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## **DRUG COUNTERFEIT AND PENAL LAW IN BRAZIL**

*Coordinator:* Marta Rodriguez de Assis Machado  
*Authors:* Marta Rodriguez de Assis Machado,  
Ana Carolina Alfinito Vieira, Carolina Cutrupi Ferreira,  
Vivian Cristina Schorscher

RELATÓRIO DE PESQUISA  
v.6 n.1 : janeiro 2009

**27**



## CADERNOS DIREITO GV

v.6 n.1 : janeiro 2009

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DA FUNDAÇÃO GETULIO VARGAS

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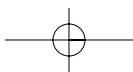
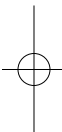
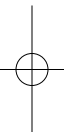


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RELATÓRIO DE PESQUISA

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27



## APRESENTAÇÃO

O texto que ora se publica é uma versão reduzida do relatório sobre falsificação e mercado ilegal de medicamentos no Brasil, preparado pelo Núcleo de Estudos sobre o Crime e a Pena da DIREITO GV, sobre minha coordenação, no âmbito da pesquisa comparada “*Drug Counterfeit and Penal Law – A Comparative Legal Analysis*”, realizada pelo Instituto Max Planck de Direito Penal Estrangeiro e Internacional sobre a coordenação do Prof. Dr. Hans-Georg Koch e da Dra. Juliane Laule.

O texto segue a estrutura geral proposta pelos coordenadores do estudo comparado, com algumas alterações, a fim de dar conta das especificidades do caso brasileiro. Ele contém basicamente (i) um mapeamento das informações disponíveis sobre as diferentes práticas de distribuição e comercialização irregular de medicamentos no Brasil; (ii) uma exposição sistematizada da legislação pátria que se refere ao assunto, bem como o nosso arcabouço institucional; e (iii) um retrato da atuação recente das principais instituições envolvidas na prevenção e repressão do comércio irregular de medicamentos.

É preciso mencionar que a pesquisa encontrou uma série de dificuldades, especialmente no que diz respeito à descrição e ao dimensionamento do problema, uma vez que praticamente não há dados públicos a esse respeito. Para poder compor um panorama ao menos aproximativo do problema, trabalhamos com dados de mídia, levantamos os casos registrados no Ministério Público Estadual de São Paulo e na Justiça, especificamente nos Tribunais de Justiça do Estado de São Paulo e nos cinco Tribunais Regionais Federais e consultamos os registros de ocorrências na Delegacia Especializada em Crimes de falsificação e roubo de medicamentos, desde 2005. Além disso, entrevistamos uma série de pessoas ligadas tanto à indústria farmacêutica, como às instituições de Justiça encarregadas de perseguir tais práticas ilícitas, cuja colaboração foi de inestimável utilidade para esta pesquisa. Tais entrevistas também nos permitiram recolher distintos pontos de vista sobre as eventuais falhas dessas instituições e distintas sugestões e estratégias de aperfeiçoamento institucional.

Por conter sistematização e esforço de compilação de informações sobre o tema ainda inéditos no Brasil, decidimos que a

# DRUG COUNTERFEIT AND PENAL LAW IN BRAZIL

publicação deste texto, ainda que em formato de relatório e em língua inglesa, pudesse interessar também ao leitor brasileiro.

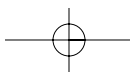
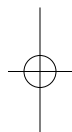
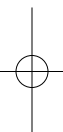
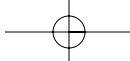
Agradeço imensamente à equipe de pesquisa pela dedicação e perseverança na busca dos dados, nomeadamente a Ana Carolina Alfinito Vieira, Carolina Cutrupi Ferreira, e Vivian Cristina Schorscher. Agradeço também a colaboração e sugestões de Heidi Rosa Florêncio, Marta Saad Gimenez, Mônica Rosina Guise e Yuri Corrêa Luz e, muito especialmente, a André Nunes Batista, Guilherme de Almeida e Máira Rocha Machado que colaboraram substancialmente com o desenvolvimento dos temas ligados, respectivamente, à proteção da propriedade intelectual no Brasil, à perseguição de crimes praticados por meio da internet e à cooperação internacional.

## **Marta Rodriguez de Assis Machado**

Professora da Escola de Direito de São Paulo  
da Fundação Getulio Vargas (DIREITO GV)

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# **DRUG COUNTERFEIT AND PENAL LAW IN BRAZIL**

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## **INTRODUCTION**

This paper presents an organized and critical description of the existing information on illegal practices regarding the drug market in Brazil and the applicable legal and administrative regulations deemed as relevant. Our research tried to cover two aspects of the issue: on one hand, the description of the formal system and institutional mechanisms; on the other hand, from a more criminological approach, it brings information both about how these institutions work and which are the problems they really have to deal with. In regards to this topic, it aimed at analyzing all aspects of this market, thereby leading us to gather information about all kinds of practices which may be encompassed by it.

Our research was based both on formal and informal sources. We prioritized the first, amongst which we include the files of cases which we gained access to in public bodies. Most of the bodies consulted during our research are those located in the State of São Paulo, mainly because these were more easily accessible than those of any other State. We resorted to informal sources – such as different types of media and interviews with people connected to the pharmaceutical industry, and/or to public institutions related to drug regulation and counterfeit persecution – as complementary sources of information.

The interviews held with specialists were very important for they pointed out that the root of the illegal drug dealing problem in Brazil, far from being restricted to drug counterfeiting, involves the theft of cargos and the commercialization of irregular products

After providing a brief overview of the pharmaceutical market in Brazil, the first section of this paper focuses on the *modus operandi* of the most common illegal practices carried out in the Brazilian

# DRUG COUNTERFEIT AND PENAL LAW IN BRAZIL

illegal drugs market and it includes information about which products have been counterfeited, which agents were involved in the schemes and – wherever possible – the damages caused by the illegal activity.

In Brazil, there is no organized database on counterfeiting practices and counterfeit products. Thus, the data built into this report was obtained through several sources, including public bodies such as the National Health Surveillance Agency (ANVISA), the State of São Paulo Public Prosecutors Office and the State of São Paulo Police Department. Each one of these institutions provided us with a separate and specific database, which we gathered and analyzed in this report.

Since the electronic database of Anvisa provided us with information on drug counterfeiting at the National level,<sup>5</sup> in order to analyse the cases involving drug counterfeiting which were brought before the Brazilian justice system –especially in the State São Paulo – we consulted the data base of the Public Prosecutors’ Office of the State São Paulo (*Ministério Público do Estado de São Paulo*)<sup>6</sup>. We had access to the database of an internal department called “Special Control of Public and Consumer Health” (*Grupo de Atuação Especial da Saúde Pública e da Saúde do Consumidor* – from now on referred to as *GAESP*), which is responsible for investigating offenses against the public health and starting class actions. Although they are specialized in Public Health, they are not in charge of pursuing criminal cases, which are sent to the general criminal sector of the Public Prosecutor’s Office, since there is no specialized group to deal with criminal cases involving this matter<sup>7</sup>.

Another important player in the combat against drug counterfeiting is the 2<sup>nd</sup> Police Precinct for the Investigation of Piracy, Counterfeiting, Theft and Drugs of São Paulo, which specializes – as the name says – in investigating piracy crimes. The appalling conditions of their databank, to which we also had access, speaks for itself in explaining part of the police’s inefficiency: this Police Precinct’s databank consists of two record books, which show (i) dates and a brief description of events related to product counterfeiting, discovered by the police; and (ii) records which describe all occurrences in more detail, stating the investigated parties and describing the illicit fact under investigation. All data available is

kept in the form of reports. These reports are written by police officers every time they discover a possible criminal occurrence – as it is their responsibility to register such occurrences – and start the investigation procedure. However, most of the facts addressed in the official reports were very poorly described, making any analysis of the illegal conducts very difficult. In search of criminal drug counterfeiting conducts (Article 273, Criminal Code) and crimes against intellectual property (Law n. 9,279/96), we also found conducts involving smuggling (Article 334, Criminal Code) and tax evasion (Law n. 8,137/90).

In the second section, we describe the legal regulation for drugs and the pharmaceutical market in Brazil, with a specific focus on the legal control mechanisms. This section presents the reader with a legal survey and with the necessary description of the role of the different Health Surveillance System and Justice System bodies involved. In regards to the Health Surveillance System, we concentrated our report on the description of ANVISA (Agência Nacional de Vigilância Sanitária), this sector's central institution, and its related legislation. In regards to the Justice System, we describe in more detail the criminal justice system, which was the main point of the original report.

Finally, in the third section, we present an evaluation of the Brazilian scenario regarding this issue and the reform proposals for the entire Brazilian counterfeiting regulation. These judgments and proposals were gathered through interviews held with health and pharmaceutical industry specialists, and reform projects that have already been proposed or are under discussion. This item is also a result of our own critical view about the data we collected.

## **I DRUG COUNTERFEITING IN PRACTICE – TYPES OF DRUG COUNTERFEITING**

### **I.1 THE PHARMACEUTICAL AND MEDICAL DEVICES INDUSTRY IN BRAZIL**

We do not intend to make an extensive and technical description of the drug sector market share in Brazil, but solely to provide an overview of it.

# DRUG COUNTERFEIT AND PENAL LAW IN BRAZIL

Since 1990, many government measures were implemented in Brazil, as for example the Commercial Law Reform and the export- oriented growth policy. These measures allowed for competitiveness between producers and products' price stability. However, while most of the industrial sector has enlarged its production and reduced its costs and prices for consumers, the pharmaceutical industry has raised drug' prices. Estimates vary, but several sources suggest that 40% to 50% of the Brazilian population have limited or no access to drugs. Notwithstanding the fact that Brazil is the second largest drug market in Latin America, this shrank considerably between 1998 and 2003, partly as a reflex to the impact of trade barriers.

In order to facilitate access to drugs, Law n. 9,787 of February 10, 1999, introduced the so-called "generic drugs" in Brazil. These drugs are known by their common Brazilian or international denominations (Common Brazilian Denominations or Common International Denominations - DCB or DCI). They are similar to a brand-marked or innovative product and seek to be interchangeable with these, meaning that the consumer may choose between using the brand-marked drug or the "generic drug" and benefit from the same effects. "Generic drugs" are usually produced after the expiration or waiver of the patent protection or of other exclusiveness rights by the original inventor. In order to be legal, the "generic drug" manufacturer must present proof of its efficiency, safety and quality (Article 3, XXI, of Law n. 6,360/1976). The Law determines that the "generic drug" must cost at least 35% less than the brand-marked drug.

The "generic drugs" regulation made access to information on drugs more democratic for consumers, doctors and pharmacists. However, according to the Brazilian Institute for Consumer Protection (*Instituto Brasileiro de Defesa do Consumidor* – from now on referred to as *IDEC*), "generic drugs" will only stand a chance in the competitive pharmaceutical market if restrictions are set forth in order to limit the brand-marked drugs' participation in the same market as the "generic drugs"<sup>8</sup>. This opinion is partially based on a decision of the Administrative Council for Economy Defense (*Conselho Administrativo de Defesa Econômica* – from now on referred to as *CADE*), which punished 20 pharmaceutical laboratories for

the formation of a cartel to block the distribution of “generic drugs”. This decision was followed by the generic ruling issued by the Department of Economic Law (*Secretaria de Direito Econômico* – from now on referred to as *SDE*) of the Ministry of Justice, in November of 2003, which forbade drug laboratories to take any action seeking to boycott the market distribution of “generic drugs”. The SDE also prohibited the exclusion of drug distributors from the market by laboratories. The impact of the Law which introduced “generic drugs” into the market and the reaction of the pharmaceutical industry against it, lead to the implementation of the Commission for Parliamentary Investigation on drugs. In 2005, the “generic drugs” sector earned over R\$ 1,5 billion and, in 2006, it was responsible for 14% of the national drug sale<sup>9</sup>.

The Brazilian “generic drugs” industry is booming and many foreign “generic drugs” leading producers have established subsidiaries and manufacturing facilities in the country. Market penetration, however, is difficult due to local industry practices, such as very low prices and market protection. Few domestic producers control the sector and multinational competition is restrained. According to the Ministry of Employment, in 2005, 647 companies were registered in Brazil with the purpose of producing human drugs. At that time, approximately 1/3 of these companies had 50 or more employees. Brazilian pharmaceutical industries are distributed among few States. Data collected by the Ministry of Employment shows that, in 2005, 40% of the industries were located in the State of São Paulo, 13% in the State of Rio de Janeiro, 11% in the State of Minas Gerais, 7% in the State of Rio Grande do Sul, 5% in the State of Paraná and 5% in the State of Goiás<sup>10</sup>.

Data from 2003<sup>11</sup> shows that the Brazilian pharmaceutical market moved USD 5,5 billion in that year, an amount which represents 1.3% of the total amount of our domestic market and which places the Brazilian pharmaceutical market 11<sup>th</sup> in ranking when compared to other economies in terms of market size in 2003. According to more recent data, the pharmaceutical sector moved USD 4,5 billion in 2007.<sup>12</sup> This represents a growth of 13.8% compared to 2006. Drugs account for 74.7% of this value, the equivalent to USD 3.5 billion (the rest is a result of non-drug

DRUG COUNTERFEIT AND PENAL LAW IN BRAZIL

pharmaceuticals' sales)<sup>13</sup>. The growth of the pharmaceutical market in Brazil was certainly due to the introduction of new technologies and to an overall income growth. Nevertheless, there are factors, which are frequently pointed out by the industry as barriers to this growth, such as the market regulation, the presence of "generic drugs", the informal market and restrictions to advertisement<sup>14</sup>.

A study made by the Getúlio Vargas Foundation – "Governmental Policy and the Pharmaceutical Sector Regulation" – concluded that according to the National Broad Consumer Price Index (Índice Nacional de Preços ao Consumidor Amplo – IPCA), the prices of drugs have increased much more than the prices of basic food supplies. We can infer that this is due to the highly concentrated price makers (only few industries control the entire Brazilian pharmaceutical market), to the difficulty new producers –wishing to take part in the market – face and to the general lack of transparency of producers.

Another cause for the price raise of drugs is this market's negative elasticity of demand. The specific uses of pharmaceutical raw material by the industry allow producers to raise market prices. Nevertheless, Brazilian drug prices are among the lowest in the world. After the Brazilian government's many complaints to pharmaceutical companies about the "abusive pricing", these agreed to keep price increases aligned to the economy's inflation rate or close to it. Government and industry have also introduced the National Broad Consumer Price Index (Índice Nacional de Preços ao Consumidor Amplo – from now on referred to as *IPCA*), which is the Federal Government's official index used for measuring price inflation. This resulted in approximately 18%<sup>15</sup> decline in prices. As another means for the reduction of prices, the Brazilian government has begun to implement more direct distribution channels (which are yet, however, of very limited reach).

The increasing regulatory measures have recently led to the instability of the industry. The new department that regulates prices (*Câmara de Regulação do Mercado de Medicamentos* – from now on referred to as *CMED*) has increased price controls. The National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária* – from now on referred to as *ANVISA*) has also rushed through a number of regulations, which have resulted in further

costs for the industry, and practices such as outsourced manufacturing have been increasingly controlled.

As a way to stop these (and other) market flaws, many complaints were made to the *CADE*, based on the claim that the pharmaceutical sector did not respect the antitrust Law (Law n. 8,884/1994). However, so far no punishment for abusive pricing resulted of any of these complaints.

## 1.2 COUNTERFEITED PRODUCTS

### 1.2.1 PHARMACEUTICALS, INCLUDING “LIFESTYLE DRUGS”

In the following paragraphs we describe the main events related to drug irregularities registered by *ANVISA*, which is vested with regulatory and investigative powers, by the Public Prosecutor’s Office and by Police Officials<sup>16</sup>.

Between 1997 and 1998, *ANVISA* received 172 complaints involving counterfeited drugs. In 1998, it was estimated that 10% of the annual pharmaceutical production consisted of falsified or stolen drugs<sup>17</sup> that somehow were illegally reintroduced into the market.

From 1999 to 2003, *ANVISA* reported the occurrence of 7 cases involving counterfeited drugs investigations: “*Ampiciline 500mg*” – the drug was being produced by a non-licensed firm; “*Keflex*” (*monohydrated cefalexine*) – apprehension of counterfeit products; “*Kytilande*” (*lavostatine*) – the product was manufactured by an irregular laboratory, which operated without the required licenses; “*Vick Vaporub*” (*mint and camphor*) – 4 cases of product counterfeit were reported.

In 2004, *ANVISA* reported the occurrence of two cases involving the following irregular drugs: “*Cefalen*” (*cefalexine*), produced without *ANVISA*’s legally required authorization, and “*Homogenin*”, which was counterfeited. The only case reported in 2005 involved the counterfeiting of the drug named “*Cialis*” by an illegal laboratory. In 2006, *ANVISA* reported the occurrence of ten drug counterfeiting cases: three cases involved the falsification of the drug “*Cialis*”, five cases involved the falsification of the drug “*Viagra*”, and one case each of falsification of the drugs “*Oxandrolona a 100% Baxter Immuno*” and of the flu vaccine “*Fluarix*”.

# DRUG COUNTERFEIT AND PENAL LAW IN BRAZIL

Until April 2007, ANVISA reported four cases involving the falsification of the drug “Cialis”; one case involving the falsification of the drug “Viagra” and one case involving the falsification of the drug “Levitra”.

In the search conducted in the data base of the State of São Paulo Public Prosecutors’ Office, (*Ministério Público do Estado de São Paulo*), we found that the most noteworthy case had been the counterfeiting of “*Androcur*”, a drug for prostate cancer treatment. It involved two large and respected laboratories in São Paulo, which developed a counterfeiting scheme that lasted from 1996 to 1998. Public authorities estimate that during this time 1,100,000 placebo pills were produced and sold as “*Androcur*”. As a result of the drug counterfeiting, over 10 deaths were reported, and the case hasn’t been solved to this day.

We searched the GAESP’s internal database for cases related to drug counterfeiting and similar felonies. From 1998 onwards we found 51 procedures (including investigations and law suits) that involved drug counterfeiting, amongst which 46 have already been dismissed (meaning the investigations are terminated and the cases belong to the institution’s archived files). Three Civil Public Actions<sup>18</sup>, involving drug counterfeiting, are currently being processed.

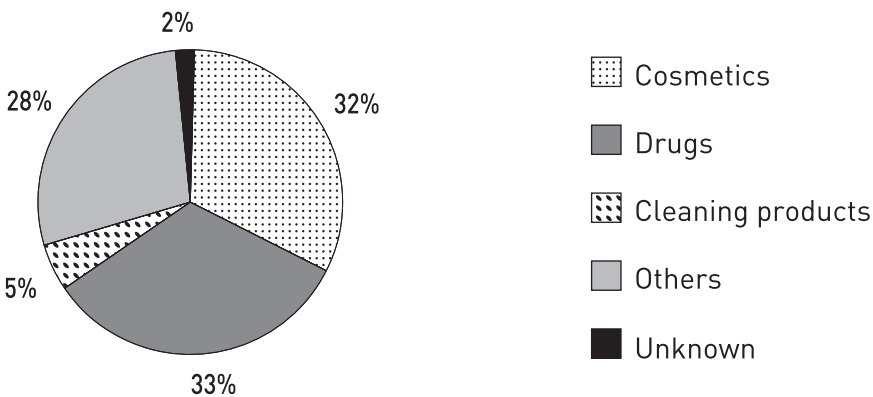
Even though the investigations were mostly listed by the name of the company, object of the complaint, we were able to identify the names of some of the products involved: Sodium bicarbonate., “*Ceptriaxona*”; “*Diane 35*”; “*Androcur*”; “*Femina*” and “*Novak*”. Only two investigations out of these cases led GAESP to the file judicial suits against offenders but none were yet sentenced.

As we mentioned above we also searched for data in the archives of the 2<sup>nd</sup> Police Precinct for the Investigation of Piracy, Counterfeiting, Theft and Drugs of São Paulo. From the register books of this Police Precinct – relative to product apprehension between years 2005 and 2007 – we came up with the following numbers: there were 43 officially filed reports on the investigation of piracy and drugs and other products’ counterfeiting (including cosmetics, food and cleaning products) from 2005 to 2007. 14 of these described drug counterfeiting or illegal sales investigations; 13 registered cosmetics related investigations; 2 described cleaning



products' investigations; and 12 had other subjects, such as medical devices and food. The following chart derives from the collected data:

**Product Apprehensions** - 2nd Police Precinct for the Investigation of Piracy, Counterfeiting, Theft and Drugs of São Paulo (2005-2007)



Out of the 43 officially filed reports, only 3 involved drug trading over the Internet. Nevertheless, this number can give a false idea of the importance of the Internet in the illicit drug market. This is probably the case since there is no strict separation of attributions between the police department responsible for piracy and counterfeiting investigations and the police department responsible for Internet crime investigations. Another comment that should be made is that the police officials do not always specify and detail the characteristics of the irregular occurrence in their internal data book, and therefore it's impossible to verify how much relevant data may be have been omitted. It's also worth noting that in only two of these reports the Police specifically identified crimes against intellectual property. Under the Brazilian legislation, crimes against industrial property and unfair competition (Law n. 9,279/96) are subject to private criminal procedures and the pursuit of these may cause many difficulties to the victim. Still, it should also be taken into account that such procedures may be, and sometimes are, initiated without previous police inquiry.

# DRUG COUNTERFEIT AND PENAL LAW IN BRAZIL

Information obtained from interviews and the media show that, with the development of the Brazilian industry, drug counterfeiting is no longer restricted to painkillers and medications against colds and the flu. Now offenders seek to counterfeit all of the most popular and most expensive medications, with drugs that treat erectile dysfunctions (“Viagra” and “Pramil”) heading the list, and also antibiotics, drugs that cause abortion (“*Cytotec*”), antidepressants and Anabolic Androgenic Steroids (“*Deca Durabolin*”, “*Hybolin Decanoate*”, “*Kab*”).<sup>19</sup>

## 1.2.2 FOODS, INCLUDING FOOD SUPPLEMENTS, MEDICAL DEVICES AND OTHERS

As evidenced by the Police database, food supplements are commonly counterfeited products. However, this research did not focus on cases involving food products and their irregularities, since this would shift the report from its objective, which is actually to study the drug counterfeiting phenomena in Brazil.

Just to give an example of irregular commercialization of food-stuff, we may mention a very recent and hugely publicized case regarding the adulteration of milk. In October 2007, the Federal Police was notified about the occurrence of a large scheme to counterfeit milk in the State of Minas Gerais. Two large milk industries were adding water and other substances to milk in order to profit from the over-production<sup>20</sup>. According to the Police, the milk was produced in farms and sold to the industries, where it was modified. Firstly serums were added to increase the volume and then hydrogen peroxide was mixed into it to kill the bacteria, which resulted from the serum-contaminated milk. Finally, sometimes sodium hydroxide was added to balance the acid nature of the product. After ANVISA analyzed the product and confirmed the fraud, the Federal Police arrested 27 people, including the industries’ owners.

With regards to medical devices, there have been cases of drug counterfeiting in Brazil in which counterfeiters used some laboratories’ old and discarded equipment to make placebo drugs. As a reaction to this kind of practice, ANVISA edited a normative act which forces laboratories to destroy all machinery before discarding it, under the argument that these equipments cannot be sold or

simply abandoned, for this creates the risk of them being used in counterfeiting practices.

In the database of the 2<sup>nd</sup> Police Precinct for the Investigation of Piracy, Counterfeiting, Theft and Drugs of São Paulo, we also found a reported case where the Police was investigating irregularities in November 2007, regarding medical devices after having apprehended dental instruments, which were commercialized without *ANVISA*'s authorization and expired.

### **1.3 MODUS OPERANDI**

In order to identify the most common illegal practices in the Brazilian drug market the following section will describe practices that have been known to occur. Thus, not only drug counterfeit and adulteration will be described, but also other conducts such as any action that makes the drug inappropriate for use, alters the information on a drug package – creating confusion and mistakes – violates registered brands and patents, or involves irregular circulation of the drug, such as the robbery of a load or cargo, smuggling, rewrapping, irregular sales etc.

It is noteworthy that the Brazilian illegal drug market is composed mainly of irregular drugs, illegal companies and stolen cargo. It is also the easiest and most profitable form of illegally commercializing drugs in Brazil today. The risks involved in cargo theft are relatively low in relation to the money that can be made (each shipment may be worth up to USD 1 million) and, thanks to the great problem of informality in this market, it is easy to introduce the stolen goods back into the regular market.

#### **1.3.1 FALSIFICATION AND ADULTERATION OF PRODUCTS**

The reported falsifications involve: a) Modifying the characteristics of purity, quality and authenticity of the drug or of one of its components, so that it becomes different from the registered product; b) Blending liquid drugs with water or other diluting material; c) Modifying the dosage of the drug or of one of its components, so that it becomes different from the registered product; d) Blending or mixing the product with a substance that modifies its therapeutic benefits; e) Removing or counterfeiting a component of the regular composition of the drug, or substituting this element by

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another of inferior quality; f) Adding a substance that does not integrate the product's composition; and g) Producing placebo pills.

### **1.3.2 IRREGULAR PRODUCTS**

Regardless of the possible changes that can be made in a product, the illegal market is also composed of drugs that circulate outside *ANVISA*'s control mechanisms. The irregular nature of a drug is determined by the fact that it is not licensed by the Ministry of Health and not controlled by *ANVISA* and therefore cannot be produced or commercialized legally. It is also necessary that all companies have their operations licensed by the public agencies in charge, otherwise they will be considered illegal. The large quantity of irregular products and unlicensed companies (such as laboratories that operate without the necessary authorization, laboratories that do not comply with the necessary sanitary requirements, products that circulate without registration or without legal documentation, etc.) is in part a response to *ANVISA*'s incapacity to monitor the health system in an efficient manner.

These products are very dangerous to public health since *ANVISA*, or other health surveillance agencies, do not control their quality. According to Mr. Marcos Moreira – who works for Schering Laboratories and whom we interviewed – *ANVISA* has the capacity to only monitor approximately 50% of the drug industries, leaving the remaining to operate irregularly, with no Good Manufacturing Practices certification.

### **1.3.3 FALSIFICATION, ADULTERATION AND IRREGULAR USE OF RECIPIENTS AND PACKAGES**

The conducts described in this section can occur together with or independently of those pointed out in the previous section. The most common are<sup>21</sup>: a) Falsification of package labels and recipients; b) expired drugs rewrapping or transferring into new packages, in order to avoid legal expiration date controls; c) False indication of the volume and content of the package; d) Rewrapping of a drug destined to free distribution (free samples or drugs distributed by the public health programs) into new packages or the removal of the “free sample” or even the “sale prohibited” labels; and e) Making the unauthentic brand appear similar to the

distinctive characteristics of known and authorized brands, with the intention of misleading the consumers and tricking them into buying the falsified drug instead of the original one.

