Medical prescription process in Brazil

MELISSA POKORNY, EDUARDO DIAS AND AUGUSTO BRANDÃO JUNIOR
Department of Electrical Energy and Automation Engineering
University of São Paulo
Avenida Professor Luciano Gualberto, travessa 3, 158, GAESI, Sala A2-18, Cidade Universitária, São Paulo/SP, CEP: 05508-010
BRAZIL
melissapokorny@pea.usp.br http://www.gaesi.eng.br

Abstract. The pharmaceutical sector in Brazil is very complex with many players in the supply chain. Given the complexity of the sector and the importance of health for the government, it was created in the country a track and trace system of medicines from the manufacturing industry to consumption by the patient, through distribution, transportation, dispensing, prescription and patient identification. It turns out that the measures taken so far range from manufacturing to dispensing, not foreseeing executive measures for the prescription. The prescription is important for the patient's health and allows access to medicines, including those controlled by the government. The prescription process is basically on paper, enabling frauds. One possible solution is to automate the prescription process and to integrate this system in the future with the National Medicine Control System.

Key-words: track and trace; medical prescription; automation; medicine control system.

1 Introduction

Globalization forces the interaction among players in the supply chain of several sectors of the economy. In addition, the search for cost reduction associated with a strategic vision of the company allows, giving an example, a raw material supplier is in a country, the industry in another and consumers possibly in a different continent.

Make this finished product reaches its final destination brings many challenges, especially when it comes to complex sectors of economy, as in the case being examined here, the healthcare industry, including pharmaceutical industries, public and private distributors, public and private hospitals, pharmacies, offices, clinics, among others.

The *Pricewaterhouse Coopers (PwC*), a private company of international consultancy, conducted a survey on this health sector framework in Brazil and found that there are currently more than: (i) 400 medicines' manufacturers and importers; (ii) 27 state distribution centers; (iii) 5,000 municipal distribution centers; (iv) 300 private distributors; (v) 5,000 private hospitals; (vi) 50 federal hospitals; (vii) 50,000 private pharmacies; (viii) 40,000 centers and health posts; (ix) Clinical 20,000; (x) 50,000 offices; plus many other players raised by PwC [1].

Another important factor to be mentioned is the significant volume of products circulating within this sector, either in financial terms or in quantity of products. Sindusfarma (Union of Pharmaceutical Products Industries of São Paulo) did a survey in 2014 on sales only in pharmacies segment from 2003 to 2014 and the progression is significant. Only in 2014 were sold in the Brazilian market 3.12 billion drug units, representing a value of R$ 65.8 billion reais. [2]

The figure below shows the progression of sales in Brazil (Pharmacy Sales) both figures on Brazilian's currency Real (light blue column) and US currency Dollar (dark blue column), and amount of drug units sold over the years (orange line).

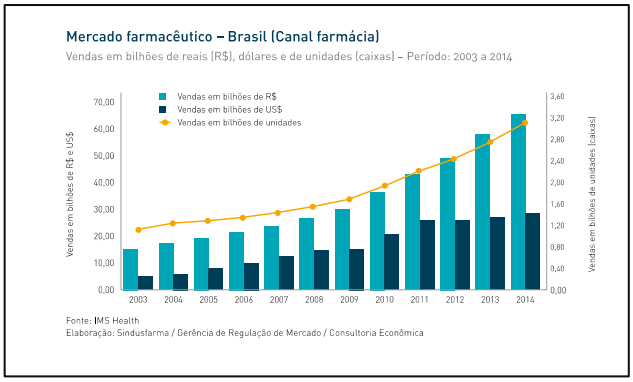

Figure 1 – pharmaceutical market - Brazil (Pharmacy Sales)
Source: Sindusfarma [2]

This figure shows the strength of the sector in the economy and also is a warning on the amount of drugs circulating in the country.

