EXISTING REGULATION?

NL: I cannot tell what is the sector’s view as a whole, but I can tell many transporters are falling into bankruptcy, and this is not a problem solely of the pharmaceutical transportation sector. It is linked to factors such as the poor conditions of the roads, the resting times for truck drivers required by law, among others.

The industry and the distributors have incorporated a number of laws and rules and require transporters to adapt to comply with them, without raising the freight price. As a consequence, several transportation companies have fallen into bankruptcy. In order to avoid it, the transporters try to adapt to tighter profit margins. Who loses with this situation, once again, is the final consumer, because it is not possible to adequately transport the pharmaceutical drugs under these conditions.

When the industry decides to outsource transport, this is often the most economical decision. Today everyone talks about compliance. In order to transport the product, the transportation company must respect a series of requirements, but compliance should also exist in product delivery at the final destination. It is the industry’s image that is at stake if someone takes a drug and it does not work. If the transporters do not meet the quality requirements, the laboratories are the ones who will suffer the consequences, given that the product will not get to the hands of the consumers in the appropriate conditions for use.

If we only consider the view from the costs’ side, we will surely lose the view from the quality side, and there should be a balance among the two, especially in this sector. Anyone can provide cheap services, but not the best services.
What is the current role of the pharmaceutical industry, the drugstore chains and the distributors in the development of the pharmaceutical supply chain?

NL: I do not see significant progress from the point of view of the concerns about the quality with which the product reaches the point of sale. The evolution occurred was only economic: looking for efficiency gains through savings in transportation and storage. Often, these sectors say, for example, that they only receive certain goods if they are palletized, but they were not palletized by the industry. Is this operation the transporter/logistics operator’s responsibility? It should be the responsibility of the two negotiating agents [the industry and the pharmacy/drugstore chains and/or distributors].

The chains and the industries talk in equal terms, but if the transporter does not do what the chain requires, she could possibly contact the industry to inform that this particular transporter provides low quality services. The transporters are the small agents of the supply chain when compared to the power of the industries and the pharmacy/drugstore chains. The highest hierarchical levels in the industry and the senior executives of the chains need to pay closer attention to the importance of drugs’ transportation and storage. I believe that such awareness still doesn’t exist.

In this context, what are the pharmaceuticals’ transportation companies doing to improve the supply chain’s performance?

NL: To answer this question, we need only look at the number of transporters going bankrupt in recent years. As it was mentioned before, the transporters are too “small” to fight with the “big ones” (the industry, the pharmacy/drugstore chains and the distributors). Hence, they are absorbing the costs of the services required, without the possibility of passing them on, until they go bankrupt. In this scenario, there is almost no room for transporters to improve the supply chain’s performance.

The sector’s background has shown that transporters are going through difficult times, and will probably do again. The worst is that we will reach a point, in which the transportation costs will burst in Brazil: when supply will be low enough for transporters to establish their prices. The ideal is to keep competition within an appropriate level of profitability. When we do not have this, we do not have competition, which leads to monopoly. When there are just a few transporters left, then they will be able to negotiate with the industries and the chains.

Is there a risk of monopoly in Brazil?

NL: I don’t think so, because of the coverage or capillarity existing in the country. But we also see less and less transporters, in other words, the market has less choice options.

A serious problem in Brazil is that the transporter will not always be able to obtain a full load in the backward journey. Thus, we have to charge a freight price that will pay for a roundtrip. If Brazil had a less concentrated industrial distribution, the freight costs would be smaller. And they could be even smaller if we used waterways, railways and coasting navigation.

What recommendations would you give the legislators to create and reform the legislation applying to the pharmaceutical area?

NL: The regulation agencies should seriously discuss with the industry, the distributors and the pharmacy/drugstore chains the subject of
“A SERIOUS PROBLEM IN BRAZIL IS THAT THE TRANSPORTER WILL NOT ALWAYS BE ABLE TO OBTAIN A FULL LOAD IN THE BACKWARD JOURNEY.”

due to the exposure to inadequate conditions. We need to be absolutely sure that the final consumer is getting a full-quality product, remembering that nothing is for free. If we require certain conditions of transport, its cost will be more expensive, of course. We are a developing country. The Government should only be concerned to ensure the infrastructure, to regulate and supervise, for the private sector to do the rest for the country. It is useless to only create the law and assume things will happen. Without control, the law is not implemented.

WHICH ASPECTS OF THE COUNTRY’S LOGISTICS' INFRASTRUCTURE MOST HINDER THE PHARMACEUTICAL SUPPLY CHAIN?

NL: In addition to the poor conditions of most of the roads, we still haven’t properly developed other transportation modes, such as the waterways and the railways. Brazil needs to improve its infrastructure in all aspects. In order to do it, the country should attract private investments, from national or foreign capital. We need to put an end to that mentality, according to which the country has the conditions to do all the investments by itself.
WHAT IS THE IMPACT OF THE LOGISTICS’ COST ON THE PHARMACEUTICAL SUPPLY CHAIN?

NL: The logistics’ costs for the pharmaceutical supply chain, regarding storage and transportation, do not exceed 3%. And it may cost us very little to increase the supply chain’s efficiency, in order to ensure the product’s safety at the end of the process. I believe it is just a question of having the industry, the distributors, the pharmacy/drugstore chains and the transporters seat together and negotiate the improvement in the quality of transport.

“IT MAY COST US VERY LITTLE TO INCREASE THE SUPPLY CHAIN’S EFFICIENCY, IN ORDER TO ENSURE THE PRODUCT’S SAFETY AT THE END OF THE PROCESS.”

The regulation of drug prices is a disturbing factor in the process, because any increase in the cost results in the reduction of profit margins, given that it cannot be reflected in the price. The country loses more with the possible ineffectiveness of a pharmaceutical product than with a 0.5% higher cost in the supply chain. Considering that we can find in the pharmacies generic drugs with a 70% or 80% discount, we can imagine that a 0.5% additional cost in logistics is not a substantial difference for the supply chain.

WHAT ARE THE MAIN CHALLENGES FACED BY THE PHARMACEUTICALS’ TRANSPORTATION SECTOR IN VIEW OF THE CURRENT MARKET DEVELOPMENTS?

NL: The biggest challenge is exactly to bring to the discussion table each one of the supply chain’s agents.

We are the eighth economy in the world in drug consumption - the sixth before the devaluation - and projections made by the World Health Organisation indicate that Brazil will become the world’s fourth largest market. We should be prepared for these problems. We
need to be a market with adequate production, quality, distribution and logistics standards, in order to provide the consumers with quality products. An expensive medicine is the one we do not have when we need it to cure a disease. A few years ago, when someone had an ulcer, it was common to go through surgery. The pharmaceutical industry discovered two revolutionary drugs and, today, we take a drug for 14 days in order to heal the ulcer. That is why I ask: has someone calculated the economic impact (surgery, hospitalisation, work leave of absence) of this discovery? No, but people do complain about having to pay R$58 for 7 ulcer tablets.

People do not appreciate the advances brought about by the pharmaceutical industry, such as the treatments for cancer and hepatitis C. People think it is just a profitable industry, that wants to make money with pharmaceutical products. But if the industry didn’t make money, it wouldn’t be able to invest in research, and without research, we wouldn’t have evolution.

WHAT PATH SHOULD THE PHARMACEUTICALS’ TRANSPORTATION SECTOR FOLLOW TO OVERCOME ITS CHALLENGES?

NL: I understand that a certain specialisation in the transportation sector, led by regulation, could bring improvements or at least be the starting point to separate the wheat from the chaff. Furthermore, we should set which type of transport is adequate for pharmaceutical products, and which type of transporter or service is necessary to achieve the desired level. Again, it is important that the industry, the transporters, the distributors and the pharmacy/drugstore chains discuss the sector’s regulation, or the government will end up making creating it, and not always in the most appropriate way. I’ve always preferred gathering all the supply chain’s elements with the government in order to formulate the best solution. If the entire supply chain was to mobilise and bring the government to discuss the problems we would end up creating rules that are more adequate and of easy implementation, with gradual application steps.
CHAPTER 1

PHARMACEUTICALS’ TRANSPORTATION SECTOR OVERVIEW

The globalisation process defined a rather challenging scenario to the Brazilian companies, characterised, among other factors, by the use of higher levels of technology, a larger variety of products and increasingly demanding consumers. Hence, the need to respond to the demand with speed, consistency and flexibility, at the least possible cost, is reinforcing the importance of logistics as a factor of competitive and strategic advantage. Regardless of the company size, in an increasingly competitive context, logistics planning is key to ensure business profitability.

The ensemble of activities related to freight logistics, which includes transport, storage, payment systems, among others, has an important role in a country’s economic growth – in 2012, the logistics’ costs represented 11.5% of the GDP and 8.7% of the companies’ net income1. Although this process involves private agents, the public policies agenda must, necessarily, include projects in this area, especially for the improvement of national infrastructure.

In Brazil, the Growth Acceleration Program (PAC) is giving priority to the development of the logistics’ infrastructure, with approximately R$ 300 billion in programmed investments since the program was launched in 2007. In addition, the Logistics Investment Program (PIL), launched by the federal government in 2012, has an estimated investment of R$ 152.5 billion only in roads and railways, most of them with private funds.

These are relevant numbers, in the sense that they show, not only the effort being made, but also the need for new investments so that Brazil can achieve the logistics performance of similar territorial extension, such as the United States, Canada or China, or even Latin American countries, such as Chile.

Recently, the changes in the Brazilian economy indicators, combined with the existing deficiencies of the logistics infrastructure, have been translated into higher costs and worse results for the companies. In an attempt to decrease this impact, one of the companies’ solutions has been to press their transport suppliers for better prices and payment conditions.