#### **1.3.4 STOLEN CARGOS AND SHIPMENTS**

As stated above, crucial information discovered during our research is the alarming fact that the largest problem faced by Brazil's drug market is not that of drug counterfeiting but rather of illegal trade (involving unregistered products or unlicensed industries and pharmacies) and theft of cargos and shipments<sup>22</sup>. There is a large amount of money to be made in this irregular market, starting with the profits derived from tax evasion. On the other hand, drug counterfeiting is expensive and very risky, and according to Dr. Gonçalo Vecina, former president of *ANVISA*, there have been few small scale cases of drug counterfeiting in Brazil, most of which involved the sale of counterfeited "Viagra". The biggest problem in Brazil has always been the theft of cargos during their transportation (from laboratories to distributors, from distributors to pharmacies). The Sanitary Surveillance Center of São Paulo received over 900 notices of stolen cargo batches only during the month of June, year 2007<sup>23</sup>.

A search for judicial decisions from State and Federal Courts lead to several cases, which resulted in the punishment for robbery (Article 157, *caput*, Criminal Code) and for the reception of stolen goods (Article 180, *caput*, Criminal Code). There are many cases involving stolen cargos, but also smaller ones, such as Drug-stores robberies, are also very common.

#### **1.3.5 SMUGGLING**

It is said that a significant part of the counterfeited drugs sold in Brazil is produced outside the country and smuggled in for sale. To this day, it seems that Brazil doesn't have a very developed drug counterfeiting industry, and most of the falsified drugs are produced in other countries and brought illegally to Brazil through smuggling practices.

According to the Federal Pharmacy Council<sup>24</sup>, the counterfeited drugs that enter Brazil come from China and Korea and they enter the country through the Paraguayan and Bolivian borders.

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### **1.4 OFFENDER CONSTELLATIONS**

#### **1.4.1 ORGANIZED GROUPS SPECIALIZED IN DRUG ROBBERY**

Organized crime groups act systematically in the illegal drug market, especially when it comes to the robbery of cargos. Our sources, mainly interviewed specialists, indicate that there are a few organized criminal groups in Brazil (around 50 groups), which specialize in the robbery of drug cargos. In these groups there are usually participants operating inside the regular drug production chain, having thus access to information regarding drug shipment schedules and location, which is useful to plan and coordinate the activities of the criminal groups' lower agents, those who actually perform the theft, and are normally instructed to practice the robbery, leaving the cargo in a predetermined site. After this first step another group usually comes into scene to take care of the drug distribution. Each shipment of drugs can be worth up to USD 1.1 million and, once stolen, these products can be easily reabsorbed by the regular market, normally by distributors who participate in the illegal schemes handing out false tax receipts.

#### **1.4.2 ILLEGAL LABORATORIES AND IRREGULAR COMPANIES**

Many cases of irregular drug distribution occur due to the existence of illegal laboratories. These laboratories are not registered with the public agencies that act as their regulators and survey the quality of their production, and thus there is no control over their product quality. They do not necessarily operate producing counterfeit drugs, but, as they are not subject to public control, the quality and hygiene of these drugs can put the life of consumers at serious risk.

The current health surveillance regulation obliges all companies to hold a Certificate of Good Practices, which is issued by *ANVISA* after the local surveillance agencies visit the laboratory or company and sends *ANVISA* a written report. Nevertheless, the State does not have enough staff to carry out this procedure, therefore many companies operate without ever being monitored by the agencies in charge.

#### **1.4.3 PHARMACIES**

The distribution of counterfeit or irregular drugs is often undertaken by pharmacies located in small towns or in the suburbs,

surrounding large cities. These pharmacies don't normally belong to large chains, and are thus less controlled by State agents who lack the capacity of monitoring drug production and distribution, whereby the surveillance generally falls upon large production and distribution networks. According to Dr. Gonzalo Vecina Neto, in order to reach small pharmacies in the isolated cities of Brazil, drugs normally pass through 2 or 3 distributors, and almost always fall into informality. This means that the second distributor involved in the commercialization does not provide a tax receipt (invoice), and thus the product cannot be traced. The drugs reach small pharmacies through irregular channels of commerce, and these pharmacies can only subsist because this allows room for tax evasion (they could never survive if they participated in the regulated market and had to pay all the taxes) and low price practices.

According to the Brazilian Institute of Competition Ethics (*Instituto Brasileiro de Ética Concorrencial* – from now on referred to as *ETCO*), pharmacies are also driven to irregular trade by the laboratories<sup>25</sup>. Some of these sell pharmacies discounted drugs, so that part of the profit remains with the pharmacy and another part is added to the income of the pharmacist who performed that sale, thereby increasing his income at each additional sale of these drugs. In other words, the laboratory sells the drug to the pharmacy for a lower price so that the pharmacy will be stimulated to sell that drug to its customers, since it will profit more with this sale. The money the pharmacist saves will be therefore kept by him and the pharmacy, and the laboratory will be able to sell more drugs.

#### **1.4.4 INFORMAL MARKET**

In 2005, *ETCO* published a broad and valuable research on market informality in the pharmaceutical business. *ETCO* suspected that many of the agents which took part in the drug production and trade would have already suffered damages and been exposed to the informal market's risky situations. Based on these suspicions, *ETCO* decided to outline and analyze this informality as a way to stimulate the growth of the pharmaceutical market's formal economy. These studies resulted in a diagnosis of the informality manifestations in the Brazilian health sector, its effects and

implications. It further proposed a number of measures as solutions to the problem.

The results of the studies show that the sector's informality is alarming, indicating that about 23% of the taxes are evaded, an amount representing between R\$ 2 and R\$ 3 billion a year. In addition, 49% circa of the pharmaceutical market's labor force is informal, implying that between R\$ 530 and R\$ 580 million of labor charges are not collected by the government.

Illegal sales were a large and uncontrolled problem discovered by the survey, where 27% of the drugs ("*amoxicillin*", "*potassium*", "*loratadine*" and "*enalapryl maleate*"), were sold illegally. These illegal sales consisted in the trade of inappropriate drugs. In other words, cases in which the customer hands the pharmacist the prescription for one drug but receives and buys a different one. This can occur for a series of reasons. It is possible that the pharmacist wants to purposely sell a drug different than the one prescribed, for he has some sort of agreement with the laboratory, which provides him with the drug he's selling. It may also be possible that the customer himself demands a different drug than the one prescribed.

The degree of informality in this market is serious, causing relevant damage to the development of the health sector and to the Brazilian society as a whole. It carries a large tax distortion which lowers the government's capacity to invest, exposes the population to health risks, - by offering low quality or inadequate drugs to people - and lowers the access to drugs since the products sold in the irregular market can also be very expensive.

The money involved in this informal trade is certainly significant. According to these studies the amount of taxes evaded as a result of informality could be very important for Brazil's Public Health System development.

One factor, which causes the large informality in our market, is said to be the drug market sector's structure. It is a fragmented market structure, especially in retail. Given the high costs implied in formal trade and the consequent minimum scale size necessary to operate formally (small laboratories and pharmacies do not have the capital required to engage in formal trade) a large part of the market operates informally.



According to *ETCO*'s report, it is difficult to point out one isolated measure that would suffice to fight irregular practices in the drug market. The solution would be for the government to act together with all the drug market agents and with the civil society in order to fight market informality. The actions undertaken by these players should follow basic lines of work, reducing informality's economic advantages, eliminating factors which enable irregular trade as well as easy and enforced barriers.

Such measures should include: a) Tax reduction and changes in the way they are charged; b) Incentives for companies and pharmacies to operate formally and to adopt trade practices that are less vulnerable to informality; c) Development and optimization of surveillance mechanisms through the use of intelligence instruments and data banks; d) Specialization and more specific surveillance in the sector; e) More severe and progressive penalties; f) Drug trade should be made more transparent to the population; g) More regulation and enforcement in the sector, imposing good manufacturing and manipulation practices and primary goods' control.

As we will see further on in this report (item 3.4), the ex-president of Anvisa, Dr. Gonzalo Vecina Neto, believes that the existing tax policy in Brazil is greatly responsible for the informal and illegal character of the country's drug market. Since the taxation, which falls upon drug sales, is very high – up to 44% of the product's value – the amount of money made out of tax evasion turns this practice very attractive and profitable, thus stimulating the informal trade. In addition to this, given the different tax policies for each State, mainly when it comes to the Tax on Distribution of Goods and Services (*Imposto sobre Circulação de Mercadorias e Prestação de Serviços* – from now on referred to as *ICMS*), it's possible to evade taxes by claiming that a shipment comes from a certain State – where the rate of this specific tax is lower and therefore more interesting for the industry and distributors – even though it actually comes from a different State. This is known as a symptom of the “fiscal war” going on between Brazilian states, and can only be overcome by some sort of agreement or harmonization of tax rates.

### **1.5 DAMAGES**

It is common knowledge that the falsified drugs market harms a

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number of social sectors: pharmaceuticals, commerce intermediaries (e.g. drugstores), consumers, public health and even the State, whose tax collection is compromised. The absence of information sufficient enough to demonstrate the size of the falsified/ irregular drugs market, as well as the difficulties related to the registration of the side effects— specifically triggered by falsified products —creates a series of difficulties in measuring the damage of this illegal practice.

The difficulties in accessing specific data on the consequences of drug falsification are also caused by the following scenario: official and public data picture the piracy of products in general and do not specify which one refers exclusively to the illegal drug market. Additionally, this sector's estimates are often produced by laboratories or private associations and are not easily accessible. We contacted a number of companies and company associations connected to the pharmaceutical industry. However, none of them was able to supply us with such specific data.

## ***1.5.1 DAMAGE TO INTELLECTUAL PROPERTY AND LOST SALES REVENUE***

The worldwide repercussion of piracy related crimes (including crimes against industrial property and unfair competition), which mobilize great sums of money, reflects in Brazil as well.

According to the report published in December 2006 by the Council for the Combat against Piracy – Ministry of Justice – falsified merchandise moved overall R\$ 56 billion (approximately USD 32 billion) that year<sup>26</sup>. This means an annual loss of USD 17 billion, and, in addition, an impediment to the creation of 2 million legalized jobs<sup>27</sup>. A research published by the Business Action to Stop Counterfeiting and Piracy (BASCAP)<sup>28</sup> revealed that Brazil is considered to be the fourth worst country in the world when it comes to protecting intellectual property, only after China, Russia and India.

Unfortunately, public data, specifically drug sector related, has not been produced in Brazil. Febrapharma estimates that the damage caused to national enterprises with the introduction of counterfeit drugs into the market, is of approximately USD 900 million a year<sup>29</sup>. Apart from the damages caused by the unfair competition, labs are subject to lawsuits for damages caused by false drugs sold

under their trademarks. We don't have any estimate of how much this represents for the pharmaceutical industry.

This scenario determines that Brazil suffers great pressure from private enterprises and investors, as well as from international organizations.

In April 2007, the USA government published the so-called "Special 301 Watch List", an annual report on the adequacy and effectiveness of the protection of Intellectual Property Rights (IPRs) in several countries of the world. This time, Brazil does not appear on the Priority Watch List, according to which China, Russia, Argentina, Chile, Egypt, Israel, Lebanon, Thailand, Turkey, Ukraine and Venezuela do not protect IPRs adequately. The report states that Brazil took significant steps in the direction of improving the IPRs protection, especially thanks to the governmental actions against piracy and against the disrespect to authors' rights.

However, the country remains "under observation", specifically in regards to the pharmaceutical industry, due to measures recently enforced by the public health sector, in reference to the compulsory licensing of drugs. According to the report, the Brazilian government was not making the efforts expected to enable open and transparent discussions with pharmaceutical enterprises. One cannot disregard the fact that these manifestations may be influenced by the economic interests of companies which may have faced profit losses due to some public sector's initiatives. Nevertheless, our position is that it's probably too early to reach such conclusion.

### **1.5.2 DAMAGES TO HEALTH AND HEALTH RISKS FOR CONSUMERS**

Consumers are largely harmed by crimes against intellectual property, as they are the weaker and less informed part in the consumer relationship. Generally, the authors of these crimes seek to lure and mislead consumers using deceiving methods, such as packaging appeals and brand manipulation, leading them to believe they are acquiring an authentic product, but eventually suffering great harm.

When it comes to drug counterfeiting, damages are to be considered more seriously, for consumers face health and safety risks. According to information obtained on laboratory Astrazeneca do Brasil's website,<sup>30</sup> the risks presented by a counterfeited drug to

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patients' health are many, and vary according to the type of counterfeiting involved. If the active components are diluted or weakened, the disease that should be treated continues to exist or gets even worse. Depending on the composition of the counterfeit drug it may itself cause intoxication or be harmful to consumers' health. In some cases, these situations can incur in serious risk to the patient's life.

We were not able to find any systemized information in public databanks on the total harm or total number of counterfeit drug related notified cases regarding consumers' safety and health. However, the main cases involving irregular or counterfeited drugs were publicized by the Brazilian media and we can state that only a few cases reported death as a result. In most cases, it was very difficult to identify the specific damage caused to consumers' health.

The most serious and known cases about consumers who suffered by using counterfeited drugs, occurred in 1998-1999 and were largely discussed by the media, the people in general and public institutions<sup>31</sup>. As an immediate response to the population's outcry, the House of Congress approved Law n. 9,677/1998<sup>32</sup>, which modified the Criminal Code and raised the penalty imposed on the crimes of counterfeiting, corrupting or altering any medically therapeutic product.

### 1.6 PROSECUTION REGULATION AND PROBLEMS

In this sub-section, we will analyse the legal and administrative regulation on drugs and Brazil's pharmaceutical market, to focus on the critical description of their legal and administrative control mechanisms.

First we will describe the Brazilian intellectual property regulation— since it is also applicable to drugs and the pharmaceutical market – further on our work will focus on the description of the administrative control mechanisms: the National Health Surveillance System, its core player *ANVISA*, and the main legal and administrative rules.

#### 1.6.1 NATIONAL REGULATION ON INTELLECTUAL PROPERTY

In Brazil, intellectual property is regulated and protected by three Federal Laws: Law n. 9,279, of May 14, 1996 (Industrial Property

Act); Law n. 9,609, of October 19, 1998 (Software Act); and Law n. 9,610, of October 19, 1998 (Copyright Act).

Among the laws protecting drug discoveries, only one is of interest: the Industrial Property Act, which regulates the granting of patents and models of utility (inventions that fulfil the requirements relative to novelty, inventiveness and industrial application) and industrial design and brand registration, as well as the protection to geographical indications and unfair competition.

In Brazil, the public office responsible for intellectual property rights granting and surveillance is the National Institute of Industrial Property (*Instituto Nacional da Propriedade Industrial* – from now on referred to as *INPI*), created by Law n. 5,648, of December 11, 1970. In addition to being responsible for such concessions and surveillance, the INPI also exercises an intellectual property related normative and regulatory function, setting forth administrative and regulatory acts.

According to the Industrial Property Act, a duly registered patent gives its owner the right to impede third parties from using, producing, selling, exposing for sale or importing the patented invention without previous consent, under any of the following arguments: a) the used, produced, sold, exposed for sale or imported product itself is the object of the held patent; or b) the product is produced by the third person as a result of the application of a process which is the object of the patent (Article 42 of Law n. 9279/1996). Patents provide legal protection for a 20 years period for inventions and 15 years for utility models, both periods starting at the filing of the patent request (Article 40 of Law n. 9279/1996). Once these periods are completed?, the invention may be used freely by any third party in free competition with the original patent owner. The extension and limits of the protection provided by the patent will be drawn based on the request filed, and interpreted according to the descriptive report and drawings delivered therewith (Article 41 of Law n. 9279/1996).

When granting a patent for a new drug, *INPI* consults with *ANVISA* to check that the essential conditions be met and the process differs from other Latin American countries. This dialogue helps evaluate the real effectiveness of a new drug because it

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allows comparing it with its predecessors as well as having a medical insight on the conceived and patented drugs.

There are further limitations to the legal protection of patents, based on the principle that the purpose of the concession granting of patents is to provide incentive for local inventions and technological productions. With this in mind, patent owners who a) no longer explore the protected activity; b) explore it in a way that doesn't fulfil market demands; or c) exercise their rights in an abusive manner (the abuse of economic power must be determined by a judicial or administrative decision) will be liable to the loss of the rights granted by the patent (Article 68 and following articles of Law n. 9279/1996).

In general, the Brazilian intellectual property legislation is in harmony with international standards and forms of protection, stipulated by international treaties established by the World Intellectual Property Organization (WIPO), as well as treaties addressing the Trade-Related features of Intellectual Property Rights (TRIP's), under the World Trade Organization (WTO). In some aspects, however, the Brazilian legislation exceeds TRIP's agreements protection requirements. The most noteworthy of these cases is article 229, of Law n. 9,279, May 14, 1996, which subordinates the granting pharmaceutical products and processes' patents to *ANVISA*'s approval.

The most important criticism that can be made to intellectual property protection in Brazil is not related to the legal system. The biggest problem lies in the functioning of the agencies responsible for the effectiveness of intellectual property, in the first place, the *INPI* and, secondly, the Justice system. Both of them suffer from a systematic lack of financial and human resources, causing difficulties to the implementation of the legally guaranteed protection. The lack of money and personnel has a number of negative consequences, such as the slow processing of cases inside the Justice system, which lead to rights violation. The *INPI* is further incapable of speeding up the patent request analyses.

The owner of intellectual property rights may evoke civil or criminal law to protect his patented rights. In the civil arena, various demands can be presented, in an isolated or cumulative manner, based on a real-world situation. The demands vary between asset compensation, referring to harm suffered from any violation

of property rights, and judicial orders, forbidding activities that disrespect property rights. It is important to state that the asset compensation addressing property rights violation, requires no proof of harm or damage, since these are presumed based on the illegal activities that can be executed only by patent owners (Article 44 and §§ of Law n. 9.279/1996).

It is also important to state that the patents can be submitted to the INPI for an administrative annulment process. This process may be initiated by demand of a third party within a period of 6 months counting from the patent granting. After this period is over, the *INPI* or an interested party may file a Patent Nullity Suit at the Federal Justice System (Article 56 and following articles of Law n. 9279/1996). Whenever the *INPI* is not the author of such suit, it is obliged to intervene in the process. Thus, any civil demand regarding the violation of rights granted by a patent may be blocked by requesting the *INPI*, for the patent to be declared null and void.

Nevertheless, it is important to remember that even after the protection given by the patent has expired (and the invention has fallen into public domain), the protection against drug counterfeiting can still be guaranteed through the protection of commercial brands, packaging and product design and restraint to unfair competition. Even if it is no longer possible to protect the product itself, the law still protects its presence in the market, through brand name, packages and labels (visual communication) and publicity in general (unfair competition).

## **1.6.2 DRUG SECTOR: ADMINISTRATIVE REGULATION AND AGENCIES**

### **1.6.2.1 THE NATIONAL HEALTH SURVEILLANCE SYSTEM**

#### **AND THE NATIONAL HEALTH SURVEILLANCE AGENCY (ANVISA)**

Until 1998, the public institutions responsible for regulating the pharmaceutical market had shown to be completely inefficient. Part of the problem was that there existed no such thing as a centralized institution capable of integrating and analysing the information relevant for the creation of a generic anti-counterfeiting policy.

As a reaction against this institutional framework deficiency, in 1999 a regulatory agency was created by a Federal Law (Law n.

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9,782, of January 26, 1999) to protect and promote public health through the control and regulation of all products which should be submitted to sanitary monitoring<sup>33</sup>. This agency, known as the National Health Surveillance Agency, is officially linked to the Ministry of Health and is responsible for dealing with all sanitary issues. Similarly to the U. S. Food and Drug Administration (FDA), *ANVISA* is responsible for regulating food, dietary supplements, drugs, bio-medical products, medical devices and cosmetics in Brazil.

Article 1 - Law n. 9,782/1999 defines the National Health Surveillance System and creates *ANVISA*. According to it, the Federal Government is responsible for: a) defining the national health surveillance policy; b) defining the national health surveillance system; c) creating rules and controlling products, substances and services of interest to health; d) enforcing health surveillance of ports, airports and frontier areas; e) monitoring and coordinating the State, Municipality and local actions in health surveillance; f) cooperating technically and financially with the States and Municipalities; g) acting in special circumstances where health faces serious risks; h) maintaining a health surveillance information system, in cooperation with the States and Municipalities.

To fulfil these competencies, the Federal Government operates via the Ministry of Health and *ANVISA*, as well as through other federal and local institutions which are also part of the National Health Surveillance System. These include the National Council of State Health Secretariats, the National Council of District Health Secretariats and the State, Federal District and Municipal Health Surveillance Centres (*Departamento Estadual de Vigilância Sanitária* – from now on referred to as *VISA*).

It is the duty of the States and Municipalities to cooperate with *ANVISA* and the federal organs aiming at making the Brazilian health surveillance system safer and more efficient.

## 1.6.2.2 ANVISA'S REGULAR ATTRIBUTIONS

Law n. 9,782/1999 also describes *ANVISA*'s attributions within its institutional mission of promoting the population's health protection by means of health and sanitary control of the products' production and commercialisation and services submitted to health



surveillance. It also includes the environment, health related processes and technologies, and the control of harbours, airports and frontiers. Article 7 specifies each one of the agency's attributions, involving preventive and restraining measures.

*ANVISA* has a very wide range of competencies, which enable it to regulate practically every aspect and step of drug supply chain in Brazil, such as production, transportation, distribution, import, export, sales and quality control<sup>34</sup>. The Agency is responsible for registering and licensing companies, laboratories and products, thus allowing all agents in the production chain to produce drugs regularly and legally.

It also plays an important normative role in Brazil's drug market, for it is legally responsible for editing the administrative rules to be followed by all agents involved i. *ANVISA* can also interfere temporarily in the management of production organizations which are financed or maintained by public resources. It may authorize the operations of health related companies' production, distribution and imports, grant product and company registrations, and grant and cancel certificates of good production practices. These assignments are very important, for they allow *ANVISA* to monitor every agent in the drug production, distribution and commercialisation, helping to prevent illegal actions such as component counterfeiting or their illegal sale.

In regards to the operating authorization, Law n. 6,360, of September 23, 1976 regulates the registration of products and licensing of health related companies. This piece of legislation determines that all companies wishing to operate with health products (manufacturers, distributors, shippers etc.), must be licensed by the health surveillance agencies. Every regular establishment must be listed at the Ministry of Health in order to operate legally and together with *ANVISA*, it is responsible for authorizing the functioning of health related facilities. Decree n. 3,029, of April 16, 1999, holds *ANVISA* responsible for authorizing companies to produce, distribute and import health related products.

For this authorization to be granted, it is necessary that the company defines the industrial activity it will be executing, presenting all legal documentation necessary for its identification (articles of association specifying the activity to be executed, the address of the

head office and of the facilities dedicated to production, distribution and storage etc.) The company must also prove that it has technical and operational capacity to perform the activities and must appoint the technician(s) responsible for the facility<sup>35</sup>.

According to the legislation, *ANVISA* is responsible for coordinating the National Health Surveillance System (*Sistema Nacional de Vigilância Sanitária* – from now on referred to as *SNVS*), and is capable of suggesting and monitoring the implementation of public health policies, as well as creating regulating norms for the sector. The *SNVS* includes the following agencies: a) *ANVISA*; b) the National Council of State Health Secretaries (*CONASS*); c) the National Council of Municipal Health Secretaries (*CONASEMS*); d) the State, Federal District and Municipal Sanitary Surveillance Centres (*VISAs*); e) the Central Public Health Laboratories (*LACENS*); f) the National Institute for Quality Control in Health (*INCQS*); g) the Oswaldo Cruz Foundation (*FIOCRUZ*); and h) the State, District and Municipal Health Councils. The idea is that all these institutions work together and promote the necessary dialogue between public agents and society. All medication, food, cosmetics, medical devices, drinks or products which may put human health at risk are submitted to the control, regulation and supervision of the *SNVS*, under *ANVISA*'s coordination.

The *SNVS* presents mechanisms of preventive and restraining control over drug counterfeiting in a system of integrated actions and guided by *ANVISA*. It regulates drug trade through preventive measures, conditioning this type of commerce to compulsory licensing and authorization, and promotes constant market investigation and monitoring. It also provides for penalties (such as fines, product apprehension and compulsory closure of companies) if the regulation is disrespected<sup>36</sup>.

This system allows *ANVISA* to decentralize actions, making surveillance more efficient and organized. It is also important to create a group since it is interesting to coordinate health surveillance with other existing health policies. Each agency has thus specific competencies and attributions that stimulate health surveillance efficiency.

Regarding its restraining assignments, *ANVISA* is empowered to shut down production, control, import, storage and distribution sites

and health product sales, whenever legislation is violated or there is imminent risk to health. In these cases, ANVISA can also ban the production, import, storage, distribution and sale of products and services related to health or cancel the operation authorization of companies, laboratories or pharmacies<sup>37</sup>.

*ANVISA* can also revoke the license of drug manufacturers who do not operate in compliance to its rules. If the Agency notices that producers and products are not meeting quality standards, it has the power to apply administrative penalties, such as drug apprehension and destruction and application of fines.

Since the Agency is capable of applying these administrative sanctions, it is important for *ANVISA* to be able to monitor the application and effectiveness of its regulations and norms constantly. In order to exercise this surveillance in efficiently, *ANVISA* counts on the cooperation and support of a number of other federal, state and local offices which help monitor the commercialisation of drugs, their quality and authenticity. These offices integrate the *SNVS* and play an important role in implementing health policies and aiding *ANVISA* in its health surveillance task.

The agencies that compose the *SNVS* also work jointly to set restraining measures in place. In addition to the joint effort with *ANVISA*, the State, Federal District and Municipal Sanitary Surveillance Centres – and other institutions that seek to fight crime (e.g. Federal Police, Civil and Military Police, Federal Highway Police) –, consumers, hospitals and health professionals also help *ANVISA* by providing important drug counterfeiting information. The drug irregularity related complaints and notices have effectively helped *ANVISA* to investigate and discover illegal practices.

