DOI: http://dx.doi.org/10.11606/issn.2316-9044.v18i2p112-121

Daniela Trejos Vargas[1]

REGULATION OF HEALTH PRODUCTS: STRIVING FOR BEST PRACTICES

[1]Pontifícia Universidade Católica do Rio de Janeiro. Rio de Janeiro/RJ, Brasil.

Correspondence: Daniela Trejos Vargas. *E-mail:* dvargas@puc-rio.br.

Received: 10/11/2017.

Introduction

The section "Argument" on this issue of the *Revista de Direito Sanitário* (Journal of Health Law) is again centered on the existing regulatory framework of Brazil in the area of health products. The three articles selected bring an approach with a comparative bias in the different areas in which the Brazilian Health Regulatory Agency (Anvisa) operates: regulation of medical supplies, analysis and registration of pharmaceutical patents and *ex post facto control* of medicines dangerousness through **recall**.

The right to health, provided on the 1988 Brazilian Constitution[1], is characterized by a set of public policies of health surveillance, regulation and control of drugs and medical supplies. The access to safe health products depends on the existence of a reliable health surveillance system, in addition to the research and development work of the pharmaceutical corporations. Regarding clinical tests, the trustworthiness of the results depends directly on the quality of the medical supplies used.

The end beneficiary of materials and medicines is the citizen, whose right to health is the State's duty to protect and guarantee. When comparing different judiciary systems, it is possible to identify some areas in the national health surveillance and patent registration system that can be improved, learning from the experience of other countries.

I. Regulation of medical supplies in Brazil

The authors *Michele Feitoza-Silva*, *Patrícia Fernandes da Silva Nobre*, *André Luis Gemal* and *Katia Christina Leandro* proposed to carry out a chronological review of the existing regulatory framework of Brazil about medical supplies under the health surveillance regime.

The creation of Anvisa, in the federal sphere, enabled the evolution of the norms regarding health not only involving medicines but also the so called "medical products", that may have medical, dental or laboratory use and that are intended for "prevention, diagnosis, treatment, rehabilitation or contraception" (p. 125).

The authors selected and classified the norms regarding medical supplies or products, including kits for *in vitro* diagnosis and equipment, in the chronological period comprehended from 1999 to 2015. From the systematization of those norms, it is possible to correlate and demonstrate in what frequency the subjects are published, the trends of themes and with this, the relevance given by health surveillance to every one of those subjects.

---

[1]Articles 6th, 196 and 200. BRASIL. *Constituição da República Federativa do Brasil de 1988*. Available at: <http://www.planalto.gov.br/ccivil_03/constituicao/constituicaocompilado.htm>. Date accessed: 13 Oct. 2017.

Special caution must be taken with imported materials, since the entry in the market of products of dubious origin or quality may put at risk the users and the professionals dealing with them. In response to this, the new technical regulation (2013) brings requirements that both, the national and foreign manufacturers, must comply with.

The emergence of the online tool Notivisa, in 2006, under the coordination of Anvisa, facilitated and systematized notifications, contributing to the improvement of the national regulatory set. The authors argue that the compulsory certification is an improvement driver for the products actually marketed.

II. Medicines *Recall*

The authors *Adirley Machado Alves* and *Elias Kallas Filho* present a comparative law study about the regulations and operation of medicines *recall* in Brazil and Portugal.

In Brazil, the withdrawal of a product from the market is the responsibility of the distributor and also of Anvisa, excluding the medicines already distributed. The burden ends up falling on the users, but they are assured to do it without any cost. In Portugal, the withdrawal of medicines is done with the end consumer, showing a legitimate concern with the citizens' health.

The major issue with the Brazilian system, remarked by the authors, is the lack of a centralized channel of information for the dissemination of medicines recall, like there is in Portugal. In Brazil, we do not have a similar centralized mechanism, and this obstructs enforcing the State to comply with its duty of protecting the citizens' health and their rights as consumers. Even if the manufacturer, the distributor and Anvisa itself, have rigorously met all the stages of the recall, they will not be completely fulfilling their obligation to inform as provided by the Brazilian consumer law. The consumer who purchased a medicine and did not have access to information about the recall, for a deficiency in the dissemination of information, may be using an inappropriate medicine or one that may damage their health.

III. The public and the private, patents and health: the study of fraud of pharmaceutical companies in Italy compared to the Brazilian legislation

The third article, authored by *Cristianne Maria Famer Rocha, Letícia Lassen Petersen* and *Lígia Daiane Fink dos Santos*, shows that, even in a profusely regulated area, as the pharmaceutical patents registration system, poor trading practices can subsist, that are damaging to the end consumer of the medicines, and also to the public health system. The authors bring to light an event occurred in Italy, where two large pharmaceutical companies registered, in different moments, different patents of the same chemical substance, resulting in medicines with distinct names and

purposes[2] – the former, for oncological treatment and the most recent, for macular degeneration. The "new" medicine, with a different prescription, started to be sold at an exponentially higher price than the previous one. Those companies in Italy were convicted for anticompetitive practices.