In the case of pharmaceuticals’ transport, this situation is aggravated by the sector’s specific characteristics, related to the legal and sanitary requirements. In addition to the country’s infrastructure deficiencies and the new requirements, there is the pressure on the transport costs, arising from the economic context and the increasing competitiveness of the pharmaceutical industry in Brazil, specially, in the generic drugs’ market.

CARGO TRANSPORTATION IN BRAZIL

Brazil is the fifth country in the world, both in territorial extension and population wise. In the case of large countries, these two factors, extension and population, imply additional challenges. They need to ensure the appropriate transport infrastructure for industry supplies and the distribution of production to the internal and external markets.

Historically, transport in Brazil has a great dependency on road transport. Several factors contribute to this scenario, including the go-

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The transport services have significant impacts on the GDP, contributing to the added value of Brazilian and imported products, indirectly facilitating market interaction and new business. The transport, storage and postal services sector contribution to the GDP in 2015 was of R$ 213.2 billion (or 3.61%)⁴.

The variation of the transport, storage and postal services’ GDP tends to reflect the variation of the total GDP, although the value is higher. For example, while Brazil’s GDP grew by 0.1% in 2014, the transport’s sector GDP grew by 0.2%. And the drop in the national GDP in 2015 (-3.8%) was also larger than in the transport’s sector’s (-1.7%). The difference in performance is due to the fact that transport services are present in every supply chain, therefore benefiting from the expansion of every sector in the economy⁵.

THE TRANSPORT OF PHARMACEUTICAL PRODUCTS

Every supply chain is composed of several stages directly or indirectly linked, including supply, industry, distribution and transport, all the way to the final consumer. Its main aim is to provide the products, according to the demand, in the shortest time and with the lower costs possible.

In the pharmaceutical supply chain, the role of the distributor is to obtain the products from the national and international industries (laboratories) and distribute them to the retail
market (pharmacies and drugstores) and to
the service providers (hospitals and clinics). The transport of pharmaceutical products
from the industry to the distributor and be-
tween the distributor and the retailer is done
through the company’s own fleet or through
subcontracted transport provider. Among the
subcontracted companies, some can be logis-
tic operators that, besides the transport, also
offer storage and stock management services
– usually for laboratories and distributors.

Besides road transport, because of its parti-
cular characteristics, pharmaceutical produc-
ts are also transported by air and waterway,
in order to serve the populations that live the
most distant from the industrial centre of the
country. In some cases, the pharmaceuticals’
transport is done through a combination of
transport modals. In fact, despite the speciali-
sation tendency of the transport market, most
transport companies need to operate with
Less Truck Load (LTL), even when they use
third parties or autonomous truck drivers.

The road freight service providers can be divided in three cate-
gories: transport companies with their own fleet (the drivers are
hired through the Brazilian Labour Consolidation Laws, CLT), self-
employed drivers or temporary contracts.
CITIES WHERE ARE CONCENTRATED THE LABORATORIES

The challenge of transporting the pharmaceutical products from the laboratories to the wholesale distributors is evidenced when considering the concentration of the pharmaceutical industry in a few areas, that in most cases are rather distant from the wholesale distribution network.

In 2013, there were 499 companies dedicated to the “production of human drugs” (laboratories), spread across 180 different cities. The largest number of laboratories in the country is concentrated in the states of São Paulo (190 companies), Rio de Janeiro (61) and Goiás (50).8

A large part of the production in these units is transported to the wholesale commerce establishments specialised in the distribution of pharmaceutical products to the retail market. There are 2,950 pharmaceuticals’ distributors in the country, spread across 567 cities.9

The main facts about the performance of the pharmaceuticals’ products transport in 2015 are:

- The transport expenditures of the human drugs’ industry where of R$ 765 million, at current prices;11
- This expenditure is equivalent to 0.36% of the GDP in the same year for transport, storage and postal services (R$ 213 billion);
- It also constitutes 0.5% of the gross revenues of the freight road transport sector, estimated at R$142 billion.12

Source: Annual Inventory of Social Information (Relação Anual de Informações Sociais, RAIS)

CITIES WHERE ARE CONCENTRATED THE WHOLESALE DISTRIBUTORS OF PHARMACEUTICALS

9. The data from the Annual List of Social Information (RAIS) does not allow to separate the human drugs wholesale establishments from the veterinary wholesale establishments. Thus, this value is higher than the actual number of human drugs wholesalers registered in the RAIS database.
10. There are pharmaceutical laboratories and wholesalers in 124 cities.
11. Value estimated using the 2013 data from the Annual Industry Research (PIA) and the GDP’s 2015 official value disclosed by the Brazilian Institute of Geography and Statistics (IBGE).
12. Value estimated using the 2013 data from the Annual Industry Research (PIA) and the GDP’s 2015 official value disclosed by the Brazilian Institute of Geography and Statistics (IBGE).
The R$ 765 million expenditures of the pharmaceuticals’ industry in 2015 had an important impact on the pharmaceuticals’ transport sector, which also influences, to different degrees, other economic sectors, in an indirect or induced manner.

For every R$ 1.00 spent in the pharmaceuticals’ transport sector, R$ 0.43 was destined to supply purchases, R$ 0.50 to the retribution of labour and capital (salaries and profits) and R$ 0.07 to tax payments. Hence, the R$ 765 million spent by the industry in 2015 can be divided into:

- R$ 329.0 million in direct supplies’ purchases;
- R$ 378.9 million in salaries and profits;
- R$ 56.9 million in tax payments.

However, the amount destined to the purchase of supplies and the payment of salaries, profits and taxes is not yet the end of the supply chain. These expenditures have also indirect effects on other economic sectors.

Hence, for every R$ 1.00 spent on the pharmaceuticals’ distribution sector generates R$ 1.79 for the economy, in the form of direct and indirect effects on suppliers, R$ 0.85 in the form of direct and induced income effects, and an additional R$ 0.16 in the form of taxes. In other words, adding the direct, indirect and induced effects, as well as the taxes, for every R$ 1.00 spent, R$ 2.79 were generated. This means that the R$ 765 million spent by the industry in this sector generated an impact 2.79 times larger, adding up to R$ 2.1 billion, divided in:

- R$ 1.4 billion in direct supplies’ purchases;
- R$ 646.4 million in salaries and profits;
- R$ 118.3 million in direct tax payments.
DIRECT EFFECTS OF THE EXPENDITURES OF THE PHARMACEUTICALS’ TRANSPORT SECTOR

**DIRECT EFFECTS**

- **Supplies**
  - Value: R$ 328,950,891
  - Multiplier: 0.43

- **Income**
  - Value: R$ 378,945,651
  - Multiplier: 0.50

- **Taxes**
  - Value: R$ 56,874,569
  - Multiplier: 0.07

**ECONOMIC EFFECTS GENERATED BY THE EXPENDITURES OF THE PHARMACEUTICALS’ DISTRIBUTION SECTOR IN 2015**

**DIRECT EFFECT**

- Value: R$ 764,771,111

**DIRECT AND INDIRECT EFFECTS**

- Value: R$ 2,134,822,323

- **Supplies**
  - Value: R$ 1,370,051,212
  - Multiplier: 1.79

- **Income**
  - Value: R$ 646,427,693
  - Multiplier: 0.85

- **Taxes**
  - Value: R$ 118,343,418
  - Multiplier: 0.16

**DIRECT EFFECT: R$ 764,771,111**

**DIRECT AND INDIRECT EFFECTS: R$ 2,134,822,323**

**DIRECT EFFECT: R$ 764,771,111**
In terms of labour, the realised investment in the pharmaceuticals’ transport sector generated 11,181 direct jobs and 6,833 indirect jobs, adding up 18,015 jobs approximately. To fully understand the importance of the transport sector, it is essential to compare the multiplication coefficients in other economic sectors.

DIRECT AND INDIRECT JOBS GENERATED BY THE PHARMACEUTICALS’ TRANSPORT SECTOR

MULTIPLIER EFFECTS OF THE MAIN ECONOMIC SECTORS

<table>
<thead>
<tr>
<th>SECTOR</th>
<th>MULTIPLIER</th>
</tr>
</thead>
<tbody>
<tr>
<td>FOOD AND BEVERAGES</td>
<td>3.40</td>
</tr>
<tr>
<td>CHEMICAL PRODUCTS</td>
<td>3.16</td>
</tr>
<tr>
<td>INKS, PAINTS, VARNISH AND LACQUERS</td>
<td>2.96</td>
</tr>
<tr>
<td>TEXTILES</td>
<td>2.94</td>
</tr>
<tr>
<td>OIL AND NATURAL GAS</td>
<td>2.91</td>
</tr>
<tr>
<td>TRANSPORT, STORAGE AND POSTAL SERVICES</td>
<td>2.79</td>
</tr>
<tr>
<td>CONSTRUCTION</td>
<td>2.77</td>
</tr>
<tr>
<td>SERVICES PROVIDED TO FAMILIES AND ASSOCIATIONS</td>
<td>2.72</td>
</tr>
<tr>
<td>AGRICULTURE, FORESTRY AND FOREST EXPLOITATION</td>
<td>2.65</td>
</tr>
<tr>
<td>SERVICES PROVIDED TO COMPANIES</td>
<td>2.58</td>
</tr>
<tr>
<td>COMMERCE</td>
<td>2.43</td>
</tr>
<tr>
<td>REAL ESTATE SERVICES AND RENT</td>
<td>2.12</td>
</tr>
<tr>
<td>DOMESTIC SERVICES</td>
<td>2.00</td>
</tr>
</tbody>
</table>

Source: IBGE

Every R$1.00 of revenue in the transport, storage, and postal services generates R$ 2.79 for the economy as a whole.
THE METHODOLOGY BEHIND THE INPUT-OUTPUT MATRIX

The input-output matrix helps to create a comprehensive overview of the socioeconomic importance of the pharmaceuticals’ transport sector. This instrument enables us to evaluate the direct, indirect and induced effects generated by the sector on employment and income, added to the sector’s revenues.