A detailed description of the measures implemented in the last years by *ANVISA* is available on the institution's website. These include shutting down irregular laboratories, and drug distribution locations and the apprehension and destruction of illegal products. Normally, *ANVISA* acts jointly with the Police institutions, whereby the responsible offenders are often immediately arrested.<sup>?</sup>

As previously mentioned, *ANVISA* plays an important role in normalizing the regulation of drug production and commercialisation. A number of laws provide this Agency with the power to establish criteria for drug production, quality and sale, and to make sure

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these criteria are met. *ANVISA*'s police power derives from its responsibility over the implementation and compliance to drug production and commercialisation norms. *ANVISA* acts as an administrative police once it can shut down companies that are operating irregularly, confiscate illegal and irregular products, control the quality of drugs in the market and grant and revoke operating licenses. parties involved in illegal practices, and this is why it is important for it to work with the Federal Police and the Criminal Justice System. While *ANVISA* can take administrative measures to prevent and combat drug counterfeiting, it depends on the police to persecute the individuals who commit the felonies. Federal Police and *ANVISA* have become partners, partly due to the fact that *ANVISA* is the information and knowledge depository; it is in charge of monitoring drug production and commercialisation and of detecting crimes in an efficient, manner since it is more specialized than the police. On the other hand, the partnership works because the police offer investigative infrastructure and are able to carry on the investigation and, if appropriate, they arrest parties involved, and eventually lead a criminal procedure in the judicial sphere.

The *ANVISA* Investigation Department is responsible for receiving complaints from consumers, other health surveillance offices or companies, related to drugs and other health related matters. Once a complaint is filed, the Department starts administrative investigation procedures, seeking to discover if there was a violation to the relevant legislation and to identify the responsible party. In 2003, *ANVISA* received 2,140 complaints reporting drugs irregularities and commercialisation. These notifications led to investigation procedures and 117 irregularities were confirmed. Among these cases, 35 regarded unregistered products, 9 referred to companies without production authorization, 2 cases related to counterfeited drugs and 52 addressed problems regarding product quality. This shows that drug counterfeiting does not play a central role in the Brazilian illegal drug market.

## 1.6.2.3 NATIONAL PLAN FOR DRUG COUNTERFEITING AND FRAUD PREVENTION AND REPRESSION

In 2001, a National Committee formed by *ANVISA*, the State Health Surveillance Centres, the Pan American Health Organization and the

World Health Organization assumed the responsibility of creating a “National Plan for Drug Counterfeiting and Fraud Prevention and Repression in Brazil”. This plan is to be developed within the National Health Surveillance System. It consists mostly of principles and political objectives to guide the Health Surveillance System, the police and the National Congress in the implementation of measures and laws seeking to put an end to drug counterfeiting.

In 2002, the Committee approved the Plan, thereby initiating a number of health related public policies. The priorities established are the following: the strengthening of inspection and control of the drug production and distribution chain, the creation of a general information and communication system, the training of Health Surveillance personnel and the strengthening and speeding up of communication and information sharing between the SNVS and the public<sup>38</sup>. The following measures were listed as a means to prevent and restrain drug counterfeiting and fraud:

(i) Action and Inspection Strategies: the Committee issued an “Investigation Guide”, to establish normal procedures for investigations addressing drug irregularities complaints. In 2003, four meetings were held with the participation of ANVISA, the VISAs, the Health Councils and State Treasuries. The intention was to start joint interventions in order to control and survey the manufacturing and commerce in the States. The cooperation is already effective in the States of Bahia, Ceará, Goiás, Mato Grosso do Sul, Minas Gerais, Pernambuco, Paraná, Rio de Janeiro, Rio Grande do Norte, Rio Grande do Sul, Paraíba and São Paulo.

(ii) Product Identification and origin: in 2002, another regulatory act (Resolution ANVISA n. 320/2002) confirmed that throughout the distribution chain all receipts should contain the product’s identification number. In 2003, a technical group was organized (*Portaria* n. 364/2003) and a public hearing was held (Public Hearing n. 24/2003) in order to determine which measures could guarantee that the origin of products were traceable, and that the products be confiscated when necessary.

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(iii) Human Resources: Four training programs took place to educate and train technicians who work with drug counterfeiting. 140 technicians participated and 27 State Drug Counterfeiting and Fraud Prevention and Restraint Plans were approved.

(iv) Information and communication: The mechanisms for communication between *ANVISA* and the *VISAs* were strengthened by creating a network of core issues and by communicating drug irregularities on *ANVISA*'s website. Here, the public may access information regarding stolen drug shipments, products whose commercialisation was suspended, counterfeited drugs, and others.

(v) Measures taken vis-à-vis consumers: It is often the producer – who has experienced losses from the counterfeiting of his drug – who starts the investigations. But very often the consumers are in a position that allows them to notify government agencies on drug irregularities, leading eventually to the detection of counterfeiting and frauds. Therefore, institutional campaigns, seeking to inform and instruct consumers, are very important. These campaigns show consumers how to verify the drug authenticity so they may analyse the package with all its identification marks, recognizing badly printed and torn up labels and broken safety seals. Many actions are being implemented to help consumers identify the original drug packages to prevent the commercialisation of counterfeit products.

(vi) Package Standardization: A further measure to help control the market is the development of patterns and signs on authentic packages.

The system previously applied to drug packages was regulated by *Portaria SVS/MS n. 802*, of October 8, 1998. This act established a drug control and supervision system on the production and commercialisation chain, including the distribution and transport of these products. It determined, among other requirements, the need of a printed bar code on every good to enable its identification and origin. According to this legal act, all drugs should carry the logo of its manufacturer, and a security seal should be

put on the secondary package of every medication. Every drug distributor should be granted an operating authorization, and only distribute registered drugs to companies registered legally.

In the 2002 National Health Surveillance Plan, a new and sophisticated mechanism for the identification of original packages was developed. This system consisted in the printing of a symbol, coated with metallic material that, once peeled off, revealed the word “quality” and the logo of the manufacturer, printed with reactive paint. When the metallic coating is removed, this paint reacts with the oxygen in the air, forming the logo of the company. Once broken, these packages’ safety seals leave a mark, so that it’s possible to tell whether the product was violated.

In order to avoid package frauds, ANVISA is developing a project for a new safety seal containing mint. The purpose is to avoid the violation of packages, and to make it easier for consumers to identify the original product. Only companies authorized by ANVISA will be allowed to buy the seal.

In addition to these measures, ANVISA is seeking to standardize names, abbreviations and definitions of the packages used in the drugs registration process. This is to facilitate the compilation of drug related data, guarantee common understanding between producers and ANVISA and reduce mistakes made at the publishing of drug registrations.

Since drug packages are often tampered in order to deceive consumers and make the counterfeited drug trade possible, ANVISA has also been showing consumers how to identify authentic drug packages.

However, even though these measures have been taken to render authentic drug packages more sophisticated and easy to recognize, the counterfeiting agents have proven themselves capable of keeping track of these changes and have increasingly become equally sophisticated. As a result, the identification of authentic packages has become more difficult due to the many details included in its composition, making it truly hard for consumers to distinguish authentic products from counterfeited ones (or from rewrapped ones etc.).

**1.6.2.4 THE MAIN PHARMACEUTICAL SECTOR REGULATORY RULES**  
The most important Law addressing drug production regulation is

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Law n. 9,782, which created *ANVISA* and systematized the Health Surveillance System. Nevertheless, it is important to know that there are many other federal laws and administrative regulations applicable to this sector. Amongst these, the following may be regarded as key rules for the pharmaceutical sector:

- Federal Law n. 9,782/1999 – creates the National Health Surveillance System and *ANVISA* - see above, item 1.6.2.1
- Federal Law n. 6,360/1976 – organizes health control over the commercialisation of drugs, pharmaceutical products and similar substances. This Federal Law is further regulated by: Decree n. 79,094/1977, Law n. 5,991/1993, Law n. 6,437/1977, altered by Law n. 9,695/1998
- Resolution n. 391, of 09.08.1999 – Approves “generic drugs” regulation
- Law n. 13,798/2001 – regulates the information given to consumers on drugs and pharmaceutical products.
- Decree n. 3,029/1999 – approves the legal regulation of *ANVISA*, specifying the agency’s attributions, function and structures.

## 1.6.2.4.1 REGULATION OF THE NATIONAL PLAN FOR DRUG COUNTERFEITING AND FRAUD PREVENTION AND RESTRAINT

- Resolution *ANVISA* n. 320/2002 - states that all receipts throughout the distribution chain should contain the product’s identification number.
- *Portaria* n. 364/03 - organizes measures to guarantee that the drug’s origins are traceable, and that the products be confiscated when necessary.
- *Portaria* SVS/MS n. 802/1998 - establishes a system of drug production and commercialisation chain control and supervision, including the distribution and transport of these products. It



determines, amongst other things, the need of a printed bar code on every good to enable its identification and origin

#### 1.6.2.4.2 LICENSE AND REGISTRATION: LAWS AND REGULATIONS

- Federal Law n. 6,360/1976 – regulates the registration of products and obligates all companies that wish to operate with health products (production, distribution, transportation etc.) be licensed by the Health Surveillance Agencies.
- Decree n. 3,029/1999 – holds *ANVISA* responsible for authorizing the operation of companies that produce, distribute and import health related products.
- *Portaria* n. 114/1994 and Normative Instruction n. 01/1994 - list the documents that companies producing drugs and pharmaceutical substances must present to the *SNVS* in order to be granted the operating authorization.
- *Portaria* SVS/MS n. 185/1999 and *Portaria* SVS/MS n. 114/1994 - list the documents that companies importing drugs and pharmaceutical substances must present to the *SNVS* to be granted the operating authorization.
- *Portaria* SVS/MS n. 802/1998 and Normative Instruction n. 01/1994 - list the documents that companies distributing drugs and pharmaceutical substances must present to the *SNVS* to be granted the operating authorization.
- *Portaria* SVS/MS n. 1.052/1982 and Normative Instruction n. 01/1994 - list the documents that companies transporting drugs and pharmaceutical substances must present to the *SNVS* in order to be granted the operating authorization.

1.6.2.4.3 THE REGULATION OF SUBSTANCES AND DRUGS SUBMITTED TO SPECIAL CONTROL (PORTARIA SVS/MS N. 344, OF MAY 12, 1998)  
*Portaria* SVS/MS n. 344 was issued in 1998 to regulate the production, commercialisation, distribution, storage, import and

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export of substances and drugs submitted to special control. This act contains a list of controlled products, in regards to which certain rules must be observed since they are subject to special surveillance. The listed substances are considered health endangering, addictive or psychotropic and are therefore submitted to special government control.

In order to extract, produce, fabricate, distribute, transport, prepare, manipulate, import, export, pack or repack any of the substances which are on the “controlled substances” list, it is necessary to obtain a special authorization from the Department of Health Surveillance of the Ministry of Health. A company intending to manipulate these products must send a set of documents to the Ministry of Health, such as a functioning license, all documents which identify the product and the persons responsible, the legal registration of the doctors, chemists or pharmacists who will work for the company, a list of drugs or substances which will be manipulated and the estimated quantities of the substances to be used. The local health authority will then visit the facility and, in case the special license requirement is fulfilled, the company will be given a Special Authorization Certificate. From then on, any changes in operations, constitution or activities must be communicated to the competent office.

A company which imports controlled substances must file a requirement at the Department of Health Surveillance of the Ministry of Health for an “Annual Import Amount”. The company has until November 30<sup>th</sup> of each year to make this requirement, which shall be valid for the following year. The Health Department thus limits and monitors the quality of controlled substances to be imported by each company. Those who wish to import or export these substances must require an authorization from the Ministry of Health.

Companies responsible for the transportation of these substances must be legally registered at the competent offices. Companies dedicated to the transportation of controlled substances require special operating authorization.

If controlled substances are found to be stored or transported without the required documentation, they will be apprehended, and the people responsible will be held accountable to respond

according to the legal administrative regulation. At the end of the administrative process, the health authority must send a copy to the competent police authority, for the police to proceed with the criminal investigation measures.

## **2 LEGAL SURVEY**

In the previous section we focused on legal regulation in the administrative sphere. In this section, we will describe legal regulation related to the civil and criminal spheres, as well as legal control mechanisms. The legal survey of the criminal Justice System agencies' role will be addressed initially; then we will move to a detailed description of the different criminal law provisions applicable to drug counterfeit and illegal conducts regarding the pharmaceutical market; finally, we will address the Brazilian criminal law enforcement in relation to the current objects of study.

### **2.1 BASIC STRUCTURE OF THE BRAZILIAN (CRIMINAL) JUSTICE SYSTEM**

#### **2.1.1 SUBSTANTIVE (CRIMINAL) LAW**

Brazilian substantive criminal law is organized as follows:

- (i) Criminal Code – divided into a generic and a specific part
- (ii) Special legislation, covering specific themes, such as environmental regulation, intellectual property, consumer law etc. The lack of systemization for this set of laws, as well as the lack of one single Code, are very often pointed out as being the obstacles to a clear understanding of Brazilian criminal law.

It is important to highlight that according to the Brazilian legal system the prosecution of crimes covered in this study should always involve pursuing the responsibility of individuals. According to the principle of individual guilt you require the existence of intent or negligence to attribute criminal responsibility. When describing the crimes relevant to this paper (Item 2.2) we will follow the system established in our Criminal Code, according to

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which the general rule is that all conducts described require the moral element *of intent*.

When the negligent form is also criminalized we will make a special remark about it.

### **2.1.2 ORGANIZATION OF POLICE AND PROSECUTION AUTHORITIES**

#### **2.1.2.1 POLICE**

In Brazil, the obligations of the judicial police are divided between the Federal Police and the Civil Police, according to the federal or state jurisdiction.

The execution of an investigation is a duty of the Civil or Federal Police authority. In this preliminary investigations phase, which may lead to criminal proceedings.

The Federal Government is responsible for maintaining the Federal Police as a permanent and organized institution. The States must organize and maintain the Civil Police, the Military Police and the Military Firemen. The Civil Police is led by a Chief Police Officer and acts as the Judiciary Police in the investigation of criminal offences, except for military offences. The Military Police is responsible for police activity and preservation of the public order; and the Military Firemen normally act with issues regarding civil defence.

In Brazil there is a separation between federal and state jurisdiction criminal jurisdiction. Although the Brazilian criminal legislation is always valid and effective on a national level, some crimes are considered to affect the nation as a whole and are therefore considered federal crimes. This means that the State related institution is responsible for prosecuting state crimes (the vast majority) and the Federal institution is in charge of investigating and charging federal crimes. Article 109 of the Brazilian Federal Constitution defines the cases in which the federal justice institutions are responsible for processing and judging legal actions.

The Federal Police has sectors specialized according to the fields of investigation. Regarding our field of interest, it is important to mention that although there is no special sector for counterfeiting, there is a Chemical Products Control Division, responsible for chemical products deviation and control. This Sector was created by Law n. 9,017, of March 30, 1995, focusing on the inspection of

substances used for cocaine production, but it is also in charge of dealing with drugs that contain controlled substances in general.

In 2005, the Federal Police suggested the Ministry of Justice the creation of an Internet related crimes department given the increasing number of cyber-crimes. Without having received any official answer to this proposal, the federal policemen created themselves a small team to investigate these crimes. This group is formed by 160 individuals, including skilled policemen, police authorities and police agents.

The Civil Police is under the responsibility of each State's Secretary of Justice, in its turn subordinated to each State Government. Every one of the 26 Brazilian States and the Federal District have a Civil Police, with its own organization and structure.

The general rule of competence for the investigation of crimes follows the territorial principle, which disposes that the occurrence of a crime will be investigated by the authority of the Police District of the region the crime was committed in. Nevertheless, some States have created specialized Departments to approach particularly important issues. It is therefore worth mentioning that the States of Rio de Janeiro, Paraná and Rondônia created specialized departments to restrain crimes against public health<sup>39</sup>. Cyber-crime Departments exist in the Civil Police of the States of São Paulo, Rio de Janeiro, Paraná and Rondônia.

The Police of the State São Paulo has a special Department to address Organized Crime (*Departamento Estadual de Investigações Criminais – DEIC*), which is also divided into several different departments, according to the subject matter.

Most of the cases involving illegal drugs practices shall be investigated, according to the case at hand, by (i) the Department responsible for drug counterfeiting, which also handles food stuffs and cosmetics (*Delegacia de Crimes contra a Fé Pública – Falsificação e Roubo de Medicamentos*); (ii) the Department responsible for investigating stolen cargo (*Delegacia de Furtos, Roubos e Desvio de Cargas*); or (iii) the Cyber-crimes Department.

The division of tasks between these three departments is not clearly established and we inferred its organization through interviews with the respective officers and police authorities. Based on the information received, we are able to assert that although the

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department above, listed as (i), is also supposed to deal with stolen drugs – in the case of stolen cargos – the investigation is led by the sector listed under (ii), above. The department listed under (i), above, also investigates the irregular sale of drugs over the Internet. The cyber-crimes department [listed under (iii), above] may lead to investigations of this kind, when the sale of drugs, food stuffs or cosmetics is not characterized as the core activity of the internet enterprise, meaning the department mainly investigates occurrences regarding other offences.

These rules must be understood as informal and flexible and may be influenced and determined by different factors as for example: where the investigation was started or the amount of work each group is already covering at the time of notice.

## 2.1.2.2 PUBLIC PROSECUTORS' OFFICE

The function of the Public Prosecutors in Brazil is also divided between Federal and State Offices, according to the nature of the crime. As stated above, the criminal jurisdiction, including prosecution, is divided between the federal government and the state governments. The competence for judging crimes will fall upon the federation or the state depending on the nature and extent of the occurrence and also depending on which players are involved in the criminal activity (according to article 109 of the Brazilian Federal Constitution).

In Brazil, Prosecutors play an important role in the persecution of public criminal lawsuits, for, according to the general rule, they are responsible not only for initiating the proceedings, but also for producing evidence for conviction. Criminal lawsuits initiated and conducted by the victims are an exception in the Brazilian criminal proceedings system and are rare. In this case the Public Prosecutors take part in the lawsuit only as *custus legis*. In this report, we will expressly mention the cases that are prosecuted through the so-called “private suits”.

Although it is a sole institution, with one only principal per State – the General Prosecutor –, the Prosecutor Offices may also have specialized departments. They are normally divided into the two big areas: criminal and civil. However, more specific departments can also exist.

In the State of São Paulo, there is an internal department – the “Special Group for Defense of Public Health” (*Grupo de Atuação Especial da Saúde Pública e da Saúde do Consumidor*) – from now on referred to as *GAESP*, which is responsible for investigating and charging civil felonies against public health, and for protecting consumer rights through class actions. In the criminal area there is no specific department specialized in this field. Since the *GAESP* was created in 1998, it has conducted many drug counterfeiting investigations, even though only a few of them became lawsuits eventually.

There are only a few records or mentions of health related public civil suits in which the Public Prosecutors’ Office was actively involved. The public civil suit is the procedural instrument used by the Public Prosecutors’ departments to protect collective and diffuse rights, such as the environment, consumer rights and public health.

Public Prosecutor Dr. José Piva, who works for *GAESP*, explained that for several reasons it was very rare that the institution started a lawsuit. Firstly, because in many cases the administrative agencies (*ANVISA* or *VISAs*) had already taken action and avoided further damage. When *ANVISA* closes down a factory, or takes the product out of the market, there is nothing left for the civil prosecution to do, and prosecutions are normally held by criminal prosecutors. In this case, *GAESP* can keep track of the of the administrative measures’ progress, monitoring their efficiency in avoiding further harm to public health, but the institution abstains from starting a law suit or promoting further investigation. Even if an identifiable damage occurs, the existence of such damage is generally too difficult to prove, and the prosecution settles with the administrative measures. It is important to highlight that *GAESP* has the assignment of working in civil causes only, and cannot be responsible for criminal charges, which are processed by the Criminal Prosecution. In its structure, the Public Prosecutors’ Office is one and united, but the internal subdivision of competencies determine that different departments have different assignments, and the areas of civil and criminal law are therefore kept separate.

In addition to the difficulties in gathering proofs for the collective rights cases and the action of other public offices, a further

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reason for the small number of public civil suites is that they are long and complicated procedures. These may often be substituted by an agreement settled by the Prosecutor's Office between State and offenders, according to which the offenders agree to cease or repair the illegal practice damages.

Dr. Piva pointed out to a serious problem, that is, the fact that the Prosecutor's Office has no technicians capable of gathering proof and data about drug related issues, a problem we faced in all offices working in the public health sector. Dr. Piva also mentioned that the participation and help of the public is very small, and this is a serious barrier to the effectiveness of prosecution and investigation. He believes that if the public does not participate actively in the prevention of irregularities, the State cannot fight against illegalities properly. The public should be more aware and inform all suspicious and irregular practices to the authorities, an important step in the battle against counterfeiting.

Complaints which encourage *GAESP's* actions generally come from other public entities or from other departments of the Prosecutor's Office, since the public rarely takes part in surveillance. An example is the Department of Consumer Defence, which often sends reports of potentially hazardous events to *GAESP*.

### 2.1.2.3 JURISDICTION

In addition to a division between Federal and State Courts, competencies regarding the subject matter of a case are divided only among judges dealing with civil, criminal, administrative and labour issues. Cases involving illegal drug related practices are concentrated in the first two areas. There is no specialized jurisdiction to deal with counterfeiting or cyber-crimes.

### 2.1.2.4 COOPERATION BETWEEN INSTITUTIONS

*ANVISA* and other *SNVS* agencies play a very important role in the investigation and detection of drug counterfeiting, as well as in preliminary investigations and the criminal lawsuit.

As previously mentioned, *ANVISA* holds an administrative police power, which means that it has an actively investigates cases of illegal drugs practices. However, as soon as it discovers circumstantial evidence of crime, it is obligated to communicate the criminal justice



authorities (Police or Public Prosecutors' Offices) and send them the information and evidences gathered in the administrative proceeding. In most cases, there will be two parallel proceedings, one in the administrative sphere and another one in the criminal sphere. The latter may use elements of proof produced in the first one.

Recently, the Federal Police has joined efforts with *ANVISA* in preparing and carrying out important operations that have revealed many illegal schemes in the drug market. The cooperation of the agency is also requested to provide the criminal justice system authorities with technical information.

Although investigations are a Police task, the Public Prosecutors for Criminal Matters (state or federal) can play an auxiliary role as early as in the investigations. The Public Prosecutors' Offices are involved in a project to inform judges and prosecutors about cyber-crimes in Brazil. Even if the project focuses on the investigation of racism and paedophilia events, the Public Prosecutors' Offices admit the urgency to study counterfeit drugs. Their intention is to standardize actions for investigating and judging cyber-crimes.

## **2.2 BRAZILIAN CRIMINAL LAW PROVISIONS**

The contemporary Brazilian law distinguishes two types of activities regarding drug counterfeiting practices: (i) alteration of the chemical product; and (ii) alteration of the drug's accessory characteristics, such as package forgery to delude consumers.

Related conducts are described in the Brazilian Criminal Code (Articles 273 and following) and in the Brazilian Industrial Property Law. Several conducts relating to distribution and sale of falsified drugs or drugs in disagreement with the rules set forth by the sanitary agency, are also considered to be crimes.

Any of the conducts, to be analysed below, may occur independently of each other or cumulatively, in which cases the rules of offence concurrence will be applied.

### **2.2.1 CRIMINAL LAW PROTECTION OF INTELLECTUAL PROPERTY**

As previously seen, Law n. 9,279/1996 provides, for the regulation of intellectual property rights (invention patents, utility models, industrial design, brand mark registration etc.), including crimes against intellectual property and unfair competition. Depending on

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the circumstances, illegal drug practices may indicate the occurrence of any of the crimes described below.

## 2.2.1.1 CRIMES AGAINST PATENTS

(ARTICLES 183 AND 184, LAW N. 9,279/1996)

Articles 183 and 184 of Law n. 9,279/1996 describe crimes against invention patents duly granted by the *INPI* (National Institute of Industrial Property - Instituto Nacional da Propriedade Industrial). The incriminating conducts are: a) manufacturing goods that are object of an invention patent without the owner's authorization (Article 183, I); b) using method or process that is object of an invention patent without the owner's authorization (Article 183, II); c) exporting, commercialising, exposing or offering for sale, storing, hiding or receiving, for economical purposes, goods manufactured in violation to an invention patent or obtained over a process or method object of a patent (Article 184, I); and d) importing goods that are object of an invention patent or obtained over a process or method object of a patent, for economical purposes, and that have not been put on the foreign market directly by the patent owner or with his consent (Article 184, II).

The conducts described in the first two items above – violation of patents – are subject to a detention penalty of three months to one year, or to a fine. The conducts described in the last two items above – circulation of the goods – are subject to a detention penalty of one to three months or to a fine.

The existence and effectiveness of the patent granted by the competent institution, as explained above, is an indispensable requirement for the identification of these crimes. In cases where the patented invention has already fallen into public domain, one cannot speak of a crime against patents. In the same manner, if the patent has not yet been granted – having only been required by the person entitled to it – there is no crime against industrial property either. The public institution's delay in granting patents is object of serious criticisms since it impedes protective measures applicable during this period of time.

If the falsification and circulation conducts occur in cases where the existence of a patent is not a legal protection requirement, they may represent crimes of unfair competition.

Because these crimes are subject to minor penalties, they fit in the “less serious crimes” category, which, as explained below, benefit from certain rules applied to the criminal procedure, such as the possibility of transaction in criminal courtrooms and conditional suspension of the process.<sup>40</sup>

#### 2.2.1.2 CRIMES AGAINST BRAND MARKS

In Article 189 of the Brazilian Industrial Property Law the description of crimes against brand marks, intends to encompass practices that refer to the undue employment of the container or other signs, copy the drug that has a registered brand mark and confuse consumers or lead them into mistake, compelling them to buy one product for another.

The conducts described in this article are: a) reproduction, without the owner’s authorization, in whole or in part, of a registered brand mark, or imitation giving rise to confusion; b) change of the registered brand for another brand mark already being used on goods available in the market; c) exporting, commercialising, exposing or offering for sale, hiding or having in stock goods marked, in whole or in part, with illegally reproduced or imitated third party brand marks; and c) exporting, commercialising, exposing or offering to sale, hiding or having in stock goods of own production or commerce, kept in container or crate that contains the legitimate third party brand mark.

The conducts described in a) and b), above, are subject to a detention penalty of three months to one year or to a fine. The conducts in c) and d), above, are subject to a detention penalty of one to three months or to a fine.

Because these crimes are subject to minor penalties, they also fit into the category of less serious crimes, benefiting from the same procedural rules mentioned previously and explained in item 2.2.2.6.

### 2.2.2 PROTECTION OF PROPERTY/ASSETS

#### 2.2.2.1 CRIME OF UNFAIR COMPETITION (ARTICLE 195, LAW N. 9,279/1996)

Fraudulent practices aimed at shifting the clientele and circulating adulterated products may be subsumed within the crime of unfair competition.

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Article 195 of Law n. 9,279/1996 describes a number of conducts which are characterized as unfair competition, i.e., practices against honest behaviour in the industrial or commercial field. Amongst the many practices that characterize the crime of unfair competition, the following relate to the illicit drugs market: a) employing a fraudulent method in order to deviate a third party's clientele, for own or a third party's benefit; b) using or imitating someone else's marketing expression or symbol, creating confusion between the products or establishments; c) using improperly a third party's commercial name, establishment title or symbol, or selling, exposing or offering for sale or storing products with such references; and d) selling or exposing or offering for sale adulterated or falsified products in the package or label belonging to a third party or using such package or label in order to negotiate products of the same nature, although neither adulterated nor falsified, if the fact does not represent a more serious crime.

