

Medication advertising in Brazil. Can it be regulated?

Propaganda de medicamentos no Brasil. É possível regular?

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Abstract *The regulation of medication advertising in Brazil has four weak points. Inspection and punishment of irregularities is carried out a posteriori to the infraction being committed (when the population has already been exposed to a sanitary risk). The fines charged by the Brazilian Sanitary Surveillance Agency (Anvisa) have a derisory value compared to investments in advertising. There is no mechanism that prevents fines from being transferred to prices. The phrase "If symptoms persist, consult your doctor", rather than warning about the risks of self-medication, encourages using at least the first medication without a prescription, advising a visit to the doctor only if symptoms persist. Anvisa data and academic studies reveal that 90% to 100% of advertising shown in the media contains irregularities. Thus, the Anvisa Collegiate Board of Directors Resolution 102/2000, which seeks to regulate the sector, makes up a system that benefits the infractor and keeps the population at risk. This work analyses alternative regulation, looking at advertising's previous compliance statute through the vigilance system; it studies international statutes and proposes an alteration in the structure of the current model, inserting the logic of sanitary risk prevention.*

Key words *Sanitary surveillance, Advertising Medication, Regulation, Media*

Resumo *A regulação da propaganda de medicamentos no Brasil incorpora quatro fragilidades. A fiscalização e punição das irregularidades cometidas são realizadas a posteriori do cometimento da infração (quando a população já foi exposta a risco sanitário). As multas cobradas pela Anvisa têm valor irrisório frente aos investimentos em publicidade. Inexiste um mecanismo que impeça que as multas sejam repassadas aos preços. A frase "A persistirem os sintomas o médico deverá ser consultado", em vez de alertar para os riscos da automedicação, estimula o uso pelo menos do primeiro medicamento sem receita, indicando a busca de um médico só no caso da permanência dos sintomas. Dados da Anvisa e estudos acadêmicos apontam que de 90% a 100% da publicidade exibida nos meios de comunicação contém irregularidades. Assim, a Resolução de Diretoria Colegiada 102/2000 da Anvisa, que procura regular o setor, se constitui em um sistema que beneficia o infrator e mantém a população sob risco. Este trabalho analisa uma alternativa de regulação, considerando o estatuto da anuência prévia da publicidade pelo sistema de vigilância; percorre estatutos internacionais e propõe uma alteração na estrutura do atual modelo, inserindo a lógica da prevenção do risco sanitário.*

Palavras-chave *Vigilância sanitária, Propaganda, Medicamentos, Regulação, Mídia*

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Introduction

Based on the weak points of the regulatory model for medication advertising directed at Brazil's general public, this article takes the following path:

1. It explains the concepts of marketing, medication, regulation and manipulation;
2. It analyses the monitoring of medication advertising for Brazil's general public, carried out by Anvisa;
3. It studies international legislation on pharmaceutical advertising;
4. It proposes an alternative to the Brazilian regulatory model.

The work seeks to answer two questions: 1) When the question is medication advertising, can it be regulated? 2) How can regulating medication advertising for the general public incorporate risk prevention logic? By proposing an alternative regulatory model, this article discusses the previous compliance statute of pharmaceutical advertising, as a way of overcoming the weak points witnessed today, considering that regulation of this type of advertising by national states is part of a set of attributes of national sanitary vigilance systems around the world.

As a form of mediation between production of goods and varied services and the health of the population, Sanitary Surveillance, according to Costa and Rozenfeld, "is the most complex form of existing Public Health, for its actions, of a fundamentally preventative nature, cover all medical-sanitary practices: promotion, protection, recovery and rehabilitation of health", acting on "risk factors associated to products, raw materials and services related to health"¹.