The input-output matrix analysis is a widely used approach to assess the importance of sectors, industries or individual ventures on the whole economy, be it regional national or even international (IBGE, 2008; Cide Foundation, 1996; Montoya, 2001). The version of the input-output matrix used here was developed on the basis of the national accounts released by IBGE in 2009, and produced by Guilhoto and Sesso Filho. The data analysis in “System of Input-Output Matrix for Brazil 2009 – 56 sectors” has permitted the estimation of the socioeconomic importance of the pharmaceuticals’ transport logistics sector.

The IBGE releases the matrices that form the input-output system in two tables: resources and utilisation of goods and services. Both tables constitute the basis for the construction of the technical coefficients matrix and the Leontief inverse matrix, necessary for the calculation of the direct and indirect effects, respectively. The instrument developed by Russian economist Wassily Leontief allows us to identify the interdependencies of the productive activities regarding the supplies and products used in the production process. The IBGE’s national input-output matrix consists of 110 products (services and goods) and 55 economic activities.

DIRECT, INDIRECT AND INDUCED EFFECTS

The input-output analysis enables the assessment of the socioeconomic importance of the pharmaceuticals’ logistics sector on employment and income, through the construction of multipliers that estimate the direct, indirect and induced effects of the sector. In other words, it enables us to identify the impacts of the potential rising or falling in a certain sector’s productivity on the other sectors of the supply chain.

Given the cyclic and interlinked character of the economy and the intermediate consumption among these activities, there are direct impacts – the effects of final demand of good and services on directly involved economic activities – and indirect impacts – the secondary impacts, resulting from the direct impacts, on the production of supplies. Finally, the induced impacts are those generated by the workers’ income on other sectors.

Thus, these effects consist of an increase of the sector’s production, due to a higher demand, resulting in a higher level of income, employment and tax collection in several sectors.
Besides given the large interconnection existing in the country’s present economic structure, these effects spread across all the rest of activities in the national economic matrix (indirect impact). Their propagation is conditioned to the level of linkages existing among the Brazilian economic sectors, which can be calculated using the input-output matrix.

The higher the level of linkages, the higher the level of employment and income generated in the sectors of supply provision for one job, or one income unit, generated directly. The additional production required by the demand generated and the additional supplies’ requirements in every sector also leads to: a higher level of consumption, given the levels of income and employment generated (induced impact or income-effect); and a higher level of tax collection, which allows the public administration to increase social welfare.

Finally, it is important to mention that, for the calculations made in this project, we used the coefficients of the transport sector as a whole, and not specifically the pharmaceuticals’ transport sector, which is not available in the IBGE’s matrix.
CHAPTER 2
CURRENT COMPETITIVE SCENARIO

The current competitive scenario in the pharmaceuticals’ road transport will now be detailed, through the information collected during the interviews done with the main actors involved – transporters, pharmaceutical laboratories and distributors, pharmacies, drug stores, and insurance companies – as well as data coming from the questionnaires filled by the transporters and from public data sources.

INFRASTRUCTURE
TRANSPORT MATRIX

According to the last chapter, transport services are the main intermediary activity in any supply chain. In the case of Brazil, the transport matrix has a clear road transport bias, with more than 60% of the transport production17.

The predominance of road transport is the consequence of some specific characteristics, such as:

• Considered the most appropriate modal for high value items and perishable products, even for long distances;

• Offers higher frequency, reliability and convenience for the manipulation of varying size batches of goods;

• Enables door to door transport, higher speed, as well as simpler, lighter and cheaper packaging;

• Low costs, compared to the same modal in other countries, and to the incurred costs;

• Abundant supply.

17. National Transport Confederation (CNT), Pesquisa CNT de Rodovias 2015: Relatório Gerencial (p. 10).
Nevertheless, it is worth highlighting that these low freight costs are due to low labour qualification, predatory competition, deficient regulation and control, which are factors that increase the sector’s level of informality.

Besides higher levels of qualification for the transporters and the drivers, and the need for better quality equipment, to increase the road freight transport sector’s efficiency an adequate infrastructure is necessary.

QUALITY OF ROADS

Only 12.4% of the road system in Brazil is paved, which is well below the Latin American average (26%) and the world’s average (57%). Besides, close to 57.3% of Brazilian paved road system is in fair, bad or very bad conditions.

In this context, the general conditions of the roads in the country generate several consequences such as: the increase in the number of accidents; the increase in travel time; the increase in the emission of particles and greenhouse gases; the increase of the freight costs due to gasoline’s additional cost; the increase of vehicle maintenance costs and lower number of journeys. The increase in freight costs can reach up to 91.5%, in extreme cases.

Other key issues are the access difficulties found in certain regions, such as the North and Northeast, the poor development of the logistic chains, specially in regards to systems, processes and technology, and the need for greater investment in alternative modals, such as railway, the waterway and coastal navigation.

CLASSIFICATION OF BRAZIL’S ROADS GENERAL CONDITIONS IN 2015

Source: CNT

18. National Transport Confederation (CNT), Pesquisa CNT de Rodovias 2015: Relatório Gerencial (p. 65-69). Note: The general conditions of the roads is evaluated by the CNT, including eventual flaws in the pavement, on the signalisation and/or in the road geometry, considering 100 thousand km of paved roads.

PUBLIC INVESTMENT

Public investment in transport infrastructure in Brazil, as a percentage of the country’s GDP, has been decreasing since the 1970s: from 1.84% of the GDP in 1975, it reached 0.29% in 201420.

As an alternative, the government has been creating partnerships with the private sector. For example, in 2012, the Federal Government created the Logistics Investment Program (PIL), aimed to enable the necessary investments in the country’s transport infrastructure, through private agents. The program’s latest phase, launched in 2015, has an estimated total investment of R$ 66.1 billion in new road concessions21.

REGIONAL DISPARITIES

The regional disparities existing in the Brazilian road transport system, particularly regarding the density and the quality of the roads.

In this sense, the North and Northeast regions, followed by the Centre-West region, are the regions with the most problems, such as22:

- The 76% of Northern roads, the 60.5% of roads in the Centre-West and 56.1% of the ones in the Northeast region have problems, their general conditions being qualified as fair, bad or very bad; only 22.7% of the roads in the South and 16.5% of the ones in the Southeast region had those qualifications;
- The North, Centre-West and Northeast regions have the lowest road densities in the country – considering paved and non-paved roads (38.4, 127.9 and 286.7 km/1,000 km², respectively);
- The North, South and Centre-West regions cause the higher increase in trucks’ operational costs, due to the pavement’s poor conditions (36.6%, 28.8% and 27.1%, respectively);

---

22. National Transport Confederation (CNT), Pesquisa CNT de Rodovias 2015: Relatório Gerencial.
• The increase in the operational cost pushes the freight’s cost-pricing relationship, which has an important impact on the products sold in the country. Hence, the impact on transport costs is reflected in supply chains’ logistics.

LOGISTICS COSTS

The logistics costs – transport, stock and storage – represent 11.5% of the Brazilian GDP and, in average, 8.7% of the companies’ net income23. These costs include transport (road, railway, waterway, pipeline and airway), stock (financial cost, facilities and equipment, labour, insurance, obsolescence, depreciation, damages and losses) and storage (cargo handling, packing and conditioning). Transport is, thus, the main component of the logistics cost, representing, by itself, near 5% of the Brazilian companies net income24 or 57.5% of logistics costs.

Compared with the United States, the cost of road transport in Brazil is almost 2.3 times lower. One of the main reasons is the country’s low road freight rate, artificially kept at low levels as a result of a series of factors such as25:

- High fragmentation and oversupply in the road freight sector;
- Low labour qualification in the sector;
- Deficient regulation and control, which results in:
  - Low truck maintenance;
  - Low entry barriers;

GENERAL CONDITIONS OF THE ROADS BY GEOGRAPHIC REGIONS IN 2015 (%)

Note: The CNT’s publication covers the whole federal paved road system and the main paved state roads.

Source: CNT

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25. Reis, M. A. S. Logistics and Supply Chain Management Concepts. Presentation of the course given at the Military Academy of Agulhas Negras. Available at: <manoel.reis@fgv.br>. Accessed: 20/05/2015.
• High fiscal burden and tax default;
• Heavy workload;
• High levels of cargo theft.

• Predatory competition, with high social costs, such as accidents, excess of vehicles and low energy efficiency.

These factors are reflected in the country’s logistics performance. Brazil is the 65th in the Logistics Performance Index (LPI) 2014 ranking, calculated by The World Bank26, across 160 countries. Hence, Brazil is well behind countries with similar dimensions – such as the United states (9th), Canada (12th) and China (28th) – and even behind other Latin American countries – like Chile (42nd), Mexico (50th) e Argentina (60th).

ALTERNATIVE MODALS

Historically, the incentive for road transport in Brazil acted to the detriment of the development of other transport modals, such as the railway, waterway and costal navigation. The freight transport matrix in Brazil is divided into: more than 61% by road, more than 20% by railway and only 18% is allocated in the rest of the modals.