These conducts are subject to detention punishments of three months to one year or fine and, exactly as those described earlier, fit in the category of less serious crimes, thus benefiting from the same already mentioned procedural rules, for this type of crime.

Some of these conducts are very similar to some described as crimes against the industrial property. The differences reside in the fact that in the present case the characterization of the crime of unfair competition does not depend on the existence and validity of a patent or of the registration of the trademark with the competent authorities.

As the crimes described above, that of unfair competition is submitted to the private criminal suit procedure. We will study the specificities of the private criminal suit in section 2.3.1.1, and we will also see which crimes it applies to.

## 2.2.2.2 CONSUMER CODE

Law n. 8,078, of September 9, 1990, known as the Consumer Defence Code, contains a number of criminal law provisions applicable in cases of drug counterfeiting.

According to this Law, consumers and competent authorities must be warned of a drug's side effects. The Consumer Code also determines that making false or misleading statements or omitting

relevant information about the products and services offered, turns the individual responsible for the action, liable to a detention of three months to one year and a fine. Whoever sponsors the sale offer is subject to the same penalties. The detention period is lowered to one to six months in cases where there is no malicious fraud, but negligence instead. Furthermore, whoever knowingly advertises or promotes advertisement containing false information (or which he/she should know to be false) is subject to detention (three months to one year) and a fine. In addition, whoever advertises or promotes advertisement, which is (or he/she should know is) capable of driving consumers to act in a way that is harmful or dangerous to their health or safety, is subject to detention (six months to two years) and a fine.

Article 78 of this Law lists other penalties that can be imposed on individuals committing the crimes described in the Consumer Defence Code, besides detention and the payment of a fine: (i) temporary suspension of rights; (ii) publication of a facts and sentence notification on a top communication media at the convict's expenses, (iii) community services.

### 2.2.2.3 PROTECTION OF LIFE/HEALTH

#### a DRUG FALSIFICATION OR ADULTERATION

Article 273 of the Criminal Code (Decree-Law n. 2,848/1940<sup>41</sup>, as amended by Law n. 9,677/1998) criminalizes the conduct of “falsifying, corrupting, adulterating or altering products with therapeutic or medicinal purposes”, subjecting these to a reclusion punishment of ten to fifteen years and fine.

The first paragraph of this article sets forth that it refers to the following products: drugs, raw materials, pharmaceutical consumption materials, cosmetics<sup>42</sup>, cleaning products and products used in diagnoses.

These criminal provisions derive from a Criminal Code amendment— to Law n. 9,677/1998 – issued as a response to the great repercussion of facts related to cases of counterfeit drug intake, which affected Brazil on a national scale in the years before its edition. Until 1998, the alteration of medicinal substances was subject to punishment of one to three years reclusion. With the legal

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reform, the penalty for this crime was altered to ten to fifteen years reclusion, one of the highest in the Brazilian criminal legislation. These conducts are legally qualified as “heinous crimes”, and are submitted to a specific and very strict treatment, as will be described below.

Article 273 of the Criminal Code also provides that the adulteration of drugs through negligence is subject to a punishment of one to three years detention and a fine. In this case, the crime is not heinous and the rules regarding the sentence serving follow the system established in the general part of the Criminal Code and the Penalty Enforcement Law (Law n. 7,210/1984), whereby it is necessary that one sixth of the penalty be served in order to move from the so called “closed system” to a less strict penalty system called “semi monitored freedom” and one third of the penalty be served in order to be eligible to conditional release (a legal institute comparable to the North American *parole*).

## b DISTRIBUTION AND SALE OF FALSIFIED DRUGS

The first paragraph of Article 273 of the Criminal Code criminalizes the conduct of anyone who imports, sells, exposes for sale, stocks to sell or, in any way, distributes or delivers the falsified, corrupted, adulterated or altered product for consumption, and makes the individual subject to the same penalties as set forth for falsification: 10 to 15 years reclusion and fine.

## c DISTRIBUTION AND SALE OF “IRREGULAR” DRUGS

Paragraph 1B, Article 273 of the Criminal Code criminalizes the conduct of anyone who imports, sells, exposes for sale, stocks in order to sell or, in any way, distributes or delivers for consumption products with therapeutic or medicinal purposes in any of the following irregular conditions: a) Without registration with the competent health surveillance agency – when it is mandatory to have one; b) In disagreement with the formula presented in the registry; c) Without the identity and quality characteristics admitted for its commercialisation; d) With reduction of its therapeutic value or activity; e) Of unknown origin; and f) Acquired from an establishment that does not have a functioning license with the competent sanitary authority, making the individuals in charge liable to the

same penalties as set forth for falsification: reclusion from 10 to 15 years and fine.

There is also a provision addressing the negligent form of this crime: one to three years detention penalty and fine.

#### d WRAPPER OR RECIPIENT WITH FALSE INDICATION

The Criminal Code provides for yet two more criminalized conducts that somehow relate to the falsification of drugs. Article 275 regulates the use of wrappers or containers with a false indication. Anyone who indicates that a medicinal or food product contains a certain substance which, in fact, is not in its composition, or exists only in smaller quantity than the one declared is subject to a reclusion punishment of one to five years.

Article 276 provides for the same punishment, to be applied to anyone who sells, exposes for sale, stores or, in any way, delivers for consumption, products in these conditions.

Both crimes (Articles 275 and 276) may receive the benefit of conditional suspension of the process due to the fact that the minimum sentence is of one year.

#### e SUBSTANCES USED FOR FALSIFICATION

Article 277 of the Criminal Code criminalizes the conduct of anyone who sells, exposes for sale or stores substances used for the falsification of medicinal, foodstuff or therapeutic products. Such use may be due to the nature of the substance (exclusively employed for such purpose) or from the specific use it will be submitted to by its buyer or recipient, on whichever title. (substances that may be used for other legal purposes).

The penalty set forth is of one to five years reclusion, which also allows for conditional suspension of the process.

#### 2.2.2.4 DRUG TRAFFICKING

Law n. 11,434 of August 23, 2006, defines “drug” as “substance or product able to cause addiction, defined as such in laws or included in regularly updated lists” by the Federal Government. According to the Brazilian legal theory, this disposition allows the Executive Power great freedom in its attribution of defining which products should be considered drugs<sup>43</sup>. This is caused not only by

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the lack of specifications – regarding which form the “list” should be delivered in (whether it should be a presidential Decree, a Resolution of the Ministry of Health or of one of its subordinate institutes or agencies etc.) – but also because, in referring to “dependency”, without specifying whether chemical or psychological, it allows for the inclusion of substances which cause either one. Additionally, since it also allows the law to define drugs, this paragraph enables the political discussion in the Brazilian Congress, of a subject which historically has always been regarded as purely technical, thereby resulting in endless debates on the so-called “light drugs”.

It should be highlighted, also, that this definition of “drug” does not really solve the problem addressed, once the real definition is guaranteed by other laws and regulations. As such, all dispositions of this law that employ the term “drug” are known as “criminal laws in black”<sup>44</sup> or open or uncomplete criminal laws, meaning that they are only valid and effective in view of the law and regulations that number the substances as dependency generators. Currently, this is fulfilled by *Portaria* n. 344, of May 12, 1998, issued by the Health Surveillance Secretary, under the Ministry of Health.

As one may infer from the wording above, the anti-drugs law is therefore also applicable to all medication, which include controlled substances in their formulas. Several of the crimes addressed by this law therefore encompass the illegal use, production, sale etc. of therapeutic drugs.

Article 2 of Law n. 11,343/2006 forbids the planting, cultivation, harvest and exploitation of plants and other substrates from which it is possible to extract or produce drugs (as defined above) or raw materials related, without legal or regulatory authorization. By introducing the possibility of a regulatory authorization, the Law allows for more flexibility in the granting of the permit, so that it may also be, released for example, by the Ministry of Health, *ANVISA* or other agencies. This understanding is reinforced by the sole paragraph of this article, which expressly determines that the Federal Government may authorize the planting, cultivation, harvest and exploitation of such plants, exclusively for medical or scientific purposes and is subject to its control.



Yet, before describing any criminal conducts, Law n. 11,343/2006 sets forth generic rules regarding drugs and raw materials related, in a very similar wording to the one used in previous anti-drug legislation (Laws n. 6,368, of October 21, 1976, and n. 10,409, of January 11, 2002). To this purpose, article 31 subjects the possibility of producing, extracting, fabricating, transforming, preparing, keeping in stock, importing, exporting, re-exporting, sending, transporting, exposing, offering, selling, buying, exchanging, acquiring, for any purpose, drugs or raw materials – destined to their preparation –, to a previous licensing by the authority in charge.

This article, combined with article 2 and its sole paragraph, reinforces the total exceptionality of the handling of drugs and raw materials related and, as there is no restriction to the drug itself, the plants and substrates do not have to present the same effects as the drug which they may produce, but simply enable such drug to be produced by any means. It should also be noted that the necessary license, mentioned in the above articles, includes not only the permission to plant (or extract etc.) specific plants or substrates, but also regards the location where the activity is to take place, as well as the period of time during which this may be executed<sup>45</sup>. The control over such licensed activity is constant and should also allow public authorities to interfere when there is any deviation of purpose. This inference suffices for the immediate revocation of the granted license.

Illegal plantations will be immediately destroyed by incineration, by the Judicial Police, after securing enough material for the forensic experts' analysis and any other necessary evidence (Article 32).

Regarding the specific crimes addressed by this law, the following are applicable to the unauthorized production and traffic of medicinal drugs: articles 33, 35, 36, 37 and 38.

Article 33 forbids a total of 18 activities executed without authorization or in disagreement with legal drug related regulations, all of which already proscribed under Law n. 6,368/1976. These activities are listed as follows: import; export; remit; prepare; produce; fabricate; acquire; sell; expose for sale; offer; lay in stock; transport; carry; keep; prescribe; apply; deliver for consumption; and supply.

These conducts are also punishable if performed free of charge, and they are known as “conduct-offences”, that is, no naturalistic result is required for their perfection.

They are also all subject to a punishment of incarceration from 5 to 15 years and payment of 500 to 1500 days of fine<sup>46</sup>, which is much more severe than the previous Law in place (3-15 years and payment of 50 to 360 days of fine). The number of days of fine is also significantly higher than the one set forth in the Criminal Code: the rule set forth in Article 49 of the Criminal Code stipulates that the number of days of fine shall vary between 10 and 360.

Even though this disposition describes several actions, in case they are all practiced within the same context, the criminal penalty will be applied once only. However, should the same individual engage in various of the described actions and in different contexts, under this provision he/she may be charged repeatedly, and the penalties applied will be added as concurring offences<sup>47</sup>.

It should be noted that Article 28 of this law also provides for the conducts of acquiring, keeping, holding in stock, transporting and carrying drugs, but for own use and therefore with different and less strict sanctions. After the last legal amendment, the sanctions for these conducts do not include imprisonment. To this day, courts have decided as to under which provision the conduct falls into a case-to-case basis and mostly in view of the amount of drugs found with the author. Other circumstances (e.g., the way the drug is packed) are also taken into account when determining whether the drug is for personal consumption or trafficking instead.

The first paragraph of Article 33 sets forth that the same penalties mentioned above are applicable to anyone who performs any of the activities described in the *caput* of Article 33 with regard to raw materials, components or chemical products destined to the preparation of drugs. Part of the legal theory understands that the conducts described in this paragraph are to be regarded as distinct from the ones of the *caput*, i.e., someone who keeps raw materials in stock to fabricate a drug and also fabricates such drug, should be punished both under this paragraph and under the *caput*<sup>48</sup>. However, it is only possible to punish someone under this paragraph whenever it is possible to verify that the intention of

the agent was to use such raw materials, components or chemical products in the preparation, production or fabrication of drugs<sup>49</sup>.

Article 35 proscribes the association of two or more persons for the purpose of practicing, repeatedly or not, any of the crimes set forth in Articles 33, *caput* and first paragraph, 34 and 36 of this law, subjecting such conduct to the imprisonment penalty of 3 to 10 years and payment of 700 to 1200 days of fine. This happens, normally, in concurrence with the other conducts. It should be noted that it is necessary to prove the intentional liaison between the agents with a view to trafficking illicit drugs, whereby it is not enough to simply verify that more than one person is involved in any of the referred conducts. It is necessary, therefore, to prove that there was a previous understanding between the people involved with a view to forming a *de facto* association in which the intent of association is separated from the intent to commit the other crimes listed<sup>50</sup>. This crime was already set forth in Law n. 6,368/1976, and its fine was also aggravated by Law n. 11,343/2006.

Article 36 punishes the financing of the crimes set forth in Article 33, *caput* and first paragraph, and Article 34 with imprisonment from 8 to 20 years and payment of 1500 to 4000 days of fine. This specific activity was not yet criminalized under previous anti-drug legislation and it aims at suppressing all forms of financing as a means of undermining criminal drug traffic organizations. It should be highlighted that such financing has to be operated on a regular basis and must represent a condition for the survival of the trafficking.

Article 37 punishes de cooperation with drug trafficking criminal organizations – imprisonment of 2 to 6 years and payment of 300 to 700 days of fine.

Finally, Article 38 proscribes the negligent prescription or application of drugs, when a patient does not need them or if they are prescribed or applied in excessive dosage or in disagreement with legal or regulatory determination. The penalty for these conducts is imprisonment of 6 months to 2 years and payment of 50 to 200 days of fine.

Articles 33, 35, 36 and 37 are all equated to heinous crimes, due to the wording of article 5, XLIII, of the Brazilian Federal

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Constitution. Additionally, Article 44 of Law n. 11,343/2006, with regard to such conducts, expressly forbids bail, conditional suspension of the penalty execution, grace, pardon, amnesty, conditional release and the conversion of imprisonment penalties to alternative sanctions<sup>51</sup>. Furthermore, probation is only possible after the execution of 2/3 of the penalty imposed upon the agent and it shall always begin under closed prison system.

## 2.2.2.5 THE CLASSIFICATION OF SOME ACTIVITIES AS HEINOUS CRIMES:

All activities described in Items 2.2.2.3.a), 2.2.2.3.b), 2.2.2.3.c) and 2.2.2.4, excluding the culpable forms, were included in the list of heinous crimes by the enactment of Law n. 9,677/1998.

Heinous crimes are punished more severely, with higher penalties and more severely executed. They are not susceptible to amnesty, grace or indult and bail; until recently, provisional release and progression to a less strict penalty system were forbidden, and the person found guilty of committing a heinous crime had to serve the sentence fully under closed prison system. However, in the judgment of the *Habeas Corpus* 82.959, of 2006, the Supreme Federal Court (*Supremo Tribunal Federal – STF*) understood that the prohibition of progression to a less strict punishment system – originally set forth in the Heinous Crimes Law – was unconstitutional. After this sentence, Law n. 11,464, of 2007, was enacted, establishing that a person found guilty of committing a heinous crime would only be eligible for progression after having served two fifths of the penalty received, if a first-time offender, and three fifths, if a recidivist. The same law also revoked the prohibition of provisional release.

## 2.2.2.6 THE CLASSIFICATION OF SOME CONDUCTS AS LESS OFFENSIVE CONDUCTS

In 1995, Law n. 9,099 (“Special Trial Law”) created a category of less serious crimes, currently defined as those subject to a maximum jail-term of two years or less.

The conducts judged under Law 9,099 are subject to a specific criminal procedure, which is conducted in most cases orally and is very brief. This means that alternatives to the criminal process and sentencing could be applied for those accused of these crimes and misdemeanours.

This Law established several new procedures for the "less offensive conducts", acts such as civil agreement before the court between author and victim and criminal courtroom negotiations (similar to plea bargaining).

The first institute allows the conclusion of the criminal procedure if author and victim come to a civil agreement to recover damages. The second one allows for the application of alternative measures prior to process and punishment. The parties involved in the dispute shall have the opportunity to endeavor in a legal negotiation with the public prosecutor. This means that before the legal procedure actually starts – while the case is still in its pre-process stage – the Prosecutors can propose an agreement, which, if accepted, puts an end to the crime's prosecution. This kind of "legal negotiation" is still a controversial subject in our legal system, for some experts consider it as punishment without trial. Nevertheless, it is not questioned in the Judiciary and it represents a quick and effective mechanism to take some work pressure off the justice system and speed up the processing of "less offensive" conducts.

In addition, this law also allows the conditional suspension of the process for a greater number of conducts – those whose minimum penalty is not higher than one year. The judge applies the conditional suspension of the process immediately after accepting the accusation, which means formally starting the process. It implies the halt of the criminal process for the period of two to four years (depending on each case) if the author accepts to submit him or herself to certain conditions. Amongst these conditions we can mention the compensation for damages, the prohibition to visit certain places, attendance to a monthly meeting in court, and the prohibition to leave the legal perimeter without the judge's authorization. It may potentially lead to the extinction of the punishment without discussing the indicted person's guilt, in case all conditions agreed upon are met during the period of proof.

As mentioned above, many of the offences described in this section fall into the category of "less offensive conducts", for the penalties they are liable to do not exceed 2 years. This is the case of the crimes described by the Industrial Property Act, e.g. crimes

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against patents, crimes against brand marks and unfair competition. As for the offences that are benefited by the conditional suspension of the process, we can mention all those whose minimum penalty is not higher than one year. These include the crimes described by the Industrial Property Act plus some of those described by our criminal code; to be more specific, the use, sale exposure for sale or stock/ storing of wrapper or container with false indication (articles 175 and 176) and the sale, exposure for sale or stock/storing of substances used for medicinal, foodstuff or therapeutic products' falsification (article 277).

It is also interesting to see that there has been some discussion about the possibility of negotiation in crimes against intellectual property. According to the legal theory, it is impossible to state that Law n. 10,259/2001 does not apply to offences against intellectual property. When we analyse the penalty of the crimes described in this law, we could say that they are considered by law crimes of "low offensive potential"<sup>52</sup>. The problem arises when it comes to the institute of negotiation. Most of these crimes are prosecuted not by the public prosecutor, but by the victim. And, as the public prosecutor is not empowered to act, there would be no point forecasting the possibility of a deal between the author and the public prosecutor. The question is if this institute is somehow applicable to crimes prosecuted by the victim. And if it is: in these cases should the negotiation and the possible dismissal of the case be led by the Public Prosecutor with the help (or acceptance) of the victim or by the victim alone? The Brazilian jurisprudence has different opinions about that and the question is still open.

### **2.2.3 RELATIONS BETWEEN NORMS AND SANCTIONS**

The relationship between criminal law provisions, especially between different legal descriptions of crimes, can be generally classified in two types: (i) a matter of finding the more adequate legal description applicable to a determined real conduct, known in the Brazilian system as "apparent concurrence or conflict of norms"; (ii) a matter of establishing legal treatment to the real concurrence of more than one crime in the same activity (ideal concurrence of crimes) or in more than one, linked to each other in specific circumstances (material concurrence of crimes).

### 2.2.3.1 APPARENT CONCURRENCE OR CONFLICT OF NORMS

In these cases there are several articles that may be suitable, but only one can be applied. The rules and principles that guide the choice are not found in the legal text, but are rather an interpretive construction of the legal theory and the Tribunals over the past decades. They can also be found in the international jurisprudence and foreign systems.

The most important principles guiding this type of norm interaction are: the principle of the more special norm; the principle of subsidiary norm; the absorption principle.

The principle of the more special norm (*lex speciali derogat legi generali*) defines that cases in which two norms are applicable to a conduct and these norms could be considered in a relation such as of genus and species, the most specific prevails.

This principle was applied, for example, by the Federal Court of Appeal of the South Brazil Region (known as the 4<sup>th</sup> Federal Region) in a case (n. 2004.04.01.012508-0-Pr) in which there was a conflict between the crime of smuggling (article 334 of the Criminal Code) and the legal description in the first paragraph of Article 273, Criminal Code, where the defendant's activity consisted in importing non registered drugs. In the decision, the judges found that the last mentioned norm was more specific than the first one, because it also mentions the act of importing, but contains the specific fact that the imported materials are drugs. It is worth highlighting that the crime of Article 273, first paragraph, is far more severe than the sanction for smuggling: 10 to 15 years, compared to 1 to 4 years.

Another possible application of this principle to the conducts described in this study could be related to the distribution and sale of "irregular" drugs (Paragraph 1B of Article 273) versus the drug trafficking ruled by Law n. 11,434/2006. Whenever the concrete conduct involves drug or substance able to cause addiction or defined as such, we can consider that the drug trafficking legislation is the most specific.

The principle of the subsidiary norm (*lex primaria derogat legi subsidiariae*) defines that in a case in which two norms could be applied and these two norms are in a centrality and *subsidiarity* relation, the subsidiary norm is put aside and the "central" norm

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must be applied. Subsidiary norm is here defined as a norm that refers only to a part of the conduct described by another norm or to one of its peculiarities or characteristics. Sometimes the subsidiary norm describes only one element of the entire conduct, or only a circumstance that aggravates the fact. Most frequently central and subsidiary norms also define more serious and less serious crimes, respectively.

The last principle is very similar to the previous one and is more frequently applied to cases in which the same fact is composed of more than only one conduct, that is, to cases of complex crimes. The absorption principle states that when a crime is committed as a means to carry out another crime or as the natural and essential path for the second practice, the first one is absorbed by the second one.

## 2.2.3.2 REAL CONCURRENCE OF NORMS

### – IDEAL AND MATERIAL MODALITIES

The Brazilian criminal law, as do other systems, has special rules regarding offence concurrence. It may occur in various forms, according to which different legal consequences are applied. Because this issue is strongly linked to the way some activities or a set of conducts are committed, the determination of these different forms of concurring offences – and possible relations between all offences mentioned previously – is only possible by analysing concrete cases. Hence, we will now describe the Brazilian criminal law's general provisions and will raise some examples of possible relations between legal provisions.

Article 69 of the Brazilian Criminal Code refers to the possibility of material concurrence, meaning the situation in which an author, while putting into practice two or more actions or omissions, also turns out to commit two or more crimes (identical or different ones). It establishes that the final sanction applied should be the sum of the individual sanctions, i.e., the sanction shall be cumulative.

Many cases in the drug counterfeit arena involve material concurrence of crimes. It is very common to have the concurrent falsification or adulteration of drugs (Article 273, Criminal Code) practice or distribution and sale of “irregular” drugs (Paragraph 1B of Article 273, Criminal Code) together with the practice of



false indication of wrapper or container (Article 275, Criminal Code) or of the crime against brand marks, described in Article 189 of the Brazilian Industrial Property Law.

Other examples of material concurrence of crimes may be found in the crime of counterfeit drug sales (Article 273, *caput* and §1º, Criminal Code) combined to the forming of a gang for illegal purpose (Art. 288, Criminal Code). This happened in a case to which we had access to, over the sentence of *Habeas Corpus* judged by the Sao Paulo Court of Appeal (*Habeas Corpus* 268.262-3/1-00), where a gang sold the counterfeited version of the drug “Androcur”.

Article 70 describes ideal concurrence cases, meaning the situation in which an author, while practicing a sole act or omission, is committing two or more crimes. It determines that in these cases the author should be punished only with the highest sanction and if the penalties are equal, the author shall be subject to only one of them, but increased by 1/6 to 1/2, according to the judge’s criterion.

#### **2.2.4 CRIMINAL LAW ENFORCEMENT**

To grasp a concrete idea of how these criminal laws and sanctions are being applied by the Brazilian Tribunals<sup>53</sup>, we searched the database maintained by the São Paulo’s Attorneys Association<sup>54</sup>, where all of the last ten years’ decisions, in eight of the Brazilian Courts of Appeal (Distrito Federal, Goiás, Mato Grosso, Mato Grosso do Sul, Paraná, Rio Grande do Sul, Santa Catarina and São Paulo) are published.

We used the Boolean text base search engine available online and searched for data containing the term “substance”, employed in the wording of the Criminal Code. Over 69,000 results were found. We then narrowed down our search to the verbs contained in the incriminating dispositions involving drug counterfeiting (Articles 273, 274, 275 and 276, Criminal Code). With these filters, we reached a result of only 4 cases:

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PETITION	NUMBER	COURT	IMPUTED CONDUCT	FACTS	JUDGMENT IN 1 <sup>st</sup> INSTANCE	JUDGMENT IN 2 <sup>nd</sup> INSTANCE
CRIMINAL APPEAL	013.770-4	TJ-SC	ART. 273, §1-B, I, V AND VI, CRIMINAL CODE	CAUGHT IN THE ACT OF SELLING COUNTERFEITED PRODUCTS	SENTENCED TO 10 YEARS OF IMPRISONMENT AND 10 DAYS OF FINE	1 <sup>st</sup> INSTANCE JUDGMENT MAINTAINED
CRIMINAL APPEAL	004.732-9	TJ-SC	ART. 273, §1-B, I AND VI, CRIMINAL CODE	ACCUSATION OF SELLING DRUGS WITHOUT ANVISA'S AUTHORIZATION	SENTENCED TO 3 YEARS OF IMPRISONMENT AND 50 DAYS OF FINE	1 <sup>st</sup> INSTANCE JUDGMENT MAINTAINED
CRIMINAL APPEAL	254.444-3	TJ-MG	ART. 273, CAPUT, AND §1, CRIMINAL CODE	CAUGHT IN THE ACT OF PRODUCING ILLEGAL DRUGS	SENTENCED TO 10 YEARS OF IMPRISONMENT	1 <sup>st</sup> INSTANCE JUDGMENT MAINTAINED
CRIMINAL APPEAL	170.191-1	TJ-MG	ART. 273, §1º, CRIMINAL CODE	SUSPECT OF COUNTERFEIT OF DRUGS	SENTENCED TO 2 YEARS OF IMPRISONMENT AND 60 DAYS OF FINE	1 <sup>st</sup> INSTANCE JUDGMENT MAINTAINED

### 2.2.5 CIVIL LAW PROCEEDINGS BY PHARMACEUTICAL COMPANIES

#### AGAINST COUNTERFEITERS/DISTRIBUTORS OF COUNTERFEIT PRODUCTS

The Brazilian civil liability system is very similar to the German one in its overall categories and principles. The Brazilian Civil Code determines that anyone who by voluntary action or omission, negligence or imprudence, violates third party rights and causes damages – even if of exclusive moral nature –, is committing an illicit act (Article 186, Civil Code). Article 927, in its turn, determines that anyone who, by committing an illicit act, causes damages to a third party, is obliged to remediate the damages. In such cases indemnification is stipulated based on the extension of the damage, according to Article 944. The determined indemnification amount shall encompass damages, unearned profits and damages to a company's image. According to Article 100, V, "a", of the Civil Procedure Code, the courts competent for indemnification lawsuits are those of the location the illicit act took place in. Regarding civil liability, it's important to highlight that it is independent from the criminal one (Article 935, Civil Code).