The data is relevant to Brazil and this situation is similar in other countries. This same survey by Sindusfarma shows that, in 2014, were sold in the pharmacy channel US$ 590 billion in 2014 globally, and, above Brazil are still countries like United States, Japan, Germany, France. [2]

After this brief overview, it must be said that the governments – either developed countries or developing countries – are concerned to trace the drugs in their health sectors, ranging from the manufacture of products, through distribution, prescription, to reach the end user (in case the patient). And this concern ranges from the requirement to control possible recall, for instance, to control the authenticity of the consumed product, since the amount of counterfeit drugs found in Brazil and in the world concerns both government itself and the World Health Organization. [3-8]

In Brazil the federal government created, in 2009, a National Medicine Control System (in Portuguese Sistema Nacional de Controle de Medicamento – SNCM) aimed the traceability of all medicines produced (whether produced domestically or imported), distributed, prescribed and dispensed in national territory. [9-11]

Although the Brazilian government is committed to deploy the traceability of medicines, all efforts to do this so far was focused from the industry to the dispensation, without, however, dealing with the prescription.

The prescription is an essential part of medicines traceability because it allows linking the prescriber to the patient and allows the patient to be binding to the medicine purchased at the pharmacy.

So after this brief overview, the article will deal with the prescription in Brazil, proposing a automation process model and integration of this system with the SNCM.

2 Prescribing model existing in Brazil and problems related to it

The prescription is the act of a professional legally qualified to prescribe the patient a drug putting in handwriting the nomenclature of the medicine and its dosage and method of use. The doctor's recipe is the document that formalizes the prescription.

In Brazil there is the sale of medicines that do not require a doctor's recipe such as simple medicines.

There is also sale of medicines that require a doctor's recipe and, if government controls the medicine, this control over sales increases due to the high risk to consumer health.

There is a federal law in Brazil from 1973 mentioning that doctor's recipe must be written in ink, in the vernacular, in full and legibly handwriting, containing the nomenclature of the drug, its dosage and method of use, and also containing the name and home address of the patient, name of the professional prescriber of drug, office or residence address, registration number in their professional department, as well as the date and signature. [12]

Although there is this law (before the digital era), there is now the possibility to prescribe a drug using computer containing exactly the same information as the prescribed handwriting recipe, and it must be printed, signed by the responsible professional. Along with the signing, the professional must stamp his professional information.

For controlled medicines, there is a specific legislation of the Ministry of Health, which determines the whole procedure to prescribe the drug as well as fill out a standardized document called Prescription Notification authorizing the dispensing of the drug, in addition to controlling the production, import, marketing, stock, balance sheet products controlled by the government, creating a series of rules to be observed by industry players. [13]

Controlled drugs are divided into three categories and each has a Prescription Notification document of a specific color: (i) numbing medicines - yellow paper - for substances on lists "A1" and "A2"; (Ii) psychotropic medicines - blue document -For substances lists "A3", "B1" and "B2"; (Iii) retinoid for systemic use and immunosuppressant medicines - white paper - for lists of substances "C2" and "C3". The description of the lists are:

- "A1" - List of Numbing Substances
- "A2" - List of Numbing Substances Permitted to Be Used Only in Special Concentrations
- "A3" - List of Psychotropic Substances
- "B1" - List of Psychotropic Substances (with different substances from "A3")
- "B2" - List of Psychotropic Substances anorectic
- "C2" - List of Retinoid Substances
- "C3" - List of Immunosuppressant Substances

This Prescription Notification is controlled by the government agency, including, requiring authorization for printing.

When dispensing the drug, the pharmacy or drugstore gets the Prescription Notification and return the stamped doctor's recipe for the patient.

Although it is so strict to purchase medicines, especially those controlled by the government, this control does not prevent fraud in the acquisition.

As an example, in 2007 the Health Department of the Municipality of Aracaju/SE (Brazil) began investigating a lot of false doctors' recipes at drugstores and pharmacies in the city, especially about psychotropic drugs. It turned out that counterfeiting occurred as follows: one person in possession of a single sheet of Prescription Notification reproduced multiple color copies and forged the doctor stamps and signatures. This discovery led the authorities to worry for possible criminal network that traded and profited from prescription controlled medicines. [14]

It is important to notice that even with the control of medicines by the government, these are still subject to fraud, considering that a single color copy and production of stamps with false information allows criminals to acquire the controlled medicine at any pharmacy.

The authors believe that the prescription should also be automated and integrated later to the National Medicine Control System (SNCM). Thus, the items below will deal with automation process proposal.

3 Authentication and Transmission System

The Authentication and Transmission System (SAT in Portuguese) is a technological model for automation and control processes developed at the University of São Paulo in partnership with the Financial Department of State of São Paulo (SEFAZ-SP).