Nevertheless, each means of transport has its own specific characteristics and comparative advantages, depending on the nature of the load, the volume transported and the distances travelled. For example, the railway and waterway are the most efficient and the cheapest modals for the transport of large volumes of low aggregated value in long distances, such as, for example, to distribute the mining and agro industrial production’s distribution.
### BRAZIL IN THE RANKING OF THE LPI OF THE WORLD BANK

<table>
<thead>
<tr>
<th>DIMENSIONS</th>
<th>2007</th>
<th>2010</th>
<th>2012</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>CUSTOMS PROCEDURES</td>
<td>74</td>
<td>82</td>
<td>78</td>
<td>94</td>
</tr>
<tr>
<td>INFRASTRUCTURE</td>
<td>49</td>
<td>37</td>
<td>46</td>
<td>54</td>
</tr>
<tr>
<td>INTERNATIONAL DELIVERY</td>
<td>75</td>
<td>65</td>
<td>41</td>
<td>81</td>
</tr>
<tr>
<td>LOGISTICS CAPABILITIES</td>
<td>49</td>
<td>34</td>
<td>41</td>
<td>50</td>
</tr>
<tr>
<td>TRACKING</td>
<td>65</td>
<td>36</td>
<td>33</td>
<td>62</td>
</tr>
<tr>
<td>DEADLINE COMPLIANCE</td>
<td>71</td>
<td>20</td>
<td>49</td>
<td>61</td>
</tr>
<tr>
<td><strong>POSITION IN THE LPI GENERAL RANKING</strong></td>
<td><strong>61</strong></td>
<td><strong>41</strong></td>
<td><strong>45</strong></td>
<td><strong>65</strong></td>
</tr>
</tbody>
</table>

Source: World Bank

### FREIGHT TRANSPORT MATRIX (TKM) IN COUNTRIES SIMILAR TO BRAZIL

**LEGISLATION**

The current legislation created the need for further qualification of labour, better equipment and infrastructure, turning the pharmaceuticals’ transport more expensive. Hence, there are additional requirements to the transport of human drugs and pharmaceutical supplies, compared to the transport of other products, such as electronics and foodstuff.

The specific legislation can be divided into two main groups: the requirements for pharmaceutical products handling, responsibility of the National Sanitary Control Agency (Agência Nacional de Vigilância Sanitária – ANVISA) and the transport regulation, defined by the National Land Transportation Agency (Agência Nacional de Transportes Terrestres – ANTT).

**SANITARY REGULATION**

Pharmaceutical products have specific conservation conditions, which vary according to the active ingredient, the excipient, the formula, the packaging and conditioning. The producer is responsible for establishing these conditions, based on stability studies, done under the supervision of National Sanitary Control Agency (ANVISA)\(^ {27} \). These tests use different temperature and humidity technical parameters to simulate the conditions under which the pharmaceutical products will be stored and handled, with the aim of studying the emergence of pharmacological and pharmaceutotechnical alterations.

The incorrect preservation of pharmaceutical products may lead to health risks for the patient, associated to the reduction of their therapeutic effect and/or the emergence of side effects and adverse reactions. Hence, to ensure the drugs’ stability the physical and chemical conditions should be maintained in each one of the phases of the supply chain of pharmaceuticals’ transportation, storage and distribution.

In this context, National Sanitary Control Agency (ANVISA) established a series of requirements for the companies operating across the pharmaceutical products’ supply chain such as: the annual operating license (with a cost ranging from R$ 1,500 to R$ 15,000 according to the company’s annual revenue), the technical responsible pharmacist in the companies dedicated to the storage and transportation of human drugs, pharmaceutical and chemical supplies\(^ {28} \), and the monitoring of the temperature and humidity conditions in which the pharmaceuticals are transported.

These requirements result into an increase ranging from 30% to 40% of the pharmaceuticals’ freight costs, according to the transportation companies.

**SANITARY INSPECTION**

The main objective of sanitary inspection is to monitor the market and identify possible irregularities in the companies and the products subject to sanitary surveillance, to avoid or reduce the health risks for the population. The monitoring activities include routine inspections, quality monitoring programs and, mainly, through claims and complaints to the sanitary inspection\(^ {29} \).

The National Sanitary Control System (Sistema Nacional de Vigilância Sanitária – SNVS) is the main instrument of prevention and health promotion in Brazil, involving the three main levels of government: at the federal level, through the National Sanitary Control Agency (ANVISA) e the National Institute for Health Quali-

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The pharmaceutical laboratories highlighted the importance of the inspection done by the National Sanitary Control Agency (ANVISA), as well as the increase of the requirements, aiming to improve drugs’ quality and safety. There are some instances in which the laboratories international headquarters’ requirements are higher than the Brazilian regulation. The laboratories also mentioned that the norms tend to be stricter in the production phase than in the other end of the supply chain, mainly the distribution activities.

The interviews done in the context of this project, with members of the pharmaceutical supply chain, have shown the consensus of laboratories, transporters and distributors around the issue. The Brazilian sanitary inspection is insufficient and asymmetric, lacking clear definitions and rules, that change among regions and according to the companies’ size (larger companies suffer with stricter inspections). Hence, one of the main challenges for sanitary inspection is the great pulverisation of the pharmaceutical supply chain, specially in a large country like Brazil, with important infrastructure problems.

The sanitary inspection should be more uniform, both in its requirements and its capacities, to enhance the transporters investments in employee qualification and training, and load monitoring technology, for example. In this sense, these investments could become an entry barrier to the sector, improving drugs’ safety for the consumer and preventing illegal practices.

**TRANSPORT REGULATION**

Besides the sanitary regulation, the transporters that do freight transport in Brazil have to comply with the requirements of the National Land Transportation Agency (ANTT). In the last ten years, the regulation of the freight transport sector has been improved, reducing informality and increasing the costs. Some examples are illustrative:

- The Law nº 12.249, from 2010, established the “means of payment” for the self-employed freight transporters (Transportadores Autônomos de Carga – TAC), substituting the “carta-frete” (a sort of voucher, given to the self-employed freight transporters as advance payment) and aiming to increase the regularisation of the transportation sector;

- The Euro 5 emission standard, approved as a part of the Control Program for Air Pollution from Motor Vehicles (Programa de Controle da Poluição do Ar por Veículos Automotores – Proconve) in 2012, introduces a series of new technologies for the reduction of vehicles’ emissions, requiring special motors and the use of a new fuel (S10), more expensive than regular diesel;

- The National Plan for Trucks Fleet Renewal (Plano Nacional de Renovação de Frota de Caminhões – RenovAr), currently being negotiated between the National Transport Confederation (CNT) and the Federal Government, aims to establish the economic, financial and fiscal incentives to the purchase of new trucks, according to the Control Program for Air Pollution from Motor Vehicles (Proconve) requirements, reducing older vehicles circulation;

- The so-called “Driver’s Law” (Law nº 12.619, from 2012, and Law nº 13.103, from 2015) that established regular and minimum resting times, limited work day, and other formalisations for the transportation sector.
Some of these changes brought about sensible impacts, in terms of costs, to the transportation sector. The Euro 5 norm increased the trucks acquisition costs around 15%\textsuperscript{32}, without any evidence of fuel economy so far, that would compensate the increase in costs. The “Driver’s Law” has significant impacts translating into higher operational costs, through the reduction of productivity, and longer delivery times, because of shorter journeys. This had also lead the transportation companies to increase their labour force, both drivers and auxiliaries, and the investment in new vehicles. According to NTC & Logística, this law has caused the operational costs for the transportation of pharmaceutical products to increase about 23.5% per unit transported, given the productivity reduction.\textsuperscript{33}

**EVIDENCE OF FUEL ECONOMY IN THE FREIGHT TRANSPORT SECTOR WITH THE EURO 5 NORM**

![Graph showing fuel economy data]

Source: NTC & Logística Yearbook 2014/2015

**AVERAGE INCREASE IN THE OPERATIONAL COSTS OF THE CARGO TRANSPORTATION OF PHARMACEUTICAL PRODUCTS CAUSED BY THE DRIVER’S LAW**

<table>
<thead>
<tr>
<th>DISTANCE BANDS (KM)</th>
<th>R$/T (BEFORE THE LAW)</th>
<th>R$/T (AFTER THE LAW)</th>
<th>% OF INCREASE</th>
</tr>
</thead>
<tbody>
<tr>
<td>VERY SHORT - 50 KM</td>
<td>569,35</td>
<td>741,35</td>
<td>24,31</td>
</tr>
<tr>
<td>SHORT - 400 KM</td>
<td>680,77</td>
<td>852,25</td>
<td>25,19</td>
</tr>
<tr>
<td>MEDIUM - 800 KM</td>
<td>857,98</td>
<td>1,059,72</td>
<td>23,51</td>
</tr>
<tr>
<td>LONG - 2,400 KM</td>
<td>1,486,10</td>
<td>1,808,88</td>
<td>21,72</td>
</tr>
<tr>
<td>VERY LONG - 6,000 KM</td>
<td>2,515,85</td>
<td>3,110,98</td>
<td>23,66</td>
</tr>
</tbody>
</table>

Source: NTC & Logística, 2012

\textsuperscript{32} NTC&Logística. Meio Ambiente: Norma Euro V elevou Custos do Transporte. 2014

\textsuperscript{33} NTC&Logística, 2015. Crise do TRC: O Modelo “ganha-perde” e o Apagão Logístico.
According to the transporters, the recent changes in legislation can be innocuous for not considering the real conditions of the Brazilian road infrastructure. For example, the lack of safe resting places for the drivers or the institutional inspection inability.

**DRIVERS SHORTAGE**

A significant part of the road transportation companies (86% of the total interviews done by the National Transport Confederation – CNT\(^{34}\)) declared having problems in their hiring process, due to the scarcity of qualified professionals, to the high social burdens and the lack of specific courses and training.