## **2.3 BRAZILIAN PROSECUTION MEASURES AND INSTRUMENTS**

### **2.3.1 *TRADITIONAL CRIMINAL PROCEDURE LAW, PERMISSIBILITY AND APPLICATION OF SPECIAL INVESTIGATORY MEASURES***

To give an overall idea of our criminal procedure legislation, one should highlight that the Criminal Procedure Code dates back to 1941 and is completely outdated. It is nowadays challenged, on the one hand, by the demands for a simpler, swifter, less bureaucratic and more open criminal process and, on the other hand, by its adequacy to the system of principles and guarantees introduced by the Federal Constitution of 1988. Many of the rules therein became obsolete due to the new constitutional order or could only be adjusted to the new Constitution through unorthodox means of interpretation.

The change worth of mention in the criminal procedure was the law of 1995 instituting the Special Criminal Courts, as previously addressed.

Other changes in criminal procedure legislation refer to the new investigation institutes related to the prosecution of organized crime, as described below.

#### **2.3.1.1 CRIMINAL PROCEDURE APPLIED TO DRUGS**

##### **COUNTERFEIT: PUBLIC AND PRIVATE CRIMINAL PROCEDURES**

The criminalization of drug counterfeiting in Brazil occurs on two fronts: the offence is regarded as a crime against public health (Chapter II of Title VIII of the Criminal Code) and also as a crime against industrial property and unfair competition (Law n. 9,279/1996).

The initiating of the criminal proceeding and, therefore, of the investigation, differs substantially from one crime to the other. While the offences described in the Criminal Code are subject to public criminal procedure, those of Law n. 9,279/1996 are subject to private criminal procedure.

This implies that, regarding the offences described in the Criminal Code, any person may notify the authorities, who are in charge of the investigation. Thus, the police investigation, which is the usual form of criminal investigation, may be initiated by the police themselves, upon requisition from the judge or by the Public Prosecutors' Office or upon notice filed by any of the parties.

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Based on the notice, the police officer who leads the investigation may set in place a number of measures provided for in the Criminal Procedure Code: search and seizure, hearing of witnesses, examination of the seized drug with the respective technical report. Additionally, provided it is impossible to collect evidence through other means and depending on the case, telephone information interception is admitted.

Specifically in regards to the negligent form of counterfeit, corruption, adulteration or alteration of a product with therapeutic and medicinal purposes (Article 273, Criminal Code), to the crime of employ of forbidden process or non-allowed substance (Artikel 274, Criminal Code), to the crime of false indication on the wrapping or container (Article 275, Criminal Code), to the offences in Articles 276 and 277, Criminal Code, conditional suspension of the process is applicable, according to the terms of Article 89,f Law n. 9,099/1995 (explained in item 2.2.2.6 above). This benefit is not applicable to Article 273, *caput*, Criminal Code (wilful counterfeit, corruption and adulteration of drugs).

The crimes of/in Law n. 9,279/1996 are always processed under the private criminal procedure. Additionally, there is a special procedure to be followed. Before initiating the process, it is necessary to prove the existence of the *corpus delicti*. This occurs after an expert examination and upon search and seizure judicially enforced, subject to stringent deadlines and formalities. The only person entitled to request such measure is the victim, who must also present proof of his / her legitimacy, e.g., that he/she is the owner of the violated patent.

Law n. 9,279, of May 14<sup>th</sup>, 1996, enforced a new discipline to the treating and processing of crimes against intellectual property. With regards to the preliminary search and seizure inquiry, it followed the same orientation determined by de Criminal Procedure Code. It brought only a few innovations, such as the one in Article 201 of Law n. 9,279/1996, which obligates the court official – in the case of crimes against patents regarding a process invention – to be accompanied by an expert to examine and verify in advance the existence of the offence, before a possible apprehension.

This preliminary inquiry is thus performed within the judicial scope and is not presided over by the police authority. The victim is given 6 months to promote criminal proceedings, counted from

the date on which the author of the crime is disclosed. Therefore, the victim must request the preliminary search and seizure inquiry within this period of time.

Although it is meant to prove the existence of the illicit act, the judicially enforced preliminary search and seizure inquiry and the formation of the *corpus delicti* proof is meant to prove the material existence of the illicit act, it may also provide elements that indicate the authorship of the offence. Falsification or counterfeit instruments and falsified or counterfeited objects, objects or products obtained by the counterfeiter with the employ of privileged means or process, documents materially respecting the illicit fact, and material elements of conviction – relevant for the clarification of the truth – may be arrested.

Henceforth, based on the technical report produced on the objects seized, the victim has 30 days (counted in the period of 6 months) to present the private accusation (known as “*queixa-crime*”), thereby initiating the second phase of the criminal prosecution. In this process, the “availability principle” is effective (i.e., the victim decides whether to initiate the criminal process or not), in opposition to what occurs in the public criminal procedure, which is mandatory.

Regarding the criminal proceeding, once the public or private criminal procedure is initiated, the indicted person is questioned, prosecuting witnesses and witnesses for the defence are heard, closing arguments are presented and the process is judged.

Evidence includes the presentation of documents, witness hearings, examinations, forensics and evaluations. Telephone call interceptions may occur in exceptional situations.

Although Law n. 9,099/1995 is not specific with regard to the above, as previously mentioned, part of the higher courts understand that, even though industrial property and unfair competition crimes are processed under the private criminal procedure, they remain in the category of less serious offences, because their maximum penalty is less than two years imprisonment. In view of the fact that these crimes may be considered as less serious offences, two alternative measures present themselves: civil composition with the victim and negotiation previous to the presentation of the accusation?.

Industrial property and unfair competition crimes may also be subject to conditional suspension of the process.

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### 2.3.1.2 ALTERNATIVES TO PRISON

To replace the loss of liberty as a penalty, the Brazilian legislation enables a series of alternative measures aside from imprisonment. These “alternative penalties” can substitute imprisonment when a series of legally required conditions are fulfilled. The general clause, which creates the possibility of implementing alternative penalties, is article 44 of the Criminal Code, which allows substituting the loss of liberty for rights’ restriction or for a fine. The nature of the alternative penalty depends on the seriousness of the crime and on the sentenced time of imprisonment

According to article 44, rights restriction penalties are independent and substitute those of imprisonment when three conditions are fulfilled. In the first place, the imprisonment sentenced should not surpass 4 years and should not have been committed with violence or serious threat to the individual, whatever the applied penalty might be, when the crime is unintentional. In the second place, the condemned cannot have been sentenced for any previous intentional crime. Finally, the subjective characteristics of the condemned, as well as the motives and circumstances of the crime, must indicate that the substitution will be a suitable and sufficient penalty for the case in question.

Moreover, the second paragraph of this same article allows for the substitution of imprisonment for a restrictive measure or for a fine when the penalty does not exceed one year of imprisonment.

Many of the crimes mentioned above can therefore benefit from the application of penalties – alternative to imprisonment –since they fulfil the requirements previewed in the Criminal Code. This is the case of the crimes described in Law 9,279, which we analysed above. The crimes against invention patents (articles 183 and 184), the crime of unfair competition (article 185), all have maximum penalties that do not exceed 2 years, even in their qualified forms. Thus, depending on the condemned individual’s subjective characteristics, on his legal records and on the crime’s objective conditions, the penalty of imprisonment can be substituted for an alternative penalty, either one regarding rights restrictions or the application of a fine.

The crimes described in articles 275 and 276 of the Criminal Code (Wrapper or container with false indication) can also benefit from the application of alternative penalties, which can vary

between the restriction of rights and the application of fines, depending on the individual's sentenced time of imprisonment. The same applies for the activity of anyone who sells, exposes for sale or stores substances used for the falsification of medicinal, foodstuff or therapeutic products, as described in article 277 of the Criminal Code.

#### **2.3.1.3 SPECIAL INVESTIGATORY MEASURES: ORGANIZED CRIME**

To this day, the Brazilian legal system has not defined, within the law, the concept of criminal organizations. Nevertheless, a number of recent changes introduced new investigatory instruments for the prosecution of crimes performed by criminal organizations. In these cases, the adoption of exceptional investigation methods and proof is allowed, yet subject to specific judicial authorization, such as: access to tax, banking, financial and elections related data (Law n. 105, of January 10<sup>th</sup>, 2001), documents and information and interception of electromagnetic, optical or acoustic signals (Law n. 9,296, July 24<sup>th</sup>, 1996).

Additionally, the Brazilian legal system provides for the institute of rewarded. delation. Anyone accused of integrating a criminal organization can have his/her penalty reduced in exchange of information regarding the other participants of the crime, reporting the victim's directions or location or any other form of contribution to solve the crime. This institute allows for the reduction of the sentence as well as a witness protection program for those whose identity should not be disclosed due to risk to their life. There are seven Brazilian laws that reward delation: Article 159, Criminal Code (kidnapping and extortion); Law n. 8,072, of July 25, 1990 (Law of heinous crimes); Law n. 8,137, of December 27, 1990 (Law of tax crimes); Law n. 9,034, of May 3<sup>rd</sup>, 1995 (Law of organized crime); Law n. 9,613, of March 3<sup>rd</sup>, 1998 (Anti Money Laundering Law); Law n. 9,807, of July 13<sup>th</sup>, 1999 (Witness and victims protection Law); and Law n. 11,343, of August 23<sup>rd</sup>, 2002 (Law of drugs).

#### **2.4 NATIONAL SIGNIFICANCE OF INTERNATIONAL LEGAL INSTRUMENTS**

Matters regarding the Internet, offences committed abroad and international cooperation shall be addressed in this item. Furthermore, we

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will present data regarding the Internet as a means through which new forms of criminal offences are committed. These offences vary across a large range of activities. We will address only the ones related to the commercialisation of illegitimate, stolen or counterfeited substances. In any case, what all of them have in common is the increased difficulty they pose for the investigation and the prosecution.

Firstly we will approach the Internet regulation in Brazil its evolution, perspectives and difficulties. Following this analysis, the focus will shift to the role played by the Internet in the commercialisation of counterfeited drugs, to show how this crime has been committed over the Internet in Brazil.

Information on drug counterfeiting and specifically on the commercialisation of these drugs over the Internet is rare and poorly organized. However, even without specific information on the role played by the Internet in the counterfeited drug market or on the amount of drugs sold over the Internet, many sources indicate that it's a relevant and very important instrument for the illegal drugs trade.

As a result of the lack of organized or scientific data on the subject, this part of our findings is based on a large scale information gathered in the media and with experts on the matter.

### **2.4.1 OFFENCES COMMITTED ABROAD AND INTERNATIONAL COOPERATION**

#### **2.4.1.1 RELATION BETWEEN BRAZIL AND OTHER COUNTRIES REGARDING DRUG COUNTERFEITING**

In Brazil there are two coexisting cooperation channels for international criminal law: the rogatory letter and the mutual assistance. Each one of them involves different instruments and legal precepts that function in cooperation with different agencies and powers of the Republic. In both cases there is a procedural provision which aims at establishing the way Brazil should send its requests abroad (active role) and how it should proceed when it receives them from other countries (passive role). When associated, those rules refer to how the Brazilian legal system agencies, in their broadest concept, should process, formulate and respond to requests of international character.



Another important institution, which encourages international cooperation and information exchange, is the Mercosur. *ANVISA*'s international relations department participates in the project creation of two working groups in the Mercosur: one responsible for "Technical Regulation and compliance evaluation procedures conformity" and the other responsible for "Health Issues". The activities are developed in the technical departments of *ANVISA*, which elaborates documents that serve as a basis for international negotiations and for the creation of common normative Resolutions. *ANVISA* thus trains the Brazilian delegates and assists them in their discussions.

Mercosur has also been an important institution for discussing piracy and its impact on the economy. In October 2006, Mercosur's member countries met to discuss the fight against piracy and to create a collective strategy against this crime <sup>55</sup>. The Seminar was held as a part of Brazil's National Plan of Combat against Piracy (*Conselho Nacional de Combate à Pirataria* – from now on referred to as *CNPC*), set in place by the Ministry of Justice.

The difficulty in defining how these channels currently work is due mainly to the fact that Brazil is in the middle of a reform process relative to rogatory letters, in parallel to a mutual assistance consolidation process. The first has just suffered a relevant change concerning its procedure and jurisdiction as a result of the "Judiciary Reform", occurred in the end of 2004. The second, structured since the nineties, was enforced vigorously during the past two years. In their current form both channels present problems and we could highlight the following: (i) the absence of proper legal support for mutual assistance and (ii) the restrictions regarding the type of request which may be demanded through rogatory letter (those points were also mentioned in the last Financial Action Task Force - FATF evaluation).

#### a MUTUAL ASSISTANCE

Mutual assistance consists of an international criminal cooperation system based on bilateral agreements between "central authorities". In Brazil, this activity is enacted by some agencies such as the Department for the Recovery of Illicit Assets and International Cooperation, under the Ministry of Justice (*Departamento de Recuperação de Ativos* – from now on referred to as *DRCI*), the Government's General Attorney and the International Judicial

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Cooperation Centre – under the General Attorney – which are responsible for processing requests related to the execution of measures received from foreign authorities to be deployed in Brazil (as well as requests sent abroad by Brazilian authorities).

Intermediations between the demanding authority and the authority expected to set in place the mutual assistance request allow shortening and improving the procedure thanks to the use of communication facilities – fax and electronic mail –, minimizing the chances of such requests being sent incomplete and, consequently, returned to the sender for amendment<sup>56</sup>.

The use of this cooperation channel depends on the existence of a bilateral agreement or on a reciprocity offer. Currently Brazil has valid agreements for cooperation and mutual assistance in criminal matters with the countries of the Mercosur, Colombia, United States of America, France, Italy, Peru and Portugal. These agreements are negotiated and carried out by the parties, but become legally binding in Brazil only after the National Congress' approval and followed by the respective enactment by the President of the Republic.

The mutual assistance requests procedure – of judicial or investigatory nature – between central authorities, is reflected in the UN convention against illegal drugs traffic (Article 7.8) and against organized transnational crimes (Article 18.13), both valid and effective in Brazil. The parties define the rules, which establish the scope and the limits of the procedure, in the bilateral agreements, which, in Brazil, are included in the legal system through a decree enactment, provided the agreement be executed and fulfilled.

Consequently, the effectiveness of this type of international criminal cooperation channel is determined by rules included in the three mentioned levels of legal regulation. However, notwithstanding the decree that assigned the *DRCI* jurisdiction to act as central authority for the cooperation requests, and the administrative act that specifies some of its duties, Brazil has not yet enacted a law to provide for the enactment of those requests.

## b ROGATORY LETTERS

Rogatory letters contain rules concerning the procedure and transit conditions stated in several parts of the Brazilian legislation<sup>57</sup>.

Conceptually, they aim at fulfilling procedural acts – citations, interrogations, witness hearings, inspections and investigations – which depend on the assistance of foreign judicial authorities<sup>58</sup>.

In the course of the last 70 years, the fulfilment of any act sent to Brazil through rogatory letter depended on the Supreme Federal Court's (*Supremo Tribunal Federal* – from now on referred to as *STF*) appreciation of the request. The jurisdiction established since the Constitution of 1934 was modified with the Constitutional Amendment n. 45/2004 of December 8<sup>th</sup>, 2004, which, among other measures, aimed at reforming the Brazilian judicial system, transferred this competence to the Superior Court of Justice (*Superior Tribunal de Justiça* – from now on referred to as *STJ*). With the institution of the Resolution n. 9 of May 4<sup>th</sup>, 2005, of the *STJ*, the rules for the rogatory letter procedure were modified.

The *STF*'s positioning vis-à-vis rogatory letters was highly criticized. Besides the requirements established by positive law – not to violate the public order, the sovereignty and the good morals – the understanding of the *STF* adds – as a possibility to the letter's denial – the investigatory character which a request may not have. This is intended to distinguish the requesting letter that incorporates an act of execution – e.g. the violation of bank secrecy – from a mere intimating one. In the first case, the impossibility of execution in Brazil is attributed to a normative act from the Brazilian Empire, quoted by the and in *STF* decisions. Nevertheless, this is the *STF*'s most commonly used argument to deny the rogatory letters' execution (*exequatur*) that request the State to provide information on banks and their data<sup>59</sup>. This has meant that many requests from abroad, involving important investigation acts, were not fulfilled by the Brazilian system.

Considering the recent modification in the jurisdiction, it is not yet possible for? the *STJ* to evaluate how the requests will be decided – whether the *STJ* will follow or not the *STF*'s understanding.

The second point indicates that the Courts will necessarily have to change their understandings about the conditions demanded for the granting of rogatory letters since they were being decided by the *STF* and will now be evaluated by the *STJ*.

The FATF's evaluation on the Brazilian international cooperation mechanisms, reports the impossibility of fulfilment of investigatory

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rogatory letters such as investigations involving bank secrecy protected information – as being one of the main obstacles to international cooperation. The other problem pointed out by FATF was the absence of a legal basis for cooperation made based on mutual assistance<sup>60</sup>. It refers to the need of regulating the requests and the fulfilment of mutual assistance in the Brazilian law. In addition, this set of rules could be built on a jointly consolidated basis with the rogatory letters rules, to establish and integrated normative arrangement for international criminal law cooperation in Brazil

Regardless of the outcome that rogatory letters will have in Brazil, to international agencies like such as FATF the improvement of the international criminal law cooperation offered by the country depends, above all, on the mutual assistance via a central authority. Thus, the explicitly recommended actions are the establishment of a solid internal judicial basis for the transit of these requests and a considerable rise in the number of bilateral agreements contemplating this possibility effectively <sup>61</sup>.

### 2.4.1.2 INTERNATIONAL AGREEMENTS AND STRUCTURES

#### a TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS)

The TRIPs Agreement is of special relevance to the Brazilian legislation, since it obliges WTO Members to (...) “provide for criminal procedures and penalties to be applied at least in cases of willful trademark counterfeiting or copyright piracy on a commercial scale. Remedies available shall include imprisonment and/or monetary fines sufficient to provide a deterrent, consistently with the level of penalties applied for crimes of a corresponding gravity. In appropriate cases, remedies available shall also include the seizure, forfeiture and destruction of the infringing goods and of any materials and implements the predominant use of which has been in the commission of the offence. Members may provide for criminal procedures and penalties to be applied in other cases of infringement of intellectual property rights, in particular where they are committed willfully and on a commercial scale.” (Article 61)

Brazilian protection to intellectual property rights is established in the Constitution and in various federal laws and international

treaties signed and confirmed by Brazil. This legislation has been recently enacted to adjust the Brazilian legal system to the minimum intellectual property protection standards established in the TRIPs, and incorporated into the Legal system by Decree n. 1,355/94.

**b WORLD HEALTH ORGANIZATION (WHO)**

By 1985 the increasing problem of counterfeit drugs had gained sufficient attention to be addressed internationally at the World Health Organization Conference of Experts on the Rational Use of Drugs, held in Nairobi. The outcomes of the conference included the recommendation to establish an organization with responsibility for obtaining data and distributing information to governments describing the nature and amplitude of counterfeit drugs. In 1985, the WHO addressed eradication of counterfeit drugs as one of its priorities.

In the 1999 *Guidelines for the Development of Measures to Combat Counterfeit Drugs*, the WHO suggested a number of broader national strategies as well as more specific measures. The major recommendations are: to know / have the information on who are the drug suppliers and not to purchase from suppliers unknown in the area or in suspicious conditions. Pharmacists should be also vigilant for any signs in the packaging, such as slight divergences from the norm. In addition, mysterious treatment failures should be reported to health care governing bodies.

WHO has also listed a number of specific measures that should be taken to effectively create individual national strategies to fight drug counterfeiting, such as: a) strengthening political will; b) promulgation of appropriate legislation – to ensure that all drugs in the distribution channels are licensed/authorized; that license renewals be required at regular intervals; that good manufacturing practices performance be assessed periodically; and that imported drugs be screened at the port of entry; c) establishment of a Brazilian drug regulatory authority; d) drug control laws enforcement; and e) fostering of partnerships between manufacturers and authorities.

Brazil coordinates its efforts to accomplish these guidelines through ANVISA's activities and through its participation in the Pan-American Health Organization (OPAS).

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### c THE PAN-AMERICAN HEALTH ORGANIZATION/WORLD HEALTH ORGANIZATION (OPAS/WHO)

Since 1997 the Pan-American Health Organization/World Health Organization (OPAS/WHO) has been annually carrying out the Pan-American Conference for Drug Regulatory Harmonization.

Amongst the proposals brought forward in the scope of these Conferences, one may point out the following: a) to harmonize the concept of falsified drugs and to establish complementary definitions; b) to create strategies for the prevention of and the fight against falsified drugs in the region; c) to establish mechanisms for international and inter-institutional cooperation and/or a permanent forum to fight the counterfeiting; d) to encourage international exchanges between the participating countries; e) to create a network of core issues among the countries of the Mercosur, to approach the subject of falsification, and establish a communication channel between them; f) timely inform the WHO database and the network secretary about falsification cases detected at the national level and participate actively in conferences addressing this subject; f) to adopt national good practice rules in drug production, as well as the necessary measures for the effective control of their fulfilment; g) to create and rely on tools and technologies that enable an effective drug traceability in the distinct stages of the production chain; h) to promote the revision of criminal legislation, including sanctions, regarding the counterfeiting of drugs related crimes.

It must be emphasized that in addition to the conferences and still in the scope of OPAS/WHO, several studies, discussions and work programs – aiming at the joint action of countries against falsified drugs – have taken place. The Drugs and Technology Technical Unit of OPAS/WHO also stimulates drug regulation by an Independent Regulatory Commission, with independence and transparency, but connected to the Ministries of Health; the creation of the Production Good Practice committee and a system of surveillance focusing on drugs' side effects.

### d ANVISA

Since its creation in 1999, *ANVISA* has invested in an international relations department, which is responsible for the implementation

of international health related conventions sponsored by Brazil and the organization of international cooperation.

*ANVISA* seeks to take the Brazilian health issues to an international level (e.g. OPAS or the WHO discussions) and to participate in the elaboration of international solutions for international problems, such as that of drug counterfeiting. *ANVISA*'s international relations department is in charge of finding possible international cooperation partners, negotiating and elaborating international technical cooperation projects and supporting technical departments in the implementation and evaluation of international projects. This enables the sharing of information and experiences between countries, promotes the dialogue between health agencies and helps in the training of personnel to deal with health issues. It is a necessary step in the identification of common interests and goals in which international cooperation is necessary and can be useful.

In terms of bilateral cooperation, *ANVISA* is currently developing technical bilateral cooperation activities actions and projects with the following countries: Argentina, Cuba (*Centro para el Control Estatal de la Calidad de los Medicamentos*), Mexico (*Comisión Federal para la Protección contra Riesgos Sanitarios*), Portugal (*Instituto Nacional da Farmácia e do Medicamento*), Paraguay (*Dirección Nacional de Vigilancia Sanitaria - Ministerio de Salud Pública y Bienestar Social*) and Uruguay (*Dirección de Productos de Salud – Ministerio de Salud Pública*).

It is also important to remember that *ANVISA* has cooperated actively with the Pan-American Health Organization in finding efficient international measures to help all participating countries develop collective strategies against drug counterfeiting<sup>62</sup>. Within this context, in 2004 Brazil and OPAS/WHO organized a national meeting for prevention and fight against drug counterfeiting.

*ANVISA* is involved internationally in updating technical knowledge, as a means to adjust itself to international standards, mainly related to the regulatory process. It also relates to international legislative assemblies, especially in the Mercosur jurisdiction. The Agency is further a member of the Pan American Network for Drug Regulatory Harmonization (*PARF Network*). Specifically in reference to counterfeit drugs measures, *ANVISA* works jointly

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with the International Conference of Drug Regulatory Authorities (ICDRA) and International Medical Products Anti-Counterfeiting Taskforce (Impact).

In the field of international cooperation, *ANVISA*, together with the Brazilian Ministry of Health, has engaged in efforts to promote the transfer of technology between countries, as for example, Australia, Argentina, Chile, Cuba, United States, Mexico, Peru and Portugal.

### 2.4.1.3 FRONTIER INSPECTION

Notwithstanding the fact that the Federal Police is usually responsible for inspections on land, sea and air, *ANVISA* is responsible for the sanitary control of harbours, airports and frontiers. It also controls activities related to transportation means, dissemination of vectors or carriers between countries and goods imported or exported, including drugs, giving assistance to Federal Authorities, in compliance with the Brazilian legislation and international agreements. In January 2006, *ANVISA* organized the First International Meeting for Sanitary Strategies on frontiers to discuss frontier control among international agents, aiming at the observance of International Sanitary Regulations. In 2002 the Brazil-Paraguay Convention was set in place as a means to fight tax evasion. The document sets forth disciplinary customs rules on imports and exports, and allows the analysis of the content of all cargo exported and imported between Brazil and Paraguay.

## 2.5 INTERNET AND DRUGS COUNTERFEITING

### 2.5.1 DATA REGARDING THE RELATION BETWEEN THE INTERNET AND DRUG COUNTERFEITING

Even though it is very difficult to find precise data about the role played by the Internet in relation to drug counterfeiting in Brazil, most sources of information on the subject indicate that the Internet has become a very important channel for the commercialisation of counterfeited drugs. Internet surveillance is still very inefficient in Brazil, and the public powers responsible for the investigation and prosecution of crimes are not prepared to deal with felonies committed online. Therefore, the lack of surveillance makes the Internet



an attractive place to sell counterfeited drugs manufactured anywhere in the world.

According to news published in the Brazilian media [i], the ease of promoting commerce over the Internet has been partially responsible for a growth of the counterfeited drug market. Recently, *ANVISA* monitored such commerce in the cities of São Paulo, Unai (in the State of Minas Gerais) and in the Federal District (Distrito Federal), uncovering the sale of counterfeited and stolen substances [ii]. As a result of this monitoring, *ANVISA* joined forces with the Federal Police in operations targeting companies, which participated intensely in the Internet drug market.

Many special investigation operations uncovered the use of the Internet as an instrument for the sale of counterfeited drugs. Since 2003, *ANVISA* has been warning consumers about the dangers of buying drugs over the Internet, declaring that the consumers are almost never well informed about the product they are buying online, and the chances of receiving illegitimate substances (e.g. stolen material, unregistered products manufactured by unlicensed producers, placebo drugs, etc.) are very high [iii].

The State Prosecutor Dr. Anna Yaryd Trotta, for instance, revealed that the Internet is a very common means of illegal and counterfeited drugs distribution, but the State does not yet count with the appropriate instruments and personnel to investigate this form of criminality.