These pharmas' business strategy is clearly detrimental to the consumers and the national health systems. In that case in particular, the authors qualify the secondary patent as fraud, because, as the drug was already known, no additional investments in research and development were necessary that justified the price charged for the "new" medicine.

The authors warn about the fact that it is possible this strategy is being reproduced in Brazil with the same drugs, since these patents are registered in the National Institute of Industrial Property (INPI), in compliance with the international agreements in force (WTO TRIPS Agreement)[3]. Regardless of the "new" medicine not be listed on the National List of Essential Medicines (Rename), it may impact the public health system due to the increasing judicialization of orders for the supply of medicines.

Final considerations

In Brazil, the concession of drug patents depends on Anvisa's previous consent. On article 8 of TRIPS Agreement, we find as guiding principles of the international system for the protection of patents, the possibility of implementing "the necessary measures to protect public health and nutrition and to foster public interest" and also "the appropriate measures to prevent the abuse of intellectual property by their leaders". In this way, TRIPS Agreement lies very clearly the prevalence of the public over the private interest, of the collective over the individual, and, in the case of public health issues, explains the existence of two federal autarchies– INPI and Anvisa – for the analysis of the patents of pharmaceutical products.

INPI's guidelines, going beyond those provided by the TRIPS Agreement, include the possibility of protecting new applications of products already known, through a new patent. This practice is known as "evergreening"[4] or secondary patenting. In the evergreening mechanism, in which a new patent is requested for the same active ingredient, but intended for another purpose, the pharmaceutical company obtains an extension of the patent protection. The misuse of this benefit as a business strategy can lead to anti-competitive practices and delay the access of

[2]Avastin®, by Roche, and Lucentis®, by Novartis.
[3]About the application of TRIPS Agreement in Brazil in the área of medicines, see CHAVES, Gabriela Costa; VIEIRA, Marcela Fogaça; REIS, Renata. Acesso a medicamentos e propriedade intelectual no Brasil: reflexões e estratégias da sociedade civil. S*ur, Rev. Int. Direitos Human*., São Paulo , v. 5, n. 8, p. 170-198, jun. 2008.
[4]Alluding to the trees that do not loose the leaves in winter, remaining always green.

the medicine to the public dominion, hindering a greater dissemination as a generic drug, that has a lower cost for the consumer and the public health system.

There is a clear conflict between the pharmaceutical industry private interests – consubstantiated on a right of ownership protected by law and it is the INPI's duty to acknowledge the strength of the current international agreements– and the duty of the State of ensuring the right to health through the implementation of public policies of universalization of the access to medicines.

In the case of health related products, it is not enough to ensure the consumers rights, because that does not guarantee that the right to health is properly respected. Therefore, if, in the medicine recall system the information about the recall does not reach the consumer, the substitution of the product or the refund will be rendered ineffective, and the health of those users who still have the medicine at home, will be put at risk.

Our system has been constantly improved, as can be observed in the improvement of the control of medical products quality. Nevertheless, we can learn from the best practices in other countries, as for instance, the medicine recall unified information system from Portugal. At the same time, and without disrespecting the international agreements on patent protection, certain practices should be reviewed, that undermine the universalization of access to medicines in the health system, and harm the consumer, like the permission of evergreening. In health, the application and interpretation of the internal law and the international conventions need always be done in the light of principles of human dignity, assuring at the same time the right to health and full protection to the consumer.

References

CHAVES, Gabriela Costa; VIEIRA, Marcela Fogaça; REIS, Renata. Acesso a medicamentos e propriedade intelectual no Brasil: reflexões e estratégias da sociedade civil. S*ur, Rev. Int. Direitos Human*., São Paulo , v. 5, n. 8, p. 170-198, jun. 2008.

Daniela Trejos Varga – PhD in Civil Law by *Universidade do Estado do Rio de Janeiro* (UERJ); master in Constitutional Law by *Pontifícia Universidade Católica do Rio de Janeiro* (PUC-Rio); bachelor's degree in Law by PUC-Rio. Coordinator of the Bachelor's degree at *Centro de Ciências Sociais da PUC-Rio*; professor at graduation and post graduation at PUC-Rio; member of the *N*úcleo *de Direitos Humanos at PUC-Rio*. Rio de Janeiro/RJ, Brazil. E-mail: dvargas@puc-rio.br.