The estimates calculated by NTC & Logística show that, in average, in 2014, 12.1%\(^{35}\) of their associates’ fleets were not working because of the shortage of drivers. The shortage is estimated to a range from 82 thousand to 106 thousand in the sector.\(^{36}\)

In order to meet the sector’s labour demand, the National Transport Confederation (CNT), the Transport Social Service (Serviço Social do Transporte - SEST) and the National Transport Training Service (Serviço Nacional de Aprendi-

<table>
<thead>
<tr>
<th>TOTAL VEHICLES</th>
<th>675.086</th>
</tr>
</thead>
<tbody>
<tr>
<td>DRIVERS’ SHORTAGE IN THE COMPANIES</td>
<td>12.1%</td>
</tr>
<tr>
<td>SHORTAGE SCENARIO FOR 1:1</td>
<td>81.685</td>
</tr>
<tr>
<td>SHORTAGE SCENARIO FOR 1:1,3</td>
<td>106.191</td>
</tr>
</tbody>
</table>

Note: The 1:1 relation means 1 driver per truck; the 1:1,3 relation means 1,3 drivers per truck, number suggested by NTC & Logística, due to the Law requirements.

Source: NTC & Logística Yearbook 2014/2015


35. NTC&Logística, 2014. Escassez de Motoristas pode Elevar Custos do TRC.

36. NTC&Logística, 2014. Escassez de Motoristas pode Elevar Custos do TRC.

37. Transportation Social Service (SEST) and Transportation National Learning Service (SENAT), 2015.

OPERATIONAL REQUIREMENTS

In a context of greater competitiveness and modernisation, transportation efficiency needs to be increased, given that the logistic efficiency has important impacts on the sector’s profitability. This need is reflected both on the transporters' selection criteria, and on the requirements made at the source (industry) and the destination (distributors, pharmacies and drugstores).

TRANSPORTERS’ SELECTION CRITERIA

The general criteria for transporters’ selection include: reliability, cost, operational and commercial flexibility, quality of operational personnel and performance information. In the sector of pharmaceutical products and supplies, specifically, there are three fundamental criteria: regulatory qualification, service quality and cost. The relative relevance of each one of these criteria can vary depending on:

• Type of pharmaceutical drug: laboratories specialised in generic drugs generally emphasize the freight cost and the performance of the transporter, while the laboratories oriented to high added value products and/or temperature-sensitive products look for high quality services and reliability in a transporter, considering the deadlines, licenses, qualification, infrastructure and adequate equipment;

• Type of operation: if the transporter selection process is done by the laboratory itself, the quality of service and the compliance with legal requirements are elimination criteria, followed by an evaluation process of the freight cost, known as “bid”. On the other hand, if the transporter selection process is done through an intermediary, generally a logistics’ operator, the emphasis will be on higher performance and lower freight cost, instead of quality, according to the interviews.

In theory, the negotiation process between the industry and the transporter should aim the reduction of costs, without prejudice to the quality of service, and according to the cost sheet. The costs, in the road transport sector, are essentially determined by fuel, maintenance, depreciation, capital and insurance. However, according to the transportation companies, the bid process focuses on quantitative variables, such as performance and price, even though the pharmaceutical load needs increasingly differentiated services.

As reported by the transporters, the logistics’ area does not have much influence in the selection process in the organisational structure of the pharmaceutical laboratories. The financial area makes the final decision, being above even the quality area. In the case of the multinational companies, many times the cost reduction guidelines come directly from the headquarters and do not necessarily consider the specific characteristics of the pharmaceutical market in Brazil.

In this context, some laboratories have been dividing the transport operation by region and product. On one hand, given the size of the country, the operation of transportation companies is very regionalised in Brazil, and the laboratories tend to select the best in each region. On the other hand, since some of these laboratories also produce generic drugs and cosmetics (products with lower added value and less requirements) they can divide their operation hiring more than one transporter, with different quality standards and prices. Additionally, some laboratories have been fostering the development and capacitation of smaller regional companies for the transportation of pharmaceuticals, generic drugs and cosmetics.
Even though the pharmaceutical market is still very atomised, with the ten largest laboratories being responsible for 38% of the market, the laboratories have been recently engaged in a consolidation process, especially in the generic drugs and biosimilars’ sector. Through this process, the laboratories have been increasing their market power, as well as the competition among them, factors that push for higher transport efficiency.

Besides, the pharmaceuticals’ market trend has been the development of higher complexity molecules, that result in stronger requirements – in terms of expiration date and temperature control, for example. Therefore, the industry will demand higher efficiency, to meet delivery deadlines, complying with the requirements for each type of product – combustible, perishable and temperature-sensitive products.

However, the improvements in the pharmaceuticals’ market, leading to greater requirements all across the supply chain are not being followed by the transportation companies. According to the industry, the new requirements triggered, at first, a reactive response from the transportation companies, that would not assume their new role.

On the point of view of the transporters, there are two main factors that have prevented their adaptation to the new requirements set by the laboratories: the selection process involving the bid, which hinders the investments in infrastructure, material resources and personnel, needed to meet the new requirements’ standards; and the high risk of the pharmaceutical load, being one of the main targets for theft, and thus, entailing the need for further investments in technology and security. Hence, the main challenge is to enable these investments using a compensation model that prioritises costs.

Some industries and transportation companies are already working, collectively, in the transporters’ capacitation to meet the new requirements’ standards.

The trend towards concentration, both of the distributors and the pharmacies and drugstores’ chains, has brought some changes to the pharmaceutical value chain as a whole. On one hand, they have increased their bargaining power with the laboratories, especially in the generic drugs and biosimilars’ segments, in some cases even imposing the delivery conditions to the laboratories. On the other hand, the increase in competition has drawn the distributors and the chains to improve their logistics’ efficiency, with the introduction of the models used by the large supermarket retailers, for example.

The greatest professionalization of the pharmaceutical retail sector has also increased the importance of performance across the supply chain, pushing every link to improve the service and logistics quality. This has been reflected into the new demands made by the distributors and the drugstore chains, such as: adequate physical infrastructure, qualified personnel for product handling and conditioning according to the required standards, and compliance with the sanitary regulation. Additionally, the new demands included palletization of the load, delivery scheduling and separation of the load by invoice, for example.

In contrast, the lack of infrastructure, organisation and/or qualified personnel for load handling, both at the source (laboratory) and

destination (distributors and pharmacy and drugstore chains) has transferred most of these demands to the transportation company. Furthermore, the cost from any load damage in the transport from the laboratory to the distributor, is under the responsibility of the transporter.

In this context, NTC & Logística releases annually a Reference Cost Structure for LTL (Less Than Truckload), calculated under the supervision of the Technical LTL Transport Chamber (Câmara Técnica de Transporte de Carga Fracionada - CTF). The methodology used reflects the cost structure of an efficient company, dividing the costs in two types: the basic fees (Componentes Tarifários Básicos) and the general fees (Generalidades do Transporte).\(^{40}\)

The general fees were an initiative of the transportation companies, through the intermediary of NTC & Logística, to introduce additional fees that would enable them to pass on the cost increase to the pharmaceutical industry, at least in part. There are 11 fees in total, and these have been applied since 2005.

Additionally, the transportation companies can charge fees related to additional services, in other words, additional activities that are not included in the transportation services but can be requested by the clients or offered by the companies as a complement. The most common are palletization, delivery scheduling, stub return (of the delivery receipt), dedicated vehicles and pick-up/delivery outside business hours. These fees have an important impact on the pharmaceuticals’ transport sector, given that the transportation companies incorporated many of the activities previously done by distributors and drugstore chains, without an increase in compensation.\(^{41}\)

Besides the additional services, there were new demands in the pharmaceutical segment, such as higher unloading times (up to three days) and the need for a driver assistant for every 200 to 300 unloaded items. In this sense, NTC & Logistica recommended, in a study from 2003, that the transportation companies should charge additional fees, specific for the deliveries to large pharmacy and drugstore chains and pharmaceutical distributors.\(^{42}\) The main ones are: driver’s assistant for unloading, increased risk (Gestão de Risco - GRIS) and damage allowance.

To charge these fees, there should be a greater alignment among the three links of the supply chain - source/laboratory, transporter and client/distributor and drugstore chains - because, even though these are requirements made by the client, who pays for the additional fees is the source. Hence, it is important that these demands are considered by the laboratory when hiring the transportation services, avoiding problems at delivery.


\(^{41}\) NTC&Logistica, 2013. Recomendações para as Empresas Transportadoras de Medicamentos (Produtos Farmacêuticos).

\(^{42}\) NTC&Logistica, 2013. Recomendações para as Empresas Transportadoras de Medicamentos (Produtos Farmacêuticos).
CHAPTER 3

ESTIMATE OF THE IMPACTS OF THE MAIN CHANGES IN THE SECTOR

This chapter is based on the analysis of the financial data sent by the transportation companies to estimate the impact of the main changes in the sector in the last years, regarding their costs and profit margins.43

COST STRUCTURE AND METHODOLOGY

The standard model of costs and revenues used to analyse the financial data provided by the companies participating in this study was the one used by the Brazilian National Statistics Institute (IBGE) in the Service Sector Annual Research (Pesquisa Anual de Serviços - PAS). Hence, the model sent out to the participating companies included the following groups44:

• Goods and Fuel:
  • Goods, Consumption and Replacement Materials, including: tyres, air chambers and dashboard; office material; parts, accessories and materials consumed in the maintenance and repair of fixed assets (buildings, vehicles, domestic appliances, machinery, boilers, generators, etc.).
  • Fuel and Lubricant, considering the costs, over the year, of fuel oil, diesel oil, kerosene, gasoline, among others.