### **2.5.2 INTERNET REGULATION IN BRAZIL**

A report published by the Ministry of Science and Technology provides an x-ray of the commerce that is operated over the Internet, showing which products were bought and sold [iv]. Although there is no information on the commercialisation of drugs or illegal products, the general picture created by the research is that all areas of commerce are operated over the Internet, from food and groceries to electronic downloads. This reveals the growing demand for legal electronic trade regulation. The fact that there is no information on the commercialisation of drugs or pharmaceutical products in general, also illustrates the lack of information available on the subject.

The Internet receives more and more attention from public authorities, which seek to adapt the legal regulation in order to

gain efficient control over Internet transactions. Some issues which should be included as themes in the national legal system are the responsibility, judgment and punishment of crimes committed over the Internet, such as libel and slander, the protection of intellectual property, the transmission of new technologies, Internet marketing and commerce, among others [v].

#### 2.5.2.1 REGULATION OF INTERNET SERVICE PROVIDERS

The rendering of Internet services in Brazil is considered a facility which adds value to the provision of telecommunication services, according to the Brazilian General Telecommunications Law (Law n. 9,472/1997). Therefore, Internet Service Providers (ISPs) are not considered as telecommunication companies, thus not being subjected to regulations and obligations concerning such companies.

The Brazilian Internet Governance Model is based on a multi-stakeholder entity, which was created on September 3<sup>rd</sup>, 2003, by Decree n. 4,829, and named Brazilian Internet Steering Committee (*Comitê Gestor da Internet no Brasil* – from now on referred to as *CGIbr*). It is managed by government members, the private sector, the third sector and the academic community. The *CGIbr* coordinates and integrates several activities related to Internet management in Brazil, and are responsible for promoting technical quality, innovation and the dissemination of Internet-related services.

On December 5<sup>th</sup>, 2005, according to Article 10 of Decree n. 4,829/2003, *CGIbr* decided to ascribe the domain name registration, the IP address allocation and the respective management of the country-code Top-Level Domain “.br” to the Brazilian Network Information Centre (*Núcleo de Informação e Coordenação do Ponto BR* – from now on referred to as *NIC.br*), a non-profit organization which is the operational branch of the *CGIbr*, pursuant to Resolution *CGIbr* n. 001/2005.

On the same date, *CGIbr* issued also Resolution *CGIbr* n. 002/2005, which determined the procedures to be followed by *NIC.br* in the execution of the activities delegated to it, under Resolution *CGIbr* n. 001/2005. Annex I of this Resolution presents the list of categories valid under the country-code Top-Level Domain “.br”, specifying that pharmacies and drugstores must use the TLD category “.far.br”.

To this date, it has been possible to identify an increase in the number of domains registered under TLD category “.far.br”, but there are yet only 208 domains registered under this category, while there are 1,130,851 registered under “.com.br”, according to the statistics available<sup>63</sup>[vi]. Domain names registered under the TLD category “.far.br” account for only 0.02% of the registered domains, and are one of the least used TLD categories (20<sup>th</sup> in ranking among the 24 listed for legal entities), while those under “.com.br” account for 91,86% (1<sup>st</sup> in ranking among the 24 listed for legal entities)<sup>64</sup>[vii].

So far, no current law or regulation dictates the recording of data concerning Internet access. However, in the lack of formal rules, best practices implemented by most of telecommunication companies and ISPs include keeping the logs of their users’ accesses, especially with respect to the designation of IP numbers to Internet users in case of non-dedicated Internet connections. The Brazilian Internet Steering Committee has issued a non-enforceable recommendation suggesting that such logs should be kept for a minimum of three years <sup>65</sup>[viii]. Access to such data has been usually granted upon court orders in the course of civil litigation and criminal investigations <sup>66</sup>[ix].

The repression of Internet crimes in Brazil has been constantly improving in the recent years, although more investment and coordination are still needed. Some Brazilian cities such as Rio de Janeiro, São Paulo and Belo Horizonte, have created specific police departments to fight crimes committed over electronic media. Other cities, such as Curitiba, Porto Alegre, Brasília and Vitória, have created groups of IT experts to assist police stations in the analysis of cyber-crimes. In regards to the Federal Police, the creation of a specific division focused on the repression of cyber-crimes has been under discussion since 2005; as of January 2008, such department had not yet been created<sup>67</sup>[x]. Anyhow, Internet crime related operations, organized or assisted by Federal Police, arrested more than 700 people in the period 2005-2007.

#### 2.5.2.2 INTERNET REGULATION AND COMMERCE

In Brazil, the growth of Internet use has influenced practically all law related areas. In the civil and commercial sphere, electronic

contracts are becoming increasingly common, a phenomenon which creates the growing necessity of regulation. However, until specific laws are issued, the laws, which regulate other commercial transactions in Brazil, are being applied to the Internet commerce, even though they are not always sufficient. These laws include the Consumers' Defence Code and the Civil Code<sup>68</sup>[xi].

After the edition of the Brazilian Consumers' Defence Code in 1990 (Law n. 8,078), all consumer relations are regulated by this legal diploma. According to the first article, the consumer rights, therein, are part of the fundamental rights.

The Legal jurisprudence asserts that there are no doubts about the applicability of the Consumers' Defence Code on transactions performed over the Internet. This Code must always be applied when a consumer relation is characterized and when all contracting parts reside in the Brazilian territory<sup>69</sup>[xii].

If one of the contracting parts is not Brazilian or lives abroad, foreign legislation is only applicable if it is not in contradiction with the Consumers' Defence Code, since the status of fundamental rights it attributes to the rights it is set out to protect in Brazil. Some authors also claim that, in case there is a conflict between foreign or international and Brazilian legislation concerning the regulation of electronic commerce, it is the national law that should prevail, even if this threatens the stability of international trade over the Internet<sup>70</sup>[xiii].

Under the Consumers' Defence Code, the company which provides access to the Internet is responsible for any defects in the service provided. Thus, the Internet access provider is obligated to guarantee the access to the Internet and the possibility of safe information exchange. In this sense, the service provider is responsible for the occurrence of "spams" or the exhibition of illegal advertisement released by the service provider (this means that the provider is not be responsible for illegal advertisements to which it is not directly related). The "illegal" character of the advertisement must be analysed in relation to the laws of the country where the provider is located.

Another important aspect of Internet commerce is that the government has recently engaged in promoting Internet transactions on a wide scale. The Ministry of Science and Technology developed a

program in 1999 oriented towards the democratisation of the Internet in Brazil; the expansion of electronic commerce in the country and public regulation regarding the electronic world. It was named “Information Society Program” and it involved the participation of all spheres of the Brazilian government (Federal, State and Municipal) alongside private investment, in order to stimulate Internet use and commerce on a national scale<sup>71</sup>[xiv].

Seeking to improve the Internet commerce regulation, the Brazilian government created an Interministerial Committee for Electronic Commerce in April 2002. This committee is in charge of the development of new information technology systems and of the integration of Internet commerce practices.

Despite all the e-commerce promotion initiatives, the government seems to forget the importance of an efficient legal system to support this new type of trade. This suggests that Brazil should seek to participate more actively in the discussions held at the WTO concerning the regulation of Internet commerce. Brazilian specialists declare that there are three important aspects to be addressed by the government: the technical-scientific, political, and legal aspects. While Brazil is working solidly on the first, as most of the developing countries, it seems that the country has not yet understood the importance of determining the normative sphere that regulates electronic commerce<sup>72</sup>[xv].

#### 2.5.2.3 CRIMINAL LAW AND INTERNET CRIMES: DILEMMAS AND PERSPECTIVES

Although there are many projects under discussion in the National Congress, in Brazil there isn’t yet any specific criminal legislation in place to punish deviating conducts practiced over the Internet, such as there are in many countries currently, where there is legislation applicable to crimes committed over the Internet.

Considering, however, that many crimes committed over the Internet can be described simply as a different *modus operandi* for the practice of normal crimes, this allows for the enforcement of the Brazilian Criminal Code and special criminal legislation to crimes performed over the Internet.

Part of the Brazilian jurisprudence considers that crimes committed over the Internet can be prosecuted based on Article 171 of

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the Criminal Code, which describes various forms of fraud. Crimes against honour are also common on the web, and can be prosecuted under Articles 138 and 139 of the Criminal Code, where libel, slander and defamation are proscribed. Media crimes, threats and exhibition of illegal sexual material can also be punished under our existent legislation.

However, many other activities, which may be considered illegitimate, need specific legislation to be liable to punishment, such as frauds regarding access to credit card numbers, data banks or identification numbers, which can be used to obtain money or other illegal advantages over the Internet. The crime of counterfeiting should also be re-evaluated, for it can no longer be restricted to the counterfeiting of physical or material support and must refer to digital documents as well.<sup>73</sup>[xvi].

According to another part of the Brazilian jurisprudence, crimes committed over the Internet differ in essence from those which occur outside the virtual world, and thus always need specific legislation for their prosecution <sup>74</sup>[xvii].

These opposing interpretations indicate the urgency for a clear legislative decision translated either into a law that lists all conducts performed over the Internet and which should be criminalized, or that extends the applicability of the Criminal Code to this new *modus operandi*. Meanwhile, the main problem will remain in the fact that, in Brazil there is no guarantee as to whether the existing criminal legislation will be interpreted in an extensive manner – regulating Internet crimes –, or whether specific legislation will be demanded by the judge. In the latter case, illegitimate conducts performed over the Internet will not be subject to criminal prosecution until specific legislation has been enacted.

Besides, one of the general difficulties the law encounters in describing and punishing crimes committed over the Internet is the fact that these do not fit into many of the necessary categories of criminal law. Hence, the notions of jurisdiction or of the place where the crime is committed are not easily identified, for decentralization is one of the Internet's main characteristics.

Another problem met by the State Prosecution, regarding crimes committed over the Internet, is the difficulty in the gathering of evidence. In order to investigate these crimes the police

must organize themselves in a new manner and the State must train new experts and investigators.

During the interview with Dr. Trotta, who integrates *GAESP*, the difficulties felt by the Prosecutors' Office when investigating Internet crimes were described based on the example of one specific case of an illegal drugs sale in Brazil through a Canadian web site. On the day the investigators were able to locate the site, it immediately became unavailable, thus rendering any further investigation impossible. Dr. Trotta declared that the Internet is, without any doubt, a very important commercialisation vehicle for counterfeited drugs, but the State does not have the structure or know-how to investigate these practices in an efficient manner.

#### 2.5.2.4 INTERNET INVESTIGATION AND POLICE ORGANIZATION

As stated above, a problem encountered by the State in prosecuting Internet crimes is the lack of specialists and infra-structure to enable the police to investigate these conducts.

In Brazil there are only six Police Departments specialized in investigating crimes committed over the Internet, and these Departments are located in the states of São Paulo, Rio de Janeiro, Minas Gerais, Paraná, Rio Grande do Sul and in Brasília. In theory, it is mandatory that all police departments specialized or not, receive complaints and investigate crimes committed over the Internet. Unfortunately, they don't have the appropriate training or know-how to investigate cyber-crimes as do the specialized police, which leads frequently to inefficient and inconclusive investigations.

#### 2.5.2.5 BRAZILIAN CYBER-CRIME LEGISLATION

Several bills of law – regarding cyber-crimes and other internet-related issues, such as the keeping of Internet access records – are under discussion (or have already been discussed and archived) at the National Congress. Currently, the main bill of law under discussion is the Substitutive Senate Bill of Law n. 76, 2000, which consolidates the Senate Bills of Law n. 76, 2000, and n. 137, 2000, and House of Representatives Bill of Law n. 89/2003<sup>75</sup>.

Originally, the main idea for those bills of law was to require Internet Service Providers to register and maintain plenty of information relative to every internet user. Experts and Internet users

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understood these bills as instruments of censure, based on their notion that Internet access is a human right.

According to the newly proposed legislation, all entities providing Internet access shall, for a period of three years, keep records of each and every Internet connection provided by them. Such information shall be held in a secure and controlled environment, and shall include at least the electronic address of where the connection originated from (such as an IP address), the date, hour and corresponding GMT reference. Such information shall be provided only to the investigating authorities upon a specific and prior court order. ISPs may also be required to preserve such data for extra periods of time whenever legal authorities demand it.

The bill of law also requests ISPs to secretly inform police authorities of any crimes they may have noticed or been notified of, which took place on computer networks or Internet connections under their responsibility. Prior versions of the bill of law sought to criminalize behaviours such as not keeping records of Internet connections and allowing non-identified Internet connections; however, the current version only considers such practices as torts, therefore subject to administrative fines and loss and damage indemnifications.

With regards to information technology crimes, the same bill of law proposes the creation of new specific technology related crimes, such as unauthorized access to computer networks or devices, unauthorized provision of digital data or of information contained in databases, the creation or intended diffusion of electronic viruses, and others. The bill of law also considers data and physical goods as equals for criminal purposes, in order to criminalize activities such as stealing or damaging – traditionally included in the Criminal Code, Articles 155-180 – against information systems.

Although the rapporteur of this bill of law points its origin at the Convention on Cybercrime of Budapest, experts consider that it restrains civil liberties. Another criticism voiced referred to the ability of ISPs to identify criminal conducts<sup>76</sup>, evidencing that this bill of law is still far too premature to be turned into a fully effective law.

The lack of consistency in most of the legislative projects is directly connected to the increase of Internet crimes in Brazil. In São Paulo and Rio de Janeiro alone, the cities with the largest



number of Internet users in Brazil, the police have registered over 394,000<sup>77</sup> Internet crime reports between 2005 and September of 2007. The Brazilian police admit that the exponential number of crimes, the deficiency of technical investigation resources and the difficulty in gathering evidence handicap the solution of crimes<sup>78</sup>, and the lack of specific legislation, which condemns these undesired behaviours, aggravates the police's performance even more.

If the Substitutive Senate bill of law n. 76, 2000, is approved in the Senate, it will then be subject to the approval of the House of Representatives, before becoming effective. In July, 2007, its voting was postponed indefinitely, due to the fact that its dispositions are excessively vague, undefined and unclear.

### **3 EVALUATION AND REFORM PROPOSALS**

As seen above, it becomes clear that in regards to the formal mechanisms and institutions in Brazil, several reforms are needed for the government to gain control over the drug market and the fight against counterfeit.

Our opinions and suggestions are based on our entire research, including the interviews held with several specialists and professionals who work in different health areas related, and who are familiar with the institutional problems of our system. Among our interviewees: (i) the directors of FEBRAFARMA, Mr. Nelson dos Santos Jr., Mr. Dan Gedankien and Mr. Lauro Moretto; (ii) the police authority who has been working for years addressing cargo theft, Mr. João Renato Weseslowski; (iii) the police notary chief in the São Paulo's Second Police Precinct for the Investigation of Piracy, Counterfeiting, Theft and Drugs, of, Mr. Vanderson Pereira; (iv) Mr. Marcos Moreira, the head of regulatory affairs at Schering-Plough; and (v) the ex-president of ANVISA's board of directors, Dr. Gonzalo Vecina Neto, who led ANVISA from 1999 to 2003 and has also been Professor of Public Health Management at the School of Public Health of the University of São Paulo since 1989<sup>79</sup>. Finally, we spoke to two District Attorneys of the State of São Paulo, Dr. Anna Trotta and Dr. José Piva.

Since the Brazilian health control system is still very incipient, this item shall relate to all of its areas and will include some reform

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attempts. These are being currently implemented as a means of confronting the measures carried out at present by the government together with those suggested by the health sector professionals we interviewed, who experience the difficulties on a daily basis. This comparison is intended to show to what extent the government's perception of the existing problems differs from the perception of the people who work in the health sector, and lead us to a suggestion of which measures should really be taken in order to fight irregularities in the drug production chain.

In the Brazilian health control system a number of topics are systematically pointed out as problems, most of which are related to the lack of efficiency in our administrative, legal and judicial systems. This can be exemplified by the fact that out of a total of 51 cases initiated in the Public Prosecutors' Office in São Paulo, 46 were dismissed. The number and seriousness of complaints, regarding the excessive administrative process' bureaucracy for the registration of a patent, is also striking.

According to public officials and lawyers, there are several obstacles to the functioning of the Brazilian judicial system, such as difficulties in the investigation and collection of evidence, the length and difficulty of procedures, the lack of communication between the different public institutions and authorities involved (e.g. criminal and civil prosecutors), the lack of specialized knowledge regarding the issue, etc.

Additionally, the suggestions of the pharmaceutical industries vis-à-vis the *SNVS*, also focus on the functioning of the public institutions and their lack of capacity and efficiency to control the production and distribution chain. One core issue aggravating the difficulties for the control mechanisms' functioning, is the great amount of informal transactions within the drug market (mainly in the distribution chain), mostly caused by tax evasion purposes. Another problematic issue is the existence of a relevant amount of unregistered products, which cannot be monitored by public authorities and, therefore, even if well produced, there is no way of proving their quality or origin.

For the pharmaceutical industry, the different forms of informal activities in the drug market prevent the State from guaranteeing consumers that the drug they are buying respects certain criteria

and standards. The industry thus believes that it's not a matter of lack of proper legislation. Our team representatives heard that if the laws were respected, then ANVISA, through regular inspections and the mandatory declarations, related to production and sales, would very well regulate the pharmaceutical industry.

In the industry's opinion, Brazilian legislation is reasonable and well regulated by administrative normative acts. The main problems in Brazil occur on the way between the pharmaceutical industry – manufacturer of the drug – and the consumer. For example, the monitoring of drug package features (one of the measures adopted by ANVISA), makes no difference, because if the drug is stolen, it will be reintroduced into the market with the same package and label, and there is simply / absolutely no way to tell the legitimate drug apart from the stolen one. The entire production chain is fragile and vulnerable – all sectors of production, transportation, distribution and commercialization must be looked at by the competent regulatory agencies.

A considerable number of reform initiatives are already taking place in Brazil and the most important measures that are being implemented to prevent and repress the illegal drug market shall be addressed below. This will provide an overview of what is being enacted / set in place and how the government conceives the counterfeiting problem and what path they intend to follow in solving it.

### **3.1 POLICE**

#### **3.1.1 GENERAL PROBLEMS**

In a research made by the Violence Research Group from the University of São Paulo (*Núcleo de Estudos da Violência* – from now on referred to as NEV)<sup>80</sup> on the “The Police the public desires”, people representing the Police (Civil and Military) and the public in general in the city of São Paulo were interviewed, revealing the most common complaints about the work of the police as well as some suggestions to change the manner in which the police operates.

According to this research, the police undergo numerous difficulties inside the corporation, such as: (i) the fact that policemen exercise other external activities, (ii) excessive control by the department responsible for internal surveillance, (iii) bad working/

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labour conditions, (iv) prevalence of political motivation within the corporation, (v) lack of integration between the Civil and the Military Police and (vi) excessive bureaucracy.

Inside the police force, the Scientific Police, in the course of criminal investigations, is responsible for the production of technical evidence regarding places, substances, objects, tools and people. This task is performed by experts, normally located in special institutions under the control of each state's Public Security Department. In São Paulo, for example, the Criminality Institute is responsible for preparing all the technical reports on evidence of crimes occurred within the State São Paulo.

To request an expert report for crimes against Public Health, such as counterfeiting of drugs, the competent officer is supposed to check the following legal requirements, before sending the substance to the Criminality Institute: (i) whether the substance was sold as medicinal; (ii) whether there are evidences of it containing different substance from those listed on the label; and (iii) whether there are evidences of damages to public health caused by the substance (the last requirement must be met only in cases where there are fake drug labels involved)<sup>81</sup>.

The Criminality Institute suffers from serious structural problems that limit its work efficiency and reliability. The lack of infra-structure in this institute was pointed out to us systematically during the interviews, and the lack of suitable materials and technicians is the most serious cause for the malfunctioning of the technical bodies in the Brazilian Police force.

## 3.1.2 INTERVIEWS WITH SPECIALIZED POLICE AGENTS

We interviewed Mr. Vanderson Pereira, the police notary chief from the police department specialized in investigating cosmetics, drugs and food supply counterfeiting. He described many of the problems, such as: (i) lack of skilled policemen for counterfeiting investigation, (ii) lack of training programs for investigating cyber-crimes and drug counterfeiting, and (iii) the need to increase specialized inspections.

In his opinion, one of the largest problems in the drug counterfeiting investigation lies in the identification of counterfeited drugs because the police has few resources for specialized inspection,

whereby most of the necessary inspection is simply not executed. Therefore, when a policeman identifies illegal drugs, instead of requesting specialized technical inspection, he consults whether *ANVISA*'s relevant authorization for especially controlled drugs exists or not. This happens because non-legally authorized drug commercialisation is a crime that does not need any technical inspection to be proven, differently from the crime of drug counterfeiting. That is why most of the cases, in which there is an effective criminal prosecution, are based simply on the lack of proper authorization, without even reaching the phase in which an evaluation –to access if it referred to an actual drug counterfeiting conduct – would be carried out. This results in an apparent low incidence of drug counterfeiting in Brazil, since there is actually no substantial data available to confirm such “conclusion”.

Mr. Vanderson Pereira stated that it is essential that the State invest more capital in the training of the police and in specialized inspection. The lack of police training is also a considerable impediment to the investigation of such crimes when committed over the internet.

The precariousness of the police became evident when Mr. Vanderson Pereira allowed us access to the official book where all investigatory records are kept, as we described in the introduction. Mr. Vanderson Pereira underlined the importance of *ANVISA*, which he holds in high consideration because it updates the list of especially controlled drugs at any new drug eventually approved as such, a record that is essential to construct the accusation for unregistered products. He also mentioned that the communication with *ANVISA* ensures swifter investigations.

We also interviewed Mr. João Renato Weseslowski, the police official responsible for the police department specialized in investigating cases of stolen cargo and who has been working in this field for many years. In his view, one of the largest investigation problems in cases regarding drug cargo is the insufficient product identification. This is due to the fact that labs produce drugs in batches, and each package must present the respective batch number, which will also represent the identification number. These batches, however, are very large and are split up when it comes to distribution. This means that the company will make

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deliveries to various areas of the country, to various distributors and/or pharmacies out of one single batch. What often happens is that when one of these shipments is intercepted taken/seized during transportation, the stolen goods can be easily “reintegrated” into the legal market through regular distributors (sometimes also part of the scheme) who issue receipts and pass the drugs onto the pharmacies.

The problem is that there is no discrimination between these cargos, meaning that the merchandise that was part of the stolen cargo (identified by its batch number) cannot be distinguished from the rest (under the same batch number but not stolen). For this reason, once the distributors reintroduce the stolen material into the market, there is no way to tell it apart from the merchandise that followed the legal commercialisation chain.

Mr. João Renato Weseslowski stated that it would be essential for the police to identify the origin of the shipped products beyond any doubt, to be able to identify the stolen products and thus take them out of circulation safely. One way of guaranteeing the identification of each cargo would be to obligate the pharmaceutical industry – which produces and ships the drugs – to distinguish the cargo of each shipment or at least separate them per area of distribution. In this sense, for example, the part of a batch “x”, shipped to São Paulo, could have a blue dot on the package, while the part of this same batch going to Rio de Janeiro would be identified by a yellow dot and so on. This would enable public authorities to identify not only production batches, but also the individual cargos, facilitating greatly the prevention of the stolen drugs’ trade. Nevertheless, according to the police, the companies involved are not much interested in implementing this identification system due to the additional costs it would create for them and the fact that they are insured against cargo theft during transportation.

Mr. João Renato Weseslowski also indicated the lack of sufficient infrastructure to proceed with technical investigations, which are absolutely necessary to identify stolen substances as well as to run quality tests. Often investigations do not proceed because there is no specialized personnel for the tracking down of organized crime schemes or for product authenticity examination.

### **3.1.3 POLICE REFORM PROPOSALS**

The reform proposals reported as urgent by several actors are: a) Creating and equipping suitable professionalised technical laboratories, auxiliary to the police forces, for the task of distinguishing authentic drugs from counterfeited ones; b) Implementing a computer network accessible to all police forces and to the Public Prosecutors' Office in order to facilitate inter-institutional exchange of relevant information on apprehensions, counterfeiters, suspects, their possible relation to other crimes etc.; c) Hiring and training experts for the task of distinguishing authentic drugs from counterfeited ones; d) Cooperation between the public and the private sectors, in order to create a new official drugs trade policy; e) Valuing the function of civil and military policemen, providing special training and recycling programs – ideally, this training should include exchange programs with different countries, enabling the study of foreign investigation methods, characteristic local *modus operandi*, etc.; f) Articulating the organization of the police in every city and creating a computer based unification of all information; g) Creating a centralized national Intelligence system; h) Establishing an efficient policemen monitoring system, stimulating their productivity and increasing their self-esteem; i) Supplement the Criminality Institutes with the material and experts needed, as well as provide the experts with recycling programs.

## **3.2 HEALTH SURVEILLANCE SYSTEM**

### **3.2.1 GENERAL SURVEILLANCE PROBLEMS**

According to Mr. Marcos Moreira, from Schering, there is a serious problem regarding the personnel and the structure of the institutions and agencies responsible for monitoring health related activities. It was said that less than 50% of the laboratories are properly monitored by ANVISA's technicians. Moreira also points out that as a reflex of this lack of capacity, it is not unusual that labs have their licences automatically renewed and not submitted, as it is mandatory, to a previous inspection. This same remark was practically unanimous amongst all our interviewees except for Dr. Gonzalo Vecina Neto, who believes that the true problem behind public health issues stands on a macro-political level. They state

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that the surveillance system needs to undergo many changes to cause a satisfactory impact on the security of health related products' production and consumption.

To address the issue of law enforcement, the *SNVS* should control the entire production chain, monitoring every movement and drug related transactions.

We also heard from Mr. Marcos Moreira that there is a lack of specialized personnel to analyse products and carry out inspections. The *SNVS* – including *ANVISA*, State surveillance agencies, laboratories, etc. – should invest in building the capacity of personnel to implement the existing regulation. The State surveillance agencies (*VISAs*) do not have the technical or human capabilities to monitor all health related entities.

It was also pointed out that the pharmaceutical industry states that *ANVISA* should adopt standard criteria when analysing a drug registration requirement. At present, it is said to be impossible to foresee how the Agency will judge any such request, for there are many technical experts and each one judges in a different way, making it impossible to be sure about their findings. This creates great insecurity in the pharmaceutical industry.

The latter also complains that there is a problem in the interpretation and application of *ANVISA*'s norms. There are no application standards or patterns, which generates insecurity. They say that there is no real problem with the regulation, but with its application.