Its development was originated by the necessity of tax control, considering the number of contributors' establishments is extremely higher than the number of government employees responsible for tax controlling. SEFAZ did a study identifying that would take 159 years for all of São Paulo State's establishments were inspected at least once. [15]

Because of this information, as well as tax evasion rates raised by SEFAZ, it was necessary to change the model by entering the issue automation in the process.

The SAT is a cross-sectional model applied in industries that on one hand generate data, with establishment of rules and necessity of guaranteed authenticity and confidentiality, and secondly, transmitting secure information to one or more centers. [15]

This automation model is developed to low cost, ease of deployment and sending data quickly and securely to the backend of the supervisory board, allowing cross-checks with other databases available. [16]

Minimum requirements for automation solution should: [16]

(I) have shielded equipment proof of fraud, which burns its internal components in the event of infringement;

(II) have digital certification;

(III) work offline if there is no connection;

(IV) updating software online;

(V) issuing alarms in case of system failure or attempted rape;

(VI) structure the XML files;

(VII) Web Service interface.

The SAT developed for SEFAZ has the following model: [15]

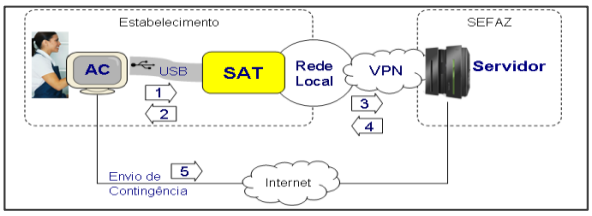

Figure 2 – SAT Model
Source: Vidal Melo [15]

Arrows (1) and (2) - integration with the business application for data reception and return of the backup of the Electronic Tax Receipt generated by the SAT equipment on the taxpayer establishment;

Arrow (3) - Periodic transmission of the SAT equipment coupons to the tax authorities automatically through the local data network connected to the Internet;

Arrow (4) - receiving data and commands from the Tax Department by SAT equipment to perform specific actions and coupons transmission confirmations;

Arrow (5) - Contingency transmission mode, in which the taxpayer must manually copy the files from the Electronic Tax Coupons stored in the commercial software application and upload the Tax Department website.

SAT therefore was developed to generate a document that exists only in electronic form, which

captures the information in the field and sends the data to the backend of the inspection agency, respecting the safety requirements and authenticity information. For the consumer, there is the printing of the document, with the QR Code to enable the consumer to verify the information.

Figure 3 – SAT Model
Source: Vidal Melo [15]

4 SAT for automation prescription

Using by analogy the case of tax SAT, designed for commercial establishment of the State of São Paulo, it is possible to think in the same automation process model for prescription.

Prescriptions will be made exclusively by electronic form, through commercial software application with all those information already defined by the law, including new patient ID field.

The doctor will be identified through a digital certificate guaranteeing the authenticity of the prescription, whereas the encrypted card is personal and not transferable, login and password will be need also. It is important to say that doctors already have the professional document with digital certificate.

The commercial software application will interact with the SAT that will produce an electronic document prescription in XML format to be transmitted automatically through the local data network connected to the Internet, integrating the database of the supervisory authority in the case. It might be the same department that will control the information of the National Medicine Control System (SNCM).

Although the document is electronic, the doctor can print an extract from SAT Prescription with all necessary information for the patient, including a printed datamatrix code in doctor's recipe.

The datamatrix has been the chosen technology for capture, storage and transmission of information to the National Medicine Control System.

With the SAT, the document Prescription Notification could be abolished whereas the information is already part of the database of the supervisory department.

When patients get the medicine, presenting the printed prescription in the case, the pharmacist will read the datamatrix and validate the prescription information at the government's system control.

By selling the product, the pharmacist will connect the information about the medicine tracked along the supply chain by SNCM system to the prescription information, including data from the doctor and the patient.

This model allows the doctor to be identified by his professional record with digital certificate, replacing the stamp that currently exists in Brazil.

The patient is also identified with the national registration number. Thus, the government system will have full control of the chain of medicine from the manufacturer, through distributors, carriers, dispensers, prescribers and consumers.

5 Conclusion

To ensure patient safety and control all medicines produced and dispensed in Brazil, it is necessary to automate the entire process. The prescription would be carried out by the system, generating information that would feed, online, the database of the medicine control agency. This information would be integrated to the National Medicine Control System, closing the drug traceability cycle in the country.

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