• Operational Expenditures:
  • Services Provided by Self-Employed Professionals (individuals), including the expenditures paid to self-employed professionals such as accountants, lawyers, electricians and builders.
  • Services Provided by Companies, including technical and professional services; surveillance, security and transportation of valuables; freight and courier, shipping chartering and renting; temporary labour contracts; goods’ maintenance and repair.
  • Storage, Load and Unload, and Terminal Utilisation, including the expenditures with storage of goods, load an unloading, weighing services, expenditures related to the utilisation of terminals, and logistics’ services.
  • Tolls
  • Taxes and Duties, such as the Urban Building and Land Tax (Imposto Predial e Territorial Urbano - IPTU), the Motor Vehicles Property Tax (Imposto sobre a Propriedade de Veículos Automotores - IPVA), Credit, Exchange and Insurance Operations Tax (Imposto sobre Operações de Crédito, Câmbio e Seguros – IOF) and licenses.
  • Insurance Pay Outs, regarding properties, vehicles, stock goods, among others.
  • Other Operational Expenditures, including: property rental; publicity and advertising; commissions to third par-

43. Six pharmaceuticals’ transportation companies sent the data on which this chapter’s analysis is based: Ativa Logistica, Atlas Transporte e Logistica, Expresso Jundiai, Luft Logistics, RV Imola and Shuttle.
44. Categories defined in the Annual Services Research (PAS) publication volume 15 from 2013.
ties; communication services (mail, fax, telephone and Internet); electric power, gas, water and sewage; travel and representation expenses; office material; copyright, franchise and royalties for trademarks and patents.

- Personnel: includes the amount paid during the year in salaries and other compensations (13th salary, holiday pay and overtime), profit participations, cooperative members compensation, directors’ fees, owners and partners’ compensation, social contributions, workers’ indemnities and terminations, and benefits (transport and food allowances).

- Others: include other operational costs and expenditures were considered separately to have a comprehensive and comparable understanding of all the information sent by the transportation companies.

The information provided were treated to eliminate the price fluctuations during the period, in other words, the data series were deflated. Broadly, the prices in the economy are divided among free and administered prices, or monitored. Administered prices are defined by contract, monitored by public and regulatory agencies and readjusted following certain rules. Hence, these are less sensitive to the market conditions than the free prices, which fluctuate according to the equilibrium between supply and demand.

Therefore, the inflation rates applied were different for the free and the administered prices, such as tolls and fuel for example. The inflation data series used in this study was the free prices index of the Broad National Index of Consumer Prices (Índice Nacional de Preços ao Consumidor Amplo – IPCA) calculated by the Brazilian National Statistics Institute (IBGE), except for the fuel expenditures, for which we used the fuel monitored prices series, and the tolls’ expenditures, for which we used the other monitored prices series, both of them calculated by the IBGE as well.

**IDENTIFIED IMPACTS**

The resulting analysis of the financial data provided by the transportation companies enabled us to draw some observations, described below. It should be noted that this is not an analysis of the full financial statements of the companies, but only of the expenditures described above. Hence, when we use the term “Total Expenditure”, we are referring to the sum of the previously mentioned items.

The first analysis consists in the ratio between the three main expenditures’ groups and the total expenditures, and the variation of this ratio in the period 2009-2015. This analysis shows that the personnel expenditures grew more than the other groups, increasing its participation in the total expenditure, from 26% in 2009 to 32% in 2015.

Further analysis shows that, as shown in the figure below, while the ratio of costs and the others group in relation to the net revenues remained constant, the largest variation came from the personnel expenditures group, which caused an increase in the net revenue of 6%, and of 3% in the operational expenditures group.

Considering the costs group (goods and fuel) as a percentage of income, it should be noted that the real reduction (deducting the inflation over the period) of the diesel prices was more than compensated by the raise in the expenditures with goods, consumption and replacement materials, which lead to the stability of this expenditure group.

The growth in the operational expenditures group, as a percentage of the net revenue of the participating companies, is even more evident when it is compared with the industry’s average. According to the data from the Service Sector Annual Research (PAS) from the Brazilian National Statistics Institute (IBGE), the companies participating in the study had higher operational expenditures than the industry’s average. The difference reaches up to 15% in the last year in which the industry’s average is available, 2013.
EVOLUTION OF EACH EXPENDITURES’ GROUP AS A PERCENTAGE OF THE TOTAL EXPENDITURES OF THE PHARMACEUTICALS’ TRANSPORTATION COMPANIES PARTICIPATING IN THE STUDY

Source: Data provided by the participating companies

EVOLUTION OF EACH EXPENDITURES’ GROUP AS A PERCENTAGE OF THE NET REVENUES FOR THE PHARMACEUTICALS’ TRANSPORTATION COMPANIES PARTICIPATING IN THE STUDY

Source: Data provided by the participating companies
In the same lines, when comparing the variation of personnel expenditures of the participating companies with the industry’s average, calculated by the Brazilian National Statistics Institute (IBGE), the first had personnel expenditures 15% higher than the second in 2009, and 38% higher in 2014.

Finally, the increase in these costs resulted in a reduction of the transportation companies profit margins. Considering as a basis the percentage of profit margin in 2009, there was a reduction of 44% in 2015, even after a significant increase in 2014.

**EVOLUTION OF EXPENDITURES AS A PERCENTAGE OF INCOME FOR THE PHARMACEUTICALS’ TRANSPORTATION COMPANIES PARTICIPATING IN THE STUDY**

![Graph showing the evolution of expenditures as a percentage of income for the pharmaceuticals' transportation companies participating in the study.](image)

Source: Data provided by the participating companies.

**COMPARISON OF THE OPERATIONAL EXPENDITURES AS A PERCENTAGE OF THE REVENUES**

![Graph comparing the operational expenditures as a percentage of the revenues for pharmaceuticals' transportation companies participating in the study and the average of road freight transport sector as a whole (IBGE).](image)

Source: Data provided by the participating companies and public data from the Service Sector Annual Research (PAS) from the Brazilian National Statistics Institute (IBGE).
**FLEET**

The data provided by the transportation companies participating in the study also has information about the current fleet. One of the main investments of a transportation company is the amount destined to fleet renewal.

Given the uncertainty context, from the point of view of sanitary and transport regulation, there is a great concern about the ageing of the fleet. Old trucks pollute more, have higher maintenance costs and greater risk of accidents. In fact, for some types of load, there

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**COMPARISON OF THE PERSONNEL EXPENDITURES (100 = 2009)**

![Comparison of Personnel Expenditures](image)

Source: Data provided by the participating companies and public data from the Service Sector Annual Research (PAS) from the Brazilian National Statistics Institute (IBGE).

**VARIATION OF THE MARGIN PERCENTAGE (2009 BASIS) FOR THE PHARMACEUTICALS’ TRANSPORTATION COMPANIES PARTICIPATING IN THE STUDY**

![Variation of Margin Percentage](image)

Note: The margin was calculated as the difference between the net revenues of these companies and the sum of the costs, operational expenditures and personnel expenditures.

Source: Data provided by the participating companies.
are age limits for the fleet – for the chemical load, for example.45

The participating companies have a fleet nearly four years younger than the market’s average. The self-employed drivers have the oldest fleet, around 17 years on average.

Assuming that the pharmaceuticals’ transportation companies participating in the study only purchased new vehicles, it was possible to calculate the volume of fleet acquired each year. It is worth noticing that the fleet acquisition trend follows the company’s revenues’ fluctuations, although with greater variation. Thus, between 2011 and 2012, while the revenues decreased by 10 percentage points, the volume of new acquired vehicles fell by almost 60 percentage points.

The data provided by the transportation companies participating in the study suggest that the investment decision is heavily influenced by the revenue, but there are other important factors. In fact, the companies’ future expectations also affect the level of investment, especially in high uncertainty contexts.

**COMPARISON OF THE TOTAL AVERAGE FLEET AGE IN 2015**

![Graph showing the average fleet age in 2015 for pharmaceuticals' transportation companies, road cargo transportation companies as a whole, and self-employed drivers.]

Note: The total fleet includes trucks, utility vans and support vehicles.

Source: Data provided by the participating companies and public data from the National Road Freight Transporters Register (Registro Nacional de Transportadores Rodoviários de Carga - RNTRC) from the National Land Transportation Agency (ANTT) for 2016.

EVOLUTION OF THE FLEET PURCHASES AND THE REVENUES OF THE PHARMACEUTICALS’ TRANSPORTATION COMPANIES PARTICIPATING IN THE STUDY

TOTAL FLEET PURCHASES  TOTAL REVENUES

Note: Assuming that the companies only buy new vehicles, hence the manufacturing date is equivalent to the purchase date.
Source: Data provided by the participating companies.

FINAL CONSIDERATIONS ABOUT THE IMPACTS OF THE MAIN CHANGES IN THE SECTOR

The analysis described above reflect a reduction trend in the profit margins of the pharmaceuticals’ transportation sector. This trend is apparently caused by the increase in personnel expenditures as a ratio of the revenues, linked, mainly, to a higher labour demand.

The increase in personnel expenditures is, in part, compensated with the improvement of the operations, although there also are cost pressures in those areas. Thus, the pressure on the companies’ profit margins can increase, since the operational improvement cannot be permanent.