In addition to this, *ANVISA* takes between 18 and 24 months to analyse new products. This is a very long period and the costs are very high for the industries. The pharmaceutical industry representatives also stated that even though the creation of *ANVISA* was an important mark for regulation in the sphere of health, the Agency must now adapt itself to new times. It should, for example, create an action plan for the next 10 years approximately, in order to allow other health related agents to plan themselves. A big problem with *ANVISA* is that every time the president of the Agency changes, so do all the policies and plans. In a technical regulation organization this should not happen. Regarding specifically this issue, the current Board of Directors has been criticized for having rather a political instead of a technical profile, another cause for insecurity vis-à-vis the Agency's future actions.



*ANVISA's* activities are said to be very sporadic and cyclical – it seems that *ANVISA* acts mostly in reaction to the news it gathers from the media or from the federal police. When the media announces a counterfeiting occurrence, for example, *ANVISA* sets off to investigate intensely, but, on the other hand, it is then not capable of performing the routine monitoring, surveillance and investigation functions.

### **3.2.2 THE NEED OF LABORATORIES**

*FEBRAFARMA* also criticizes the lack of good laboratories capable of executing the necessary counterfeited drugs analysis and tests. This institution lacks of professional laboratories, capable of distinguishing authentic drugs from the counterfeited ones, which simply do not exist. This poses a big problem since the State is unable to produce strong evidence of guilt in trials or during investigations, thereby rendering it impossible to establish penal responsibility in cases of drug counterfeiting. Without the means to investigate, it is impossible to identify the agents' guilt and, consequently, to make them liable for their actions. *FEBRAFARMA* is therefore very emphatic in stating that the government should invest in specialized laboratories for the analysis of drugs and in the training of specialized personnel to work in the area.

### **3.2.3 ANVISA'S SURVEILLANCE ACTION PLAN**

Soon after *ANVISA* was created, it published an action plan, which would allow the *SNVS* to trace back the origin of products in the market. This plan was created in 1998 through *Portarias* n. 801, n. 802 and n. 803. The most important measures implemented by these norms are: (i) all drug packages should present a safety seal, bar code and a scratch-off seal which aids to identify authentic products; (ii) the batch number on the drug package should be the same as the batch number on the secondary package; (iii) old machinery used for drug production should undergo well controlled treatment; and (iv) all drugs' batch number should be on the tax receipt, so that the surveillance system may know what is bought or sold.

It is important to highlight that, according do Dr. Gonzalo Vecina Neto, this last measure is not respected at all due to the informality of the Brazilian market. Since many distributors do not

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give out tax receipts to avoid tax payments, the products' traceability is lost.

### **3.2.4 CONSUMER ORIENTED REFORMS**

As we mentioned above, the first efforts made by the Brazilian health surveillance agencies, aimed at the safety of the drug market, were directed toward the consumer. The pharmaceutical industry saw itself obliged to print distinctive marks on the drug packages, such as bar codes, watermarks and reactive paint. According to *FEBRAFARMA*, it was soon noticed that the consumer was not always able to tell these packages from the counterfeited ones. Consumers are not technicians; they are not able to tell an authentic drug from a counterfeited one by the colour or the printing on the package or by the size of the bar code. At first *ANVISA* came up with a consumer focused process, but after realizing that this would not suffice, the Agency soon began to regulate all steps of the production chain.

This is why, according to *FEBRAFARMA*, the *SNVS* should aim more specifically at monitoring the entire production chain, including every movement and transaction involving drugs, making sure they are all safe and no irregularities occur. This is already a recognizable tendency in *ANVISA* and this is the direction towards which all reforms should point.

We could say that it is indeed a work in progress and, as pointed above, depends strongly on improvements to increase the institution's capacity as well as to provide infrastructure and personnel.

### **3.2.5 COOPERATION BETWEEN THE PUBLIC AND THE PRIVATE SECTORS**

*FEBRAFARMA* and *CREMESP* presented several suggestions to address the need of cooperation between the public and the private sectors. They declare that it is extremely important to adopt a new political view for the drug market, which can (i) change the tax burden, which they report to be excessive; and (ii) change the intellectual property rules, which they regard as being highly inconsistent<sup>82</sup>.

### **3.2.6 LEGAL REGULATION OF THE SNVS**

As reported by Dr. Vecina Neto, the Brazilian legal system is solid

and consistent in regulating drug production and trade; we have many (and enough) laws and regulations. Unfortunately though, this system is very outdated for it was conceived in the sixties and seventies, when many problems faced today did not yet exist. These laws were created by health specialists, but still in the spirit of a time in which many sectors of commerce were unthinkable as for example, the Internet, which did not yet exist, and today needs urgent regulation. This and many legal aspects of commerce must be rethought.

### **3.3 PUBLIC POLICY REFORMS**

According to Dr. Gonzalo Vecina Neto, the true problem behind the irregular drug trade in Brazil consists of a mistaken public policy, rather than of the insufficiency of surveillance entities and police. He states that those responsible for monitoring the drug production chain (*ANVISA* and *VISAs*) cannot be expected to constantly act using repressive police power. According to Dr. Vecina Neto, the function of surveillance is to monitor regular and legal activities and to make sure they continue that way. Surveillance should therefore not be expected to accomplish anything if everyone – or almost everyone – is operating irregularly, for that is not the function of the regulatory bodies. In a democratic regulatory State, it must be possible to trust and operate on an self-regulating dynamic, where the State makes sure everything is in order, but is not constantly exercising its repressive functions.

In this sense, surveillance system flaws, systematically pointed out in all other interviews (lack of personnel, lack of technical capacity to analyse products etc.) are at the low end of a long chain of problems, but they are not, according to Dr. Vecina Neto, the origin of these problems and it is not by tackling them that the irregular drug market in Brazil will be extinguished. He states that it is certainly impossible to train enough technicians to monitor and analyse the drug production and market while the illegal drug trade (including counterfeiting, smuggling and, above all, load theft) is as out of control as it is today in Brazil.

According to Dr. Vecina Neto, the most serious problems are embedded in our tax system and health assistance system, both of which make it too attractive, profitable and easy for people

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to involve themselves in the illegal market (see items 3.4 and 3.5 below).

### 3.4 TAX REFORM

The tax burden on drug commercialisation is very high, reaching 44% of the products' value. Because of this, there is a large amount of money to be made solely through tax evasion. This makes the illegal market very profitable, attracting people to participate in the informal trade (with no tax receipt emission). The large amount of informal operations in this field makes it even more difficult to identify other types of illegal activities, such as load theft and drug counterfeiting. According to Dr. Vecina Neto, tax evasion is the territory for theft, far more than for drug counterfeiting. We have had a few local cases of drug counterfeiting in Brazil, but it does not take place at an industrial scale. Our problem has always been with people who earn enormous amounts of money stealing drug cargos and then selling them elsewhere. The profits made by the agents involved in these schemes are monstrous, and the risks are relatively low because nobody makes formal complaints since the whole commercialisation chain is informal.

Additionally, there is a true fiscal war going on between the Brazilian states, for they have very different tax rates when it comes to the Tax on Distribution of Goods and Services (*Imposto sobre Circulação de Mercadorias e prestação de Serviços* – from now on referred to as *ICMS*), which is one of the most important taxes that fall upon the production and circulation of goods in general in Brazil. One very popular form of evading (at least partially) this tax is to claim that a shipment is coming from a certain State where this specific tax rate is lower and therefore more interesting for the industry and distributors, even though the shipment in fact comes from another State. The private agents thus cover the real route of the cargo in order to avoid high tax rates. By doing so, the stolen cargo traceability becomes harder.

All this stimulates the appeal to operate irregularly and should be publicly discussed by the government. Dr. Vecina Neto believes that drug sector should be submitted to a new tax policy, starting with an equal tax rate for the *ICMS* in all States, in order to discourage the informal market.

A drug sector oriented tax reform has been suggested more than once. In Brazil, the tax burden has been object of public discussions for a long time now, especially with regard to the production distribution on a national scale. According to *FEBRAFARMA*, between 2000 and 2004, the average tax burden on the pharmaceutical industries was of 35.07% on the final price of drugs. Specialists state that the magnitude of the tax burden is contrary to any production encouragement on one hand, and, on the other hand, encourages illegal alternatives to avoid the payment of the taxes. It is in this context that the informal drug market, central *locus* of counterfeited drugs, thrives.

The common opinion of the non-governmental institutions is that such situation is a result of mistaken regulatory politics. The incidence of indirect taxes is the pharmaceutical industries' main concern, specifically the *ICMS*, as well as the social contributions. As a rule, the incidence of these taxes depends on the specific qualities and structures of the different markets; hence producers may or may not transfer the tax burden to their products' final price. Although it cannot be empirically proved that such transfers exist, it may be presumed that they are made effective with certain intensity, since drugs are goods with an inelastic demand, once their essentiality is undisputed.

In Brazil, drug taxation does not seem to obey the constitutional principle according to which the tax burden imposed must be applied proportionally to the essentiality of the taxed good (Article 15, third paragraph, Brazilian Federal Constitution). For instance, one may assert that the *ICMS* tax rate applied on drugs in the State São Paulo is of 18%, yet the tax rate on diamonds is of 15% and the one on veterinarian products is of 0%. In monetary terms, the value of taxes paid annually by the pharmaceutical industry is of about R\$ 5 billion (R\$ 52 billion were collected for *ICMS* and social contributions in 2004<sup>83</sup>).

This high tax rate, beyond having negative effects on the final price of drugs sold in Brazil, is a considerable factor related to, fiscal evasion, unfair competition and, mostly, the counterfeiting of drugs.

In view of these problems, the pharmaceutical industries and the regional councils of pharmacy suggest a proportional reduction

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of the *ICMS* tax rate of 12%. Yet, they fight for the elimination of all charges for the entire segment of human use drugs, as well as for the social contributions. This, according to *FEBRAFARMA*, would be an effective means to fight informality, tax evasion and, most importantly, the abusive increase of drug prices.

### 3.5 PHARMACEUTICAL ASSISTANCE

We have a serious gap in our public health system when it comes to public pharmaceutical assistance. According to Dr. Vecina Neto, if Brazil had a serious pharmaceutical assistance policy and drugs were handed out by the government upon prescription, then people would stop self medication, for no one would need to buy. If the State started distributing drugs in official or licensed pharmacies, then there would be a smaller number of more controlled pharmacies, and this would lower the occurrence of irregularities. But if the essential drugs are not distributed legally, then the informal market is once again encouraged, for the regulating agencies lose control of the market informality (e.g. people buying drugs without prescriptions).

This scenario becomes even worse when we consider the high prices of the national drug market and most of the population's precarious economic situation. These circumstances certainly contribute to the increase of the illegal drugs commerce.

### 3.6 CRIMINAL LAW

In this session we will systemize the main critics made in regards to Law n. 9,677/1998, which defines drug counterfeiting as a crime against public health and establishes the penalties for it, as well as the general problems regarding the regulation of communication interception in Brazil, which affects all fields where complex investigations of organized criminality play an important role, as is the case of the Brazilian illegal drug market.

#### 3.6.1 ASSIMILATION OF COSMETICS, CLEANING PRODUCTS AND DRUGS

Law n. 9,677/1998 includes "cosmetics" and "cleaning products" as objects of the crime of falsification, corruption, adulteration or modification, previously applied only to medical substances. This

measure is very criticized by experts, who allege lack of proportionality and reasonableness, once the penalty (ten to fifteen years of imprisonment) is the same for falsifying drugs and cosmetics or cleaning products, thus including items, which clearly have no therapeutic use, under the protection of this legal disposition.

According to the definition of Law n. 6,360/1976<sup>84</sup>, cosmetics are products used for external application, for the embellishment of different body parts. Vis-à-vis this extensive legal definition and the serious problem of incoherence in this crime's legal definition, sectors of the Brazilian legal jurisprudence<sup>85</sup> developed a restrictive interpretation of this law, once it specifically states that it aims at protecting public health. They therefore interpret that the sanctions set forth in this law are only applicable when real injuries to health may derive from the act. Thus the legal theory tries to give a strict sense to the term "cosmetic", but it does not solve the legal problem and there is no guarantee of uniform interpretation. This is a point in our legislation that, in our opinion, urges reforms.

There are also many criticisms regarding the severity of this legislation and the high penalties foreseen by the law (ten to fifteen years of imprisonment). This lack of proportionality can lead the authorities responsible for applying the law to take decisions against the law, because they find it unfair in certain cases.

### **3.6.2 TELEPHONE TAPPING AND COMMUNICATION INTERCEPTION**

Most of the apprehensions of illegal products result from the police's long-term investigation efforts, and not from specific complaints. These investigations, using telephone interception as a central instrument, have the purpose of arresting organized groups, which are specialized in cargo theft.

However, the current Brazilian legislation that regulates the interception of data and communication (Law n. 9,296 of July 24<sup>th</sup>, 1996) has many faults and omissions. In the Federal House of Representatives, there is a new bill of law (Bill of Law n. 1,443/2007<sup>86</sup>), which aims at introducing a number of changes to improve the current regulation and eliminate its main failures.

One of the sensitive points of the present law is that it stipulates a timeframe of 15 days during which the interception can occur. Clearly, this period is insufficient when dealing with long-term

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investigations involving months of recording telephone conversation between members of organized criminal groups. The bill of law under discussion allows this interval of time to be extended to 90 days.

Another problem in the current legislation is the omission of regulations regarding the so-called “environmental interception”. This is a non-regulated practice in Brazil – a fact, which, on the one hand, allows for abusive practices and, on the other, makes the investigation fragile, for the legality of the act can always be contested.

The need to transcribe telephone conversations resulting from interceptions is another serious point of discussion. A literal interpretation of the first paragraph of Article 6, Law n. 9,296/1996 leads to the belief that the transcription of the complete material recorded is necessary. However, in cases of investigations that involve months of telephone tapping, this is impossible. In the interview police officer João Renato Weseslowski granted us, he stated that whenever judges make such a requirement the production of proof is rendered impossible. This is due to the fact that the Criminology Institute, responsible for the transcription, does not have enough personnel to transcribe all the material. It happens not only because the Institute is poorly equipped, but also because of the huge amount of material to deal with.

The bill of law under discussion makes it unnecessary to transcribe all the material collected. It determines that the interested parties and the police may listen to the recordings and point out the parts they would like to have transcribed. Another important change targeted by this bill of law seeks to build stronger control mechanisms to prevent abusive practices, which unfortunately have been recurring in police investigations. The reform proposes more control over requirements and judicial authorization for interception, over the authorized timeframe and, above all, control mechanisms on technical operations, currently left exclusively to the will of police officers, without establishing any standards.

Finally, something that is not necessarily a problem in the case of crimes against public health, but can be for other crimes described in this report (such as negligent conducts of drug counterfeit or sale of products which are damaging to health<sup>87</sup>), is the fact that the current law only allows interception in the case of



crimes punished with confinement<sup>88</sup>. It does not take into consideration the type of crime or the technical needs of an investigation. The crimes punished with imprisonment cannot be investigated with the help of telephone interception nowadays, even if it presents itself as the most adequate form of investigation.

### **3.7 THE BRAZILIAN SYSTEM OF INTELLECTUAL PROPERTY RIGHTS PROTECTION**

#### **3.7.1 THE NATIONAL INSTITUTE FOR INTELLECTUAL PROPERTY – INPI**

After the GATT/TRIPs agreements became effective in Brazil in 1995 and after the implementation of the National Industrial Property Act (1997), the number of requests for patent-letters increased significantly. This is especially true in the chemical field, and particularly with regard to pharmaceuticals. Consequently, the National Institute of Industrial Property (*INPI*) must analyse a very large number of patent-letter requests, which it is unable to do in timely manner. In October 2006, there were 100,000 procedures in the *INPI*, and the number of delays in their processing was very high<sup>89</sup>.

With the purpose of making these patent-letter procedures more speedy and efficient, the *INPI* recently announced a series of reform proposals. In the first place, 235 new examiners were hired to help analyse patent requests. Secondly, the *INPI* has announced that it will establish certain criteria for the analysis of incoming requests, determining which ones will be considered priority. Although there is still no decision on the subject, the purpose is to establish criteria to prioritise the examination of special requests. A product or process which has already been copied or products that are about to go on the market, are two examples of patent analysis that may be prioritised by the *INPI*.

If these reforms are really implemented, it is possible that the processing of patent requests will be much faster, and there might be a reduction in the number of requests put on hold by the *INPI*<sup>90</sup>.

Some of the efforts made by the *INPI* to develop and improve its services have been criticized by the media and by groups interested in the protection of intellectual property rights. Such is the

case of the *INPI*'s recent efforts to computerize its patent request system. According to an article published by *Danneman & Siemsen Intellectual Property Law Firm*, all reforms that promote efficiency are welcome, just as long as they do not violate the rights of those who need to have access to the *INPI*. This means that making the system computer-based can be good for efficiency, but turning it into the only way to file a request can also interfere with the possibility people have in accessing the Institute, as in Brazil a large percentage of the population does not have access to the internet<sup>91</sup>.

Considering the rules and procedures for patent registration as one of the most serious problems in the patent system, *FEBRAFARMA* and *CREMESP* suggest a broad reform.

These associations state that the yield that patents offer is just provisional and that it guarantees only the compensation for investments made on a certain discovery. Therefore, the patent owner cannot be considered a monopolist in the strict sense of the term. The encouragement is just temporary and it may be lost as a result of competing innovations. However, price regulation in Brazil – Resolution CMED n. 2, of March 2004, treats patented goods as deriving from natural monopolistic companies.

In view of these facts, two important proposals for industrial property regulation related reforms are raised: first, a reform to increase the functionality of the registration system, which is currently seen as very bureaucratic and inefficient; second, a reform regarding the control of patented product prices. In order to make these ideas concrete a number of measures are suggested, amongst which: (i) the operational strengthening of the *INPI* (investments in capacity building, equipment acquisition etc.); (ii) revision of the patent registration procedures; (iii) new regulation of patented product prices; and (iv) creation of a non-governmental agency that specializes in this field of consultancy.

From the industry perspective, the National Industrial Property Act represents an advance in the legislation and an encouragement for drug research and innovation. The discussions in Brazil point to the fact that the innovation process is risky (risk of failure of the research) and demands expressive amounts of real resources, which must be financed and rewarded. *FEBRAFARMA* states that the Brazilian legislation on drug patents is deficient; according to them,

in order to have efficient legal protection it is not enough to have the patent registered, but that the whole process be accomplished. That is why it is central that procedures be expedited in so as to offer the innovator security about the registration procedure's progress, including fatal dead-lines for the *INPI*. In Brazil, there is a high level of functional-bureaucratic complexity for the examination of requests. To fight this problem, several suggestions are being presented, aiming at rationalizing procedures, making them faster and more efficient.

### **3.7.2 ANTI-COUNTERFEITING LEGISLATION**

Brazil has made a significant effort in updating and improving its legislation to prevent and repress counterfeiting and other crimes against intellectual property for example, by implementing the TRIPs agreement in 1996, the Industrial Property Act (Law n. 9,279/1996), the Software Law (Law n. 9,609/1998) and the Copyright Law (Law n. 9,610/1998). These laws establish more severe penalties against infractors and counterfeiters, providing the authorities and the intellectual property rights owners with strong new tools to fight piracy, such as the authorization to destroy counterfeited goods, moulds, machines, etc.

Some of these laws have been criticized for their omissions and insufficiencies by the legal jurisprudence in Brazil. For example, Professor Vladmir Garcia, from the Catholic University of Santos (Unisantos), criticized the Industrial Property Law before the National Commission for Economic Development, Industry and Commerce, stating that it does not properly protect national interests because it refers only to the protection of genetic material, and does not include all biological material or specify the important necessity of indicating the origins of the biological material when requesting patent protection.

Other authors also indicate the need for more severe sanctions in the criminal sphere and of better defined criteria for civil indemnification<sup>92</sup>. Lawyers who work in the intellectual property arena also underline that it would be desirable to introduce into our legal system the concept of criminal liability – in Brazil only applied to crimes against the environment –<sup>93</sup>, for legal entities, in cases of violation of intellectual property rights.

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As we mentioned in item 2.2.2.6 it would be desirable to reach a definition about the applicability of Law 9,099/95 to these cases.

## 3.7.3 LAW ENFORCEMENT EFFORTS

The solution for the systematic violation of intellectual property rights cannot be expected to derive from purely legal measures. In spite of all the efforts of the Brazilian Government to fight piracy, there are still several measures that should be taken in order to decrease the astonishing numbers of pirated products. The first, and maybe the most important of all, is the need to educate the authorities about the importance of intellectual property legislation enforcement, and of the protection of intellectual property rights. Another paramount measure to avoid the distribution of counterfeited products would be the creation of a centralized Brazilian customs system (broadening the existing internal system called Siscomex, which aims solely at controlling fiscal issues), since the large majority of counterfeit goods enter the internal market via Brazilian borders. Another recommendation is the revision of the commercial relationship with Paraguay, which already decreased USD 1 billion between 1997 and 2001. However, the amount of counterfeited products that cross the border, from Paraguay to Brazil, corresponds to USD 1,2 billion per year, representing four times the amount of the legal trade between these countries. Finally, the creation of more specialized police precincts and consumer education (to avoid the purchase of counterfeited products) would also be recommended measures to be taken on, in a joint effort, by many of the affected industries<sup>94</sup>.

These are very important steps to be taken in order to promote the effectiveness of intellectual property rights, focusing on the enforcement of existing legislation. Some of these steps are already beginning to be implemented, such as the creation of specialized police departments in the States of Rio de Janeiro and São Paulo, the reformulation of our customs system and some legislation improvement. But Brazil still has to put in place a number of system reforms in order to guarantee legislation compliance.

There is also a problem of lack of enforcement when it comes to the intellectual property criminal legislation. It has not only to

do with the general characteristic of the police and criminal prosecution in Brazil, but also with the special rules applied.

As mentioned above, crimes against industrial property and unfair competition (Law n. 9,279/1996) are subject to private criminal procedures and this may imply a lot of difficulties for the victim to pursue it.

### **3.7.4 INPI REFORM PROPOSALS**

Several criticisms were voiced both by *FEBRAFARMA* and private industries regarding the functioning of the *INPI*. Among the most relevant reform suggestions were (i) Enhancement of the registration system's functionality; (ii) Promotion of operational strengthening of the *INPI* (investments in training, acquisition of equipment etc.); (iii) Revision of patent registration procedures; (iv) Issuing of new regulations for the pricing of patented products; and (v) Creating a non-governmental agency that specializes in consultations regarding the registration of patents.

### **3.7.5 CREATION OF A SPECIAL INSTITUTION TO FIGHT PIRACY: THE NATIONAL COUNCIL OF COMBAT AGAINST PIRACY AND CRIMES AGAINST INTELLECTUAL PROPERTY (CNCP)**

In view of the inefficiency of intellectual property crimes investigations, the Brazilian government has been organizing a number of measures to fight illegal activities tied to the counterfeiting and commerce of counterfeited products.

After the Parliamentary Inquiry Commission responsible for investigating piracy had finished, in August 2004, the President of Brazil determined that the agencies which act to fight piracy should strengthen their activities' cooperation and coordination. A normative act issued by the President (*Medida Provisória* n. 220 of 2004) created the *CNCP* within the Ministry of Justice, and this act was regulated by Decree n. 5,244 of 2004. The *CNCP* received the responsibility to create and implement a National Plan to combat Piracy and Intellectual Property Crimes.

The Brazilian Government's initiative, in this case, is unique for having put together public and private entities with equal rights of speech and vote. One of the first steps taken by the *CNCP* in 2005 was the creation of a National Plan against Piracy. The idea

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was to issue a consistent action plan that would help the country improve the fight against piracy in all levels of State and private intervention. The result was the publishing of a list with 99 reform proposals, classified in short, medium and long-term measures, gathered in the “Action Plan against Piracy”.

These actions are concrete measures to effectively fight piracy at a national level, counting with the help of relevant agents and with the establishment of targets to be pursued. They include the organization of seminars to explicit the dangers of piracy, the education of the population and the creation of public institutes specialized in piracy control (e.g. special police departments, administrative offices and judiciary courts). They include a number of recommendations to be made to the existing public agencies to make piracy control more efficient.

The Action Plan against Piracy determined that the short-term measures should be implemented in 6 months (by 11.01.2005), the medium-term measures in 18 months (by 11.01.2006) and the long-term in 24 months (by 05.01.2007).

The implementation of some of the short-term proposals started immediately after the publishing of the National Plan, but we cannot say for sure which actions were actually implemented and which were not, because there is no organized data source to verify this information. However, from all the data we had access to, it is possible to conclude that most of the measures established have not yet been implemented.

## 3.8 INTERNET

As mentioned above, in Brazil there isn't yet any specific legislation on crimes practiced over the Internet. Several bills of law, regarding the keeping of Internet access records, have been discussed in the National Congress. However, the main bill of law under discussion – Substitutive Senate Proposed Law n. 76, 2000 – was not voted yet and has been postponed as described before. In addition to this, there are no initiatives for Internet regulation that deal specifically with online drug sales or drug counterfeiting so far.

However, general discussions addressing the prevention of cyber-crimes, such as illegal drug commerce and the violation of

intellectual property rights (e.g. patent or trademark rights), may be partly applicable to drug counterfeiting,

Effective enforcement of legal provisions against crimes performed over the Internet is a current international concern and entails discussing internet-governance related issues. The Internet's intrinsic cross-border nature remains a challenge and a dilemma to such regulation attempts.

The challenge is to, at some extent, achieve international harmonization, thereby ensuring realistic possibilities of investigation and enforcement. The dilemma consists in defining an appropriate degree of regulation, which would neither serve potentially as a massive instrument for human rights' violations nor hinder current positive externalities of internet communications. In this respect, it is worth mentioning that the right to privacy, intimacy and political opinion could be severely restricted by more stringent Internet identification and authentication controls, particularly in non-democratic countries. Many of the Internet's positive externalities arise from its open nature, where information is presumed to flow freely and proper authentication and formal identification mechanisms are applicable only when strictly necessary. Inverting such logic for the benefit of security and law enforcement may not only prove to be ineffective, for the purposes of criminal prosecution, but also represent harmful hindrance to the Internet's features and functionalities. In summary: changing the Internet into a fully controlled structure, which would allow full compliance and responsiveness to attacks, could generate such an "Orwellian" communication system that its negative externalities would easily surpass its positive effects.

Nonetheless, some general measures could be implemented to minimize the negative effects of counterfeited drugs commercialisation over electronic means, in the international sphere. These measures should include: (i) the development of campaigns and public policies focused on the education about the risks of counterfeited drugs and mechanisms for their proper identification, either by electronic or regular media; (ii) the creation and execution of effective and public denunciation and complaint mechanisms concerning the advertising, distribution and commercialisation of counterfeited drugs, driving the collected information to related

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public administration, prosecution and investigation entities; and (iii) the implementation of cooperative investigation initiatives in the Brazilian and foreign police aiming at the identification, prosecution and repression of counterfeited drug selling.