This trend can imply the exit or bankruptcy of the transportation companies specialised in the pharmaceuticals’ sector, which would lead to the concentration of the market and, eventually, to higher prices.
The relevant factors for the analysis of the future prospects of the Brazilian pharmaceutical distribution supply chain, focusing on the transporters’ role and the dynamics between the chain links, are the following:

- Interaction between the chain links and the public sector, and its results, given that the internal and external interactions of the pharmaceutical supply chain are the essential to understand the sector’s main challenges, and especially, the transporters’.

- Need for greater integration and dialogue between the pharmaceutical supply chain links.

- Impact of further possible changes in legislation on the quality of service and the financial situation of the transportation companies.

- Competitive structure of the transportation companies.

The following considerations are based on the interviews done with representatives from each one of the link of the pharmaceutical distribution supply chain – national and international laboratories, transporters, distributors, pharmacy and drugstore chains, and insurance companies – complemented by some of FGV opinions.

**THE MAIN CHALLENGES PUT BY THE PUBLIC SECTOR ON THE BRAZILIAN PHARMACEUTICAL DISTRIBUTION SUPPLY CHAIN**

Many of the difficulties presented by the interviewed are conditioned to factors directly linked to the public sector, especially regarding the sanitary and transportation regulation and control, the tax system and the infrastructure. All of these elements affect the logistics’ operation between each one of the chain links, to different levels, and directly or indirectly. Additionally, they also have an impact on the quality of service, the companies’ cost structure and the competitive structure of the supply chain.

**SANITARY AND TRANSPORTATION REGULATION**

According to the pharmaceuticals’ transporters, some of their main challenges are related to: the uncertainties regarding the implementation of the sanitary and transportation regulations; the lack of adequate infrastructures to comply with the regulations (such as the poor road conditions); the existing informality (resulting from asymmetries in the regulatory control); and the vagueness or even absence of the relevant norms necessary for the sector’s proper functioning.

The difficulties in the implementation of new norms has lead the transporters to pressure the government for changes. For example, regarding the transportation regulation, and more specifically the Driver’s Law (n° 12.619/2012), the transporters achieved a first change, brought up by Law n° 13.103/2015. As a result, the normal eight hours’ workday could be extended up to two extra hours, or up to four extra hours, through a union agreement for example.

However, there is considerable concern about the lack of adequate truck stops on the roads, especially in the North and Northeast regions. Hence, according to the transporters, the legislation should evolve to regulate the truck stops not only on toll roads, which are already regulated by Decree n° 944, issued on July 8th 2015 by the Brazilian Ministry of Labour and Employment (Ministério do Trabalho e Emprego - MTE), but also on state-run roads. Additionally, they have been advocating for the introduction of “gradually implemented” legislation, in other words, with intermediary targe-
ts, that could reduce informality in the sector. The increase in downtime (meal breaks, daily, night and weekly rests) brought up by Driver’s Law, for example, could have been implemented more gradually, until the appropriate infrastructure conditions were ensured.

The Brazilian sanitary legislation was mainly developed since the creation of the National Sanitary Control Agency (ANVISA) in 1999 through the Federal Law nº 9.782. However, some requirements are not clear or are not yet established in current regulation, such as the temperature control rules.

Although the sanitary legislation establishes the maximum and minimum temperature limits recommended to maintain the properties of pharmaceutical products, it does not give any parameter for monitoring and/or maintaining the temperature. For example, the rules do not stipulate if the transporter should monitor the temperature inside the truck with a thermo-hygrometer – that sends out the information to the responsible pharmacist at the operations base – or if the driver should manually control the temperature.

The legislation is also quite vague regarding whether the trucks used for pharmaceuticals' transportation should be insulated and/or refrigerated. In this scenario, the transporters have adopted a conservative approach. The vagueness of the requirements hinders and even discourages the companies to invest in new technologies that could improve security in the pharmaceuticals’ transportation.

Additionally, the transportation companies raised the need to create new norms, specific for pharmaceuticals, with the introduction of a maximum age for the fleet, which already exists for chemical products46, and a minimum salary for the drivers. The introduction of new labour qualification requirements for the pharmaceutical load is also being discussed, in order to complement the only supervision of a responsible pharmacist. Hence, the possibility for new changes, both in the sanitary and the transportation regulations, has also contributed to a situation in which most transporters are postponing new investment decisions.

“FISCAL WAR”

Most of the laboratories’ representatives interviewed raised the problems brought up by the “fiscal war” to the transport operation. The analysis on this topic is based on the main observations made during these interviews.

Some states, like Goiás, have established fiscal incentives to attract pharmaceutical laboratories and distributors. However, this situation created distortions in the market and higher logistics’ costs. The increase in costs, as a consequence of the expansion of the routes used, could become even greater with the lack of the necessary investments in infrastructure at the destination.

If the “fiscal war” has a great impact on the laboratories that have patented products, it certainly affects even more the laboratories who mainly commercialise non-patented products, such as generic drugs and biosimilars. These products have radically different freight costs, transported volumes and distribution needs, considering that their market value is much lower than the patented products. Overall, a fiscal reform could enable a market shock, ending the distortions and emphasising production logistics.

During the interviews, the laboratories have also shown their preoccupation with possible changes in legislation and their implementation. The pharmaceutical products have been developed from increasingly complex substances, that demand further conservation requirements. Hence, temperature control is one of the main challenges mentioned by the laboratories, especially at the end of the supply chain, in other words, at the destination, with

more than 70 thousand pharmacies in Brazil. As a result, higher logistic demands are falling on the transportation companies, both from the laboratories end, and from the distributors, drugstores and pharmacy chains.

Hence, there is a clear need for greater involvement of the public sector, regarding the sanitary legislation, the tax reform and the infrastructure investments. However, according to the laboratories, the pharmaceuticals’ transportation sector has not been sufficiently involved in these questions. In their opinion, the transporters should be more organised to be able to pressure the government for improvements in the infrastructure, the sanitary and transportation legislation and the existing fiscal barriers.

Most of the transportation companies have adopted a conservation posture. In other words, they have been waiting for the approval of every new law, to then study the difficulties to its implementation and appeal, instead of getting previously involved in its elaboration. According to the laboratories, there are only a few transportation companies that demonstrate some initiative in that sense.

INSPECTION ASYMMETRIES

The existing sanitary inspection asymmetries are one of the main challenges faced by the distributors and the chains of pharmacies and drugstores. The inspections are mainly focused on the last links of the supply chain, closest to the final consumer. In this context, the pharmaceuticals’ distributors have been very active towards the government, claiming for improvements, heavily investing in logistics and pressuring the rest of the sector to do the same. According to the distributors, making the sanitary inspections more homogeneous across the supply chain could bring important benefits, in terms of security for the final consumer.

Another difficulty mentioned during the interviews is that, often, the changes in the transportation legislation are not accompanied by appropriate infrastructure improvements. For example, the circulation restrictions implemented in the largest cities, such as São Paulo and Rio de Janeiro, and that are gradually been replicated in other capitals, have resulted in greater challenges and logistics’ costs for the pharmaceuticals’ transportation sector.

If the transporters have had an important role in pressuring the government for more transparency in the legislation’s elaboration and implementation and better infrastructure conditions, they have been kept aside in the discussions around the Traceability Law. Brazil has been a pioneer in this area, aiming to create and implement a track-and-trace system for pharmaceutical supply chains, with alphanumeric barcodes that would minimise security risks and bring transparency to the entire process.

GREATER INTEGRATION OF THE PHARMACEUTICAL SUPPLY CHAIN

The pharmaceutical supply chain needs to be more integrated and foster dialogue among the different sectors, in order to overcome the challenges described. One of the conclusions of this study is that, both the transporters and the laboratories have mentioned the importance of working together to create an action plan to adapt the transportation services to the clients (distributors and chains of pharmacies and drugstores) new requirements.

This is a critical matter for the laboratories, given the current trends of pulverisation in the industry and concentration in the pharmaceutical retail sector. In fact, the chains of pharmacies and drugstores are increasing their market power in comparison to the pharmaceutical industry. Hence, the laboratories now compete to have their product on the pharmacy shelf, and this depends on the efficiency and effectiveness of the logistics’ operation.

In this context, it is necessary to foster dialogue and information sharing among the industry, the transporters, the distributors and the retail sector, in the aim of improving the operation
across the pharmaceutical supply chain. The distributors and the chains of pharmacies and drugstores agree about the need of greater interaction and cooperation. Avoiding supply chain breakdowns, for example, depends on that interaction, and specially on information sharing, to identify the problems and define the best strategies to overcome them, improving efficiency and reducing costs. In this sense, the Traceability Law could enable greater information sharing across the pharmaceutical supply chain.

THE TRACEABILITY LAW

The Traceability Law, Law nº 11.903 of January 14th 2009, created the National Drug Control System (Sistema Nacional de Controle de Medicamentos - SNCM), which involves the production, commercialisation and prescription of medical, dental and veterinary drugs, as well as the other movements object of sanitary inspection. According to Law’s 3rd Article, the system will introduce an exclusive identification system for the products, service providers and users. The system will be based on an electronic data collection, storage and transmission technology.

For each pharmaceutical product, the system will store the following information:

- **I – manufacturer** (operating permit, state license and municipal sanitary permit of the manufacturer’s facilities);
- **II – suppliers** (wholesalers, retailers, exporters and importers of pharmaceutical supplies);
- **III – buyers** (including establishments requiring non-prescribed products in multiple products’ prescriptions);
- **IV – product** (product and amount prescribed);
- **V – transportation/logistics units**;
- **VI – consumer/patient**;
- **VII – prescription** (including non-prescribed products in multiple products’ prescriptions);
- **VIII – doctor, dentist and veterinarian** (registration in the council of the professionals authorised to prescribe).