It is equally important to identify which changes to substantive criminal law should be implemented, in order to punish online trade of counterfeited drugs, and to establish national regulation standards for Internet Service Providers' obligations of keeping users' access records. There should be appropriate sanctions in case of unauthorized use or distribution of such information, which should be disclosed to investigation authorities only upon court order.

It may be also useful to implement procedural "fast track" mechanisms to standardize requirements and to facilitate court orders' release to determine the authorship identification and the provision of confidential Internet Service Providers' user records, to investigate potential criminal activities performed over the internet.

Finally, it is urgent to provide the police, experts and any other investigation agents with suitable and proper training in order to generate the necessary knowledge on electronic media and e-commerce of falsified drugs, for the purposes of proper investigation and enforcement.

## FINAL CONSIDERATIONS

Based on all the information gathered in this report we now feel capable of making an accurate diagnosis of the main characteristics of the illegal drug market in Brazil. Perhaps the most important data obtained, concerning this market, is the fact that drug counterfeiting is a relatively scarce practice in our country, and that other illegal conducts, namely cargo theft and irregular drug commercialisation, present a much more serious risk to the legal and economic integrity of our drug market and to the health of consumers. Furthermore, it is noteworthy that these illegal activities take place despite a system which aims at encompassing the broadest prevention and repression possible, seeking to avoid illegality in the drug market from all possible angles by employing judicial, police, and administrative forces in the process.



Hence we reach the conclusion that the most serious problems affecting the commerce of drugs take place at the law enforcement level and are related to the actors who participate in our global health surveillance system, including *ANVISA*, the State surveillance agencies, police departments involved in crime investigation and the Public Prosecutors' Offices. It seems that these institutions, which have a central role in the prevention and prosecution of the illegal practices discussed above, are unprepared and ill-equipped to face the problems involving illegal drug trade. The measures, necessary to ensure safety, are only viable when the public powers may rely on trained agents and sufficient personnel to monitor the effectiveness and implementation of the legal system.

On one side, the problems we face vis-à-vis the commerce of irregular products are caused by structural problems in our public institutions: *ANVISA* does not have sufficient personnel and public offices in general (including *ANVISA*, the police and the Public Prosecutors' Offices) cannot rely on efficient public laboratories and technicians to run the tests on counterfeit and irregular drugs in addition to these offices' bureaucracy blocking their efficiency.

On the other side, we concluded that our Health Surveillance System's lack of capability in preventing many illegal practices may be a result of the Brazilian authorities' relative inexperience in the field of health control (*ANVISA* was created in 1998 and the National Health Surveillance Plan, issued in 2002). Uncovering precisely *what* the problem consists of and framing it clearly is the first step, since there is a strong need for developing solutions appropriate to the Brazilian reality. Only after such diagnosis it will be possible to create and implement adequate measures for the increase of the Health Surveillance System's full efficiency.

Even though some efforts, oriented to restructure our Health Surveillance System – in terms of hiring more personnel and providing the public agency with the necessary capabilities for law enforcement (e.g. labs for analysis and technicians) – seem to be already taking place, these agencies are very aware of what the problems are and what solutions can be suggested and ideally implemented shortly. In other words, we are not in the dark. Proof of this is *ANVISA*'s constant publicity on cargo theft issues, and

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*SNVS*' endeavours to prevent this crime. Reports of cargo theft in the State São Paulo may be found on the website of the local Health Surveillance Agency and, on *ANVISA*'s website one finds news on cargo theft from all across the country.

As stated by our *FEBRAFARMA* interviewees, the problem with drug control in Brazil occurs mostly on the way from the laboratory to the consumer – when the product can be stolen and redistributed informally and illegally – and any efficient health regulation efforts must take into account the viability of monitoring the entire drug commercial chain, from the producer to the end consumer. Almost as if responding to this claim, *ANVISA* recently published a new plan to make all drugs identifiable and traceable during all steps of the commercialisation chain<sup>95</sup>. If this plan works, it will be much easier for the police to identify stolen products and remove them from the market, or for the consumer to identify and report the sale of irregular drugs to competent authorities. This may represent the first step to an efficient mechanism in the fight against cargo theft.

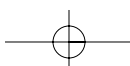
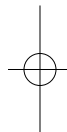
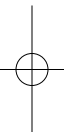
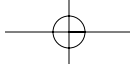
The public and private sectors also seem to be acting based on the premise that cooperation is necessary to fight against irregularities in the drug market. However, if the laboratories do not find *ANVISA*'s drug identification plan attractive, *ANVISA* will have a very hard time setting the new system in place. Meanwhile laboratories depend on the public system's efficiency in licensing products and companies to operate. Cooperation may be identified in the organization of public hearings by *ANVISA*, in the search for dialogue between the pharmaceutical industry and the government and in the creation of public-private committees set up to find the best way to fight illegal practices.

This last case, specifically, can be illustrated by the creation of the National Council of Combat against Piracy and Crimes against Intellectual Property (*CNCP*), which puts together public and private entities to create the National Plan Against Piracy. Sadly enough though, this plan, which contains 99 reform proposals for the public and private area, was never completely addressed or implemented. But the structure of the committee clearly proves a growing inclination to promoting dialogue and cooperation between such sectors, and the idealised reform proposals prove that

the *CNPC* was aware of the necessity to improve the State's law enforcement institutions. This may be exemplified by the proposals that seek to transfer more funding to surveillance institutions and to promote seminars and education programs for public agents involved in the fight against piracy.

Of course, even the best of intentions don't do much good while they remain abstract ideals. Many problems remain unsolved, especially those concerning the institutional organization of the offices responsible for health surveillance, as we've seen that the current institutions are inefficient in pursuing their goals (e.g. as described above, very few of the *CNPC* proposals were implemented and, in addition to that, there is no way of accurately monitoring the actions of this committee<sup>96</sup>). Nevertheless, from the information we gathered, we understand that Brazil has been and is creating specialized offices that are progressively discovering the national dilemmas in health surveillance and taking on the responsibility of solving them in a cooperative and public manner.

However, it would be deluding to end this Brazilian drug market diagnosis on a purely optimistic note, since we are yet starting the first of a very long list of measures to secure a well functioning Health Surveillance System. This would translate into a thorough institutional reform of all public institutions involved in the National Health Surveillance and in the Justice Systems, aimed at transforming them into well prepared and efficient institutions for the prevention of and fight against illegal practices in the drug market.



## NOTAS

1 Criminal Law and Criminal Procedure Law Professor at the Law School of the Getulio Vargas Foundation, Researcher at the Law and Democracy Group in the the Brazilian Analysis and Planning Center (CEBRAP), LLM equivalent and Ph. D at the Law School of the University of São Paulo.

2 Law student at the Law School of the University of São Paulo and research assistant at the Law School of the Getulio Vargas Foundation.

3 Law student at the Law School of the University of São Paulo and research assistant at the Law School of the Getulio Vargas Foundation.

4 Ph.D candidate at the Law School of the University of São Paulo and researcher at the Law School of the Getulio Vargas Foundation.

5 All electronic databases of Anvisa can be found in [www.anvisa.gov.br](http://www.anvisa.gov.br).

6 For more information concerning the role of the Public Prosecutors in preventing and repressing drug counterfeiting, see sub-section **2.1.2.2**. *Public Prosecutors Office*, located in section 2 of this report.

7 In the criminal sphere, offenses evolving drugs are investigated alongside other investigations, meaning there is no special institution for investigating criminal violations against public health as occurs in the private sphere. For this reason, our search for information related to criminal manners was very difficult and we decided to concentrate our research efforts on GAESP.

8 Available at: <http://www.idec.org.br/emacao.asp?id=1012>, last access on January 10<sup>th</sup>, 2008.

9 Available on <http://www.idec.org.br/emacao.asp?id=1012>, last access on January 9<sup>th</sup>, 2008.

10 Data available on: [http://www.febrafarma.com.br/download.php?tbl=estudos\\_febrafarma&id=19](http://www.febrafarma.com.br/download.php?tbl=estudos_febrafarma&id=19), last Access on January 31<sup>st</sup> 2008.

11 Data available on: <http://sistemas.aid.gov.br/imprensa/Noticias.asp?NOTCod=52856>, last access on May 7<sup>th</sup> 2008.

12 Data available on: <http://www.pod1.com.br/noticias/mercado-farmaceutico-pode-melhorar-em> 2007, last access on January 31<sup>st</sup> 2008.

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13 Data available on: <http://www.pod1.com.br/noticias/farmacias-faturaram-r-7-7-bilhoes-em-2007>, last Access on January 31<sup>st</sup> 2008.

14 Most of these factors seem to result from a particular point of view of the industry, but we do not intend to go deeper in the analysis of these arguments here.

15 Data available at: [http://www.remburssi.org/projects/brazil/Part\\_III.htm](http://www.remburssi.org/projects/brazil/Part_III.htm). Last access on 30<sup>th</sup>, January, 2008.

16 he following data is available at: <http://www.ANVISA.gov.br/medicamentos/falsificados/index.htm>, last access on 28<sup>th</sup> January, 2008. Unfortunately, no further data on the cases of counterfeiting stated below could be found.

17 Ministry of Health, ANVISA, OPAS/OMS, *Preventing and combating drug counterfeiting: a shared responsibility*, Brasilia, 2004, p.3.

18 Public Civil Action is a creation of Law 7.347/85, which permits District Attorney's Office, civil associations and State to defend diffuse and collective interests, such as protection of environment and consumers rights. The entire law is available at: <http://www.planalto.gov.br/ccivil/LEIS/L7347orig.htm>. Last access on 18<sup>th</sup> December, 2007.

19 Data available at: [www.veja.abril.com.br/080798/p\\_040.html](http://www.veja.abril.com.br/080798/p_040.html). Last access on 9<sup>th</sup> August, 2007.

20 All information on milk fraud available at <http://oglobo.globo.com/economia/mat/2007/10/28/326933992.asp>, Last access on January 18<sup>th</sup> 2008.

21 Information provided by Laboratório Astrazeneca: [http://www.astrazeneca.com.br/azws006/site/paciente/farmaco/perguntas\\_frequentes.asp](http://www.astrazeneca.com.br/azws006/site/paciente/farmaco/perguntas_frequentes.asp), Last access on 18<sup>th</sup> September, 2007.

22 This information was repeated in all the interviews realized during our research and seems to point to the heart of the illegal drug trade problem in Brazil.

23 Available at [http://www.cvs.saude.sp.gov.br/com\\_rbcarga.asp](http://www.cvs.saude.sp.gov.br/com_rbcarga.asp). Last access on 18th September, 2007.

24 Available at <http://www.cff.org.br/cff/mostraPagina.asp?codServico=67&codPagina=465> . Last access on 27<sup>th</sup> September, 2007.

25 Instituto Brasileiro de Ética Concorrencial, “Informalidade no Setor Farmacêutico: barreira ao crescimento da economia brasileira e risco à saúde pública”, 2005.

26 Available at: <http://www.mj.gov.br/combatepirataria/relatorio.asp>. Last access on 24<sup>th</sup> June, 2007.

27 According to Jaldo Souza Santos, president of the Federal Pharmaceutical Council, the unchecked commercialization of pirate products harms Brazilian economy: “The damage annually caused to public finances with the sale and distribution of falsified drugs is of 30 billion Reais. Apart from that, piracy impedes the creation of around 2 millions of legal jobs”, he affirms.

28 BASCAP was launched by the International Chamber of Commerce in order to “connect all business sectors and cut across all national borders in the fight against counterfeiting and piracy”. More information available at: <http://www.iccwbo.org/bascap/id883/index.html>. Last access on January 29<sup>th</sup>, 2008.

29 This estimated number was announced by the Brazilian Pharmaceutical Industry Federation (Febrafarma), without more details about what kind of damages are they referring to and how do they got to this number.

30 Data available at: [www.astrazeneca.com.br/azws006/site/paciente/farmaco/perguntas](http://www.astrazeneca.com.br/azws006/site/paciente/farmaco/perguntas). Last access on 18th September, 2007.

31 The first case involved a nine month old baby died because of the use of an innocuous medication. The baby had been diagnosed with pneumonia and meningitis, and should have been treated with a strong and efficient antibiotic. But it was accidentally treated with counterfeited drugs and, because of her illness, these drugs had a lethal effect. The second one involved a farmer named Cândido Nunes Ferreira, who took counterfeited drugs to treat prostate cancer (“Androcur”). Because the drug was innocuous, his tumor tripled in size in less than two months, affecting the lungs and the urethra and causing immense damages to his health. The last case is the one of the “flour contraceptive pills”, which resulted in the unwilling pregnancy of more than 200 women (estimated).

32 See item 2.2.2.5 - The classification of some conducts as heinous crimes.

33 Ministry of Health, ANVISA, OPAS/OMS, *Preventing and combating drug counterfeiting: a shared responsibility*, Brasília, 2004, p. 6-7.

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34 The list of competences attributed to ANVISA can be found in the agency's website: <http://www.ANVISA.gov.br/Institucional/ANVISA/comp.htm>, last access on January 9<sup>th</sup>, 2008. Other important sources which may be consulted to find ANVISA's competences are Law n. 9.782/1999 and Decree n. 3.029, of April 16, 1999.

35 Available on [http://www.ANVISA.gov.br/medicamentos/autoriza/autoriza\\_requisitos.htm](http://www.ANVISA.gov.br/medicamentos/autoriza/autoriza_requisitos.htm), last access on January 10<sup>th</sup>, 2008.

36 For a detailed look at the competences of ANVISA, see Law n. 9.782/1999 and Decree n. 3.029/1999. It is impossible to list all the regulatory norms that have been edited by ANVISA and by the National Health Surveillance System, for they are too many and too specific. Each area of health products has a specific set of norms which applies to it, but the important thing is to have in mind that ANVISA not only edits many of these norms but also guarantees their effectiveness.

37 Information may be found in Article 7 of Law n. 9.782/1999.

38 The information that follows was retrieved from the text "Oficina Nacional – Prevenção e Combate à Falsificação e Fraude de Medicamentos: uma responsabilidade compartilhada", written with the participation of the Ministry of Health/ ANVISA and of the Pan American Health Organization/ World Health Organization (OPAS/OMS), 2004. Available at: [http://www.ANVISA.gov.br/divulga/eventos/oficina\\_falsif\\_medica\\_referencia.pdf](http://www.ANVISA.gov.br/divulga/eventos/oficina_falsif_medica_referencia.pdf), last access on January 10<sup>th</sup> 2008.

39 The benefits which are applicable to "less offensive" offences will be explained in item 2.2.2.6.

40 Before Law n. 9.677, of July 2<sup>nd</sup>, 1998, the crimes against public health were defined in the original wording of 1940. Article 273 was completely altered in 1998: previously to the law of 1998, it only incriminated the alteration of the composition of drugs, and not their falsification, corruption and adulteration. The other relevant articles were only altered to include the category of therapeutic drugs expressly. Additionally, all penalties were considerably aggravated.

41 A part of the Brazilian legal doctrine criticizes the fact that, in the criminal law, cosmetics are considered to be equivalent to drugs and other pharmaceutical products, even though they do not pose the same threats to consumer health. "*There is no way we can assimilate, in in terms of offense capacity, drugs and other therapeutuc products to cosmetics, for these serve only for the purpose of cultivating beauty, or for cleaning and disinfecting*". (FRANCO,



Alberto Silva, Há Produto Novo na Praça, Boletim IBCCrim n° 70, p. 5, free translation).

42 TUCUNDUVA SOBRINHO, Ruy Cardozo Mello, *Arts. 1° a 17*, in GUIMARÃES, Marcello Ovídio Lopes (Coord.), *Nova lei antidrogas comentada*, São Paulo, Quartier Latin, 2007, p. 21.

43 GONÇALVES JÚNIOR, Ulysses de Oliveira, *Arts. 33 a 36*, in GUIMARÃES, Marcello Ovídio Lopes (Coord.), *Nova lei antidrogas comentada*, São Paulo, Quartier Latin, 2007, p. 144.

44 CANTON FILHO, Fabio Romeu, *Arts. 31 a 32*, in GUIMARÃES, Marcello Ovídio Lopes (Coord.), *Nova lei antidrogas comentada*, São Paulo, Quartier Latin, 2007, p. 135.

45 The Brazilian Criminal Code sets forth that fine penalties shall be applied according to two factors: the number of days of fine and the amount to be paid per day of fine, which may vary between 1/30 of the legal minimum salary and 5 times its value (Art. 49, Criminal Code).

46 GONÇALVES JÚNIOR, Ulysses de Oliveira, *Arts. 33 a 36*, in GUIMARÃES, Marcello Ovídio Lopes (Coord.), *Nova lei antidrogas comentada*, São Paulo, Quartier Latin, 2007, p. 144.

47 NUCCI, Guilherme de Souza, *Leis penais e processuais penais comentadas*, São Paulo, Revista dos Tribunais, pp. 776-777.

48 GONÇALVES JÚNIOR, Ulysses de Oliveira, *Arts. 33 a 36*, in GUIMARÃES, Marcello Ovídio Lopes (Coord.), *Nova lei antidrogas comentada*, São Paulo, Quartier Latin, 2007, p. 160.

49 GONÇALVES JÚNIOR, Ulysses de Oliveira, *Arts. 33 a 36*, in GUIMARÃES, Marcello Ovídio Lopes (Coord.), *Nova lei antidrogas comentada*, São Paulo, Quartier Latin, 2007, pp. 175-176.

50 Alternative sanctions are used to substitute the penalty of imprisonment. They cannot be added to the penalty of imprisonment, but may be added to a fine. Their application is possible only when enough of the following conditions are verified to the judge's satisfaction: (i) the conduct constitutes a negligent crime; or (ii) the conduct constitutes an intended crime, but the imposed penalty is not higher than 4 years. In the second situation, the crime shall have been committed without violence and the defendant shall not have been convicted of any felonies in the past 5 years. The application of alternative sanctions by the judge includes considerations

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regarding the social conduct, precedents, the personality of the defendant and the reasons and circumstances of the crime (Article 44, Criminal Code). The Brazilian alternative sanctions are: fines, social services, restriction of certain rights for a determined period of time (e.g., prohibition to exercise public services, drive vehicles, or frequent certain places), or spending the weekend at public rehabilitation institutions (Articles 45, 46, 47 and 48, Criminal Code).

51 PIERANGELI, José Henrique, Crimes contra a propriedade industrial e crimes contra a concorrência desleal, Revista dos Tribunais, São Paulo, 2003, p.402.

52 It was impossible to have access to the data from the trials which occurred in first instance, for there is no search instrument which operates through the insertion of key words.

53 Available at [www.aasp.org.br](http://www.aasp.org.br), last access on January 9<sup>th</sup>, 2008.

54 Information available at: <http://www.mj.gov.br/data/Pages/MJ57BB9237ITEMID1CE317BE980A4BC993E01D5AC55E7FF9PTBRIE.htm>  
Last access on 03<sup>rd</sup> January 2008.

55 The possibility of using other means of communication is clearly stated in some bilateral agreements settled by Brazil. The agreement with the Mercosur, for instance, establishes that “if the request is transmitted by telex, fac-símile, electronic mail or similar, it should be confirmed by the requesting authority through sending the original document in 10 (ten) following day of its initial formulation...” (Art. 6.2). In the same sense, but with a different deadline, the agreement with Colombia (Art. 4.2).

56 Art. 105, I, i and Art. 109, X, Brazilian Federal Constitution; Arts. 780 to 786, Criminal Procedure Code; Arts. 211 and 212, Civil Procedure Code; Arts. 12 and 17, Law of introduction to the Civil Code; besides, Decree n. 26 of 14.08.1990 of the Ministry of Justice, and Resolution n. 09 of 04.05.2005 from the Superior Court of Justice.

57 About the course and the necessary conditions to the fulfillment of the active and passive requesting letters, see, besides the information available in the Ministry of Justice webpage, KLEEBANK, Susan. *Cooperação Judiciária por via diplomática. Avaliação e propostas de atualização do quadro normativo*. Brasília: Instituto Rio Branco. Fundação Alexandre Gusmão, 2004, p. 39-78; MADRUGA, Antenor. “O Brasil e a jurisprudência do STF na Idade Média da Cooperação Internacional” *Revista Brasileira de Ciências Criminais*, n.º. 54, maio-junho de 2005 and MACHADO, Máira Rocha. “Cooperação penal

internacional no Brasil: as cartas rogatórias passivas”. *Revista Brasileira de Ciências Criminais*, nº 53, março-abril de 2005, p. 98-118.

58 According to a research made in 400 requesting letters judged by the STF in the last decade, amongst the 110 letters of criminal nature, 17 involved bank information and, from those, 14 were denied. Among the denied, 7 decisions indicate the “executory character” as the fundament to the denial of the *exequatur*. MACHADO, Máira Rocha. “Cooperação penal internacional e o intercâmbio de informações bancárias: as decisões do STF sobre quebra de sigilo em cartas rogatórias”. *Lavagem de dinheiro e recuperação de ativos: Brasil, Nigéria, Reino Unido e Suíça*. Máira Rocha MACHADO e Domingos Fernando REFINETTI (organizadores). São Paulo: Quartier Latin, 2006, p. 99-112.

59 “Executive Summary of the Second Mutual Evaluation Report. Federative Republic of Brazil”. *FATF Annual Report 2003-2004*, Annex C, § 23.

60 “Executive Summary of the Second Mutual Evaluation Report. Federative Republic of Brazil”. *FATF Annual Report 2003-2004*, Annex C, § 23 e 48 (Table 1, V – Recommended Action).

61 See, for example, the report published in 2005 by PANHO and ANVISA on prevention and combat techniques against drug counterfeiting. The report seeks to show the shared responsibility of these countries and the necessity of cooperation in action. Document available in Portuguese and Spanish on [http://www.opas.org.br/medicamentos/site/UploadArq/HSE\\_PRE\\_FAL\\_0305.pdf](http://www.opas.org.br/medicamentos/site/UploadArq/HSE_PRE_FAL_0305.pdf). Last access on January 3<sup>rd</sup>, 2008.

62 The latest version of the substitute senate bill of law is available, in Portuguese, at: <http://webthes.senado.gov.br/sil/Comissoes/Permanentes/CCT/Pareceres/PLC2007121289.rtf>, last access on January 2<sup>nd</sup>, 2008. The updated status of the Congress discussions concerning such bill of law may be found at [http://www.senado.gov.br/sf/atividade/materia/detalhes.asp?p\\_cod\\_mate=43555](http://www.senado.gov.br/sf/atividade/materia/detalhes.asp?p_cod_mate=43555), last access on January 2<sup>nd</sup>, 2008.

63 Available at: <http://www.denuncia.org.br/twiki/bin/view/SaferNet/Noticia20070712181345> (in Portuguese), last access on January 3<sup>rd</sup>, 2008.

64 Available at: <http://www.denuncia.org.br/twiki/bin/view/SaferNet/Noticia20071023093506> (in Portuguese), last access on January 3<sup>rd</sup>, 2008.

65 Available at: <http://www.denuncia.org.br/twiki/bin/view/SaferNet/Noticia20071023093506> (in Portuguese), last access on January 3<sup>rd</sup>, 2008.

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66 We tried several times to get in touch via telephone and email to directors and technicians of ANVISA and the CNCP, but the contact with the current staff of these organs are being extremely difficult. A personal approach would be advisable in this case, but ANVISA's end CNCP are located in the Federal District, Brasília, what would demand the team of researchers to incur in travel expenses, which is not possible in order of the currently unavailability of financial support to this investigation.

67 Data available at: [http://www.nevusp.org/portugues/index.php?option=com\\_content&task=view&id=763&Itemid=104](http://www.nevusp.org/portugues/index.php?option=com_content&task=view&id=763&Itemid=104). Last access on January 16<sup>th</sup>, 2008.

68 This information is available at Manual de Polícia Judiciária – doutrina, modelos e legislação. Polícia Civil do Estado de São Paulo. São Paulo, Delegacia Geral de Polícia 2003, 2<sup>a</sup> edição revista e atualizada, p. 214-215.

69 About these subject, see item 3.7. on the Brazilian regulation of Intellectual Property.

70 Data available at: <http://www.febrafarma.org.br/divisoes.php?area=co&secao=visualiza&modulo=clipping&id=6648> . Last access on January 17<sup>th</sup>, 2008.

71 This law speaks of the health surveillance to which drugs, pharmaceutical products and similar substances, cosmetics, cleaning substances and other substances should be subject to.

72 FRANCO, Alberto Silva and STOCO, Rui (coord.). Código Penal e sua interpretação: doutrina e jurisprudência. São Paulo: Editora Revista dos Tribunais 2007. p. 1310-1311.

73 Data available at: <http://www.camara.gov.br/sileg/integras/476224.pdf>. Last access on January 21<sup>th</sup>, 2008.

74 Article 273 and Article 278 Brazilian Criminal Code, respectively.

75 It is important to note that in Brazilian criminal legislation there are two kinds of liberty restriction penalties – reclusion and detention. In reclusion, the penalty shall be concluded in closed, semi-open or open regime. In the case of detention, the regime can be semi-open or open.

76 Data available at: <http://www.dannemann.com.br/site.cfm?app=show&dsp=ccp&pos=5.2&lng=pt>, last access on January 16<sup>th</sup>, 2008.

77 Data available at: <http://www.dannemann.com.br/site.cfm?app=show&dsp=ccp&pos=5.2&lng=pt>, last access on January 16<sup>th</sup>, 2008.

78 Data available at: <http://www.dannemann.com.br/site.cfm?app=show&dsp=jac8&pos=5.1&lng=pt> , last access on January 16<sup>th</sup>, 2008.

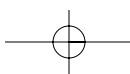
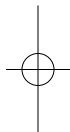
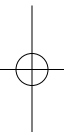
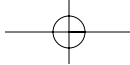
79 Data available at: <http://www.dannemann.com.br/site.cfm?app=show&dsp=jhw&pos=5.52&lng=pt>, last access on January 17<sup>th</sup>, 2008.

80 Data available at: <http://www.dannemann.com.br/site.cfm?app=show&dsp=jhw&pos=5.52&lng=pt>, last access on January 17<sup>th</sup>, 2008.

81 Data available at: <http://www.dannemann.com.br/site.cfm?app=show&dsp=jgg&pos=5.52&lng=pt>, last access on January 17<sup>th</sup>, 2008.

82 Data available at: <http://www.anvisa.gov.br/divulga/noticias/2008/070308.htm>, last access on March 26<sup>th</sup> , 2008.

83 There is no public data available on the subject. We tried several times to get in touch with those agency in order to obtain more detailed information, but unfortunately we had no answer.



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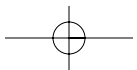
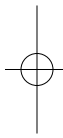
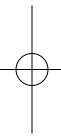
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