The great amount of information required, shows the complexity of a system that will demand important investments in technology and equipment, especially on behalf of the laboratories. The main objective of this system is to reduce theft and counterfeit labelling of pharmaceutical and veterinary drugs, as well as tax evasion. In fact, every time the product’s property changes, the system will be activated and the transaction’s information recorded.

However, the deadlines for implementation and the execution procedures of the system are being discussed. Normally, only the laboratories, distributors and pharmaceutical retail sellers will be responsible for entering the products’ information into the system. Hence, despite the transportation services being a part of the information required, the transporters’ role in the system has not yet been defined. That is why the transportation companies have not been officially involved in the law’s elaboration, despite some of them having already made themselves available for the integration of their technology information systems.

Among the positive aspects of the drugs’ traceability mentioned during the interviews, is that it could enable a greater integration of the pharmaceutical supply chain. Information sharing about product damage and theft, for example, could improve load control, stock management, as well as the logistics’ strategy. Additionally, the system’s implementation will require great investments in technology and infrastructure, that will work as entry barriers, improving the sector’s competitive structure.

Regarding the negative aspects, the interviews have shown the lack of important definitions regarding the development and execution of the system, such as: the data base type and
responsibility, the system’s intelligence and language, and the integration method among systems. According to the laboratories, the National Sanitary Control System (ANVISA) is studying to make the drug’s registration holder (the laboratory) responsible for the entire supply chain’s data base. This is seen as an attempt to exempt the sanitary authorities of the main responsibility.

Additionally, there is a growing concern, especially among the laboratories, about the system’s implantation costs. Besides their fear of it becoming a burden upon them, the laboratories also have doubts about the correct implementation of the traceability system across the supply chain. In their opinion, some of the sectors involved are not yet adequately prepared for it. Finally, in the view of the distributors and the chains of pharmacies and drugstores interviewed, great part of the system’s responsibility could fall on them, given that the sanitary inspection is easiest at the final stages of the supply chain.

The implementation of the Traceability Law is one of the main factors of uncertainty in the pharmaceutical sector as a whole, for its potential impacts on the companies’ cost structures. But, despite the financial impacts of the implementation of this and other regulations, it will certainly improve the quality of the services provided across the supply chain, and especially, by the transportation companies.

**The Impact of the Possible Changes in Legislation on the Quality of Service and the Finances of the Transportation Companies**

The expected changes in legislation, given the greater specialisation and modernisation of the transportation services, could have important impacts on the quality of service in the pharmaceutical sector. All the transporters interviewed agree that the investments needed will increase in the next years, in areas such as transportation, refrigerated vehicles, fleet renewal, qualified personnel (pharmacists in every subsidiary), security, technology, packaging and processes.

**Qualified Personnel**

There is a growing concern in the sector about the increasing lack of drivers, probably due to the low salaries and the higher drivers’ demand as result of the Driver’s Laws (nº12.619/2012 and 13.103/2015). Additionally, the operational requirements (temperature control, security restrictions, among others) have increased the driver’s functions and responsibilities.

This vision was confirmed by the insurance and risk management companies. According to them, the technological advances have allowed the transporters to have more control over the truck loads, to improve logistics’ efficiency and to gather more information about the operation. The information gathered about the fleet and its efficiency, enabled the risk management companies to advise the transporters about their logistic processes, improving the quality and the amount of services provided.

For the laboratories, the trends in the coming years, including the patents’ expiration process and the growth of the generic drugs’ market, could increase competitiveness in the sector. As mentioned before, the logistic management of generic drugs and brand name drugs is quite different. Generic drugs have a larger profit margin, and thus a higher cost reduction effort. Besides, generic drugs compete with other drugs with the same active ingredient, and it becomes a question of which one will be available at the pharmacy shelf first. In this context, the logistics’ efficiency is becoming increasingly important in the pharmaceutical sector.

The laboratories’ strategy has been to attract professionals from other sectors, in which competition is higher, bringing along new practices to achieve greater logistic efficiency. The interviews have shown that facing the logistics as a strategical activity is quite a recent
trend in the sector, but it is likely to increase. Among the new practices that could be adopted, the industry representatives mentioned the performance indexes, the greater control of the operation and also, the transporters’ development programs.

Achieving these objectives will depend on several factors: overcoming the regional difficulties (especially in the Centre-West and Northeast regions), involving more the transporters, and standardising the requirements of the most demanding sectors, the distributors and the chains of pharmacies and drugstores.

The retail pharmaceutical market has also undergone important transformations in the last five years. According to the interviews, the mains ones have been the market’s consolidation with the emergence of large chains of pharmacies and drugstores and the increasingly demanding sanitary inspections. These transformations have pressured the end stages of the pharmaceutical supply chain to focus on logistics.

However, this modernisation trend has affected every sector of the pharmaceutical supply chain except for the transportation companies. According to the interviews to the retail sector, the introduction of innovative practices and the demands for better quality service and performance, should lead the transporter to specialise and maybe, regionalise. They even suggested the creation of operation niches, in the routes to the Northeast region, for example.

COST STRUCTURE

Another point of great concern in the pharmaceutical sector are the future impacts that the legislation changes and the pressure for a greater quality of service can have on the finance and investments of the transportation companies. Among the transporters, there are both optimistic and pessimistic views.

The current economic situation of the pharmaceuticals’ transportation companies is guided by three main factors: the increasing trend of the operation costs, the increasing need for investments and the decreasing trend of the pharmaceutical load profitability. In fact, the fixed costs of the pharmaceuticals’ transportation are quite high, due to the legal and operational requirements.

The transporters are not always able to pass on the additional costs, given that the pharmaceutical prices are controlled by the government and the freight is calculated according to the value transported. Hence, for some transporters, the future perspectives on the short and medium terms are challenging, because the freight value will probably not increase enough to compensate the investments made, nor the new investments required.

Some transporters have also mentioned the impacts of the sanitary inspection flaws, which have led to predatory competition, by competitors operating in the informal market. This situation hinders even further the finances and investments of the transportation companies that already have or intend to meet the requirements made by the legislation and the market’s new demands. In the absence of improvements, some transporters are increasingly losing their motivation to continue in the pharmaceutical segment, and are starting to diversify the loads transported.

On the other side, there are some transporters that have a more optimistic view about the future, mainly because they believe there is still room for growth in the pharmaceuticals’ transportation sector. There are structural factors that make this market very attractive. First, pharmaceuticals are high value-added products and basic goods, with low seasonality. Second, given the increasing Brazilian life expectancy, the consumption of pharmaceuticals will probably increase in the medium and long run.

Additionally, the greater sanitary requirements, including the Traceability Law, and the modernisation of the pharmaceutical retail market, will probably create further develop-
ment opportunities for the transportation companies. According to some of the transporters interviewed, it is important to ensure the continuity of the modernisation and specialisation process, in order to offer more services and higher quality services, which could lead to an increase of the freight value.

The main challenge for the transporters that see opportunities for growth, through service specialisation and modernisation, is the need for greater organisation and standardisation among the transportation companies. This view coincides with the laboratories opinion, about how the transporters have evolved quite slowly so far. According to them, the transportation companies profit margins must be decreasing because of the higher costs and the greater amount of services required.

Additionally, the uncertainty context regarding the legislation changes also hinders the companies’ investment decisions. However, since the requirements are probably going to increase, the only way is through the transportation sector’s adaptation and modernisation, just like the rest of the supply chain.

THE COMPETITIVE STRUCTURE OF THE TRANSPORTATION COMPANIES

Given the difficulties imposed by the new client demands and legal requirements, and the fragile financial situation of the pharmaceuticals’ transportation companies, another challenge mentioned during the interviews is the risk of monopoly. According to the transporters, despite the decrease in the number of
active companies in the market, the risk of monopoly does not yet exist.

On one hand, there are new competitors attempting to enter the market. These are generally smaller transportation companies, that have had many difficulties to adapt to a highly regulated and complex market, with high fixed costs and many legal requirements.

On the other hand, some of the transporters operating in the pharmaceuticals’ sector, have already opted for diversification and new business strategies. To diversify, the transporters can both operate on Full Truck Load (FTL), choosing products that are compatible with the pharmaceutical load, such as electronics, or create new services focused on the laboratories, such as reverse logistics. As for the new business strategy, it could include the development of new activities oriented to pharmaceutical supply chain as a whole, including hospitals and transport through customs.

Most of the laboratories interviewed do not believe in the imminent risk of monopoly in the pharmaceuticals’ road transportation sector, despite its urgent need for drastic changes. There have been fast transformations at the end stages of the pharmaceutical supply chain, with the recent mergers and the creation of large conglomerates. In this context, the transporters will have to adjust to a higher degree of specialisation, and possibly, will have to create different market niches for different transportation standards. Given that the pharmaceutical industry is not planning on internalising the transportation services, some laboratories are introducing transport regionalisation projects, focusing on smaller companies to increase service quality and reduce costs.

This view, about how the regionalisation of transportation, by hiring smaller companies could improve the service, is shared by the distributors and the chains of pharmacies and drugstores. These already work with smaller transportation companies in their own distribution operations, tending to compare with the companies that operate the transport from the industry to them.

Regarding the consolidation of the transportation sector, the interviewers believe it should not be a problem, given that it has increased the quality, the level of dedication and professionalism of the service. However, there are still serious specific problems, that have even led some distributors to operate their own transport to some laboratories. In such cases, the operational problems go beyond the transporter, highlighting the need for greater integration in the pharmaceutical supply chain as a whole.

Perhaps this view on regionalisation does not bring about the expected improvements, considering the difficulties of smaller transportation companies to meet the requirements associated with the pharmaceuticals’ sector and the great volumes involved.
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