Still according to the authors, the actions of Sanitary Surveillance are inserted in the scope of social relations of production and consumption, where the largest part of the health problems that the state should interfere in originates: ***Such problems may come from flaws, or defects, at some point of the production chain, or intentional transgressions by manufacturers, traders or service providers. Thus, there is a need to regulate the relations of production and consumption, the consumer's vulnerability is recognized and instruments to protect the health of the entire collective are created.***

Recent studies developed by Nascimento² and Soares³ demonstrate the existence of a significant weak point in the regulatory model for medications advertising in Brazil. By analyzing 100 pieces of medication advertising and comparing the content of these advertisements (images, text and therapeutic indications of each product) with the re-

quirements of the legislation that regulates the practice of pharmaceutical advertising – Collegiate Board of Directors Resolution (RDC) 102/2000 of the Brazilian Sanitary Surveillance Agency (Anvisa), Nascimento concludes that all 100 pieces infringe at least one article of the regulations, with the average per piece surpassing four infractions².

After analyzing 6,002 pieces of advertising, Anvisa itself declared that "90% of the medication advertising pieces present irregular information, which contributes to the disinformation of professionals and consumers"⁴.

In the study developed by Nascimento, he concludes that Anvisa RDC 102/2000 presents substantial weak points in at least four aspects:

1. The Resolution incorporates a regulatory action model with initiatives that are made ***a posteriori***, that is, only after the piece of advertising has been transmitted, when the population has already been submitted to a sanitary risk. Thus, the regulatory action does not consider the importance of prevention.
2. The fines gathered have a derisory value compared to the total expenditure on advertising made by the regulated sector, which turns punitive action into a mere formality.
3. There are no mechanisms that prevent these derisory values collected by agency fines from being transferred by the regulated sector to the price of medications paid by consumers.
4. By making it compulsory to insert the phrase "If symptoms persist, consult your doctor" in each advertisement, the current regulatory model encourages at least the first incorrect, unaware or irrational consumption of medication.

According to the author, the logic contained in the regulatory model plays an inestimable role for industry, communication and advertising companies, and the medication trade, and does not contribute to minimizing the exposure of society to risk. The current model only serves to give an appearance of regulation, which does not exist in practice.

Marketing, medication, regulation and manipulation

For Philip Kotler and Gary Armstrong^{5,6}, the main task of marketing is to attract new clients and keep the existing ones, reaching profit growth for the company. For them, marketing must identify, assess and select market opportunities, as well as formulate strategies to capture these opportunities. According to them, the development of any industrial sector must consider the fact that, now and in

the future, good companies satisfy needs, while excellent companies create markets. "Taking good care of clients", in modern marketing's view, is an essential factor for elevating market share and increasing profits.

Kotler and Armstrong cite examples such as that of Coca-Cola, the owners of which know that Americans place 3.2 ice cubes in a glass (...), while the Abbott Laboratory discovered that one in every four people has a dandruff problem. In the same line, the pharmaceutical industry knows that, every year, 52 million aspirins and 30 million sleeping pills are consumed. According to them, the companies know that, every year, in the United States 650 million dollars are spent every 12 months on anti-acids.

To analyze how marketing strategies are used in the pharmaceutical area, we turn to Shenkel⁷, who defines medication as a substance or preparation, elaborated in a pharmacy or pharmaceutical industry, which meets technical and legal specifications with a view to guaranteeing consumer safety, being similar in all countries. It aims to diagnose, prevent, cure illnesses or relieve their symptoms. The author explains that, when using medications, it is important to be clear about what action to expect. The component responsible for the medication's main effect is called *pharmacon*, active ingredient or active substance. Apart from the component responsible for the main effect, others are needed to arrive at the final product, formed by the *pharmacon* plus the excipients. A same medication can be commercialized under many brand names and by various different companies. The expression "brand name" has nothing to do with the chemical or pharmaceutical characteristics of medications. The brand is created in order to fulfill the function of identifying a certain product, being thus one of the fundamental instruments of medications advertising.

As brand names are the ones currently used in advertising campaigns, most people do not know the active ingredient present in that specific medication. Many industries, distributors, advertising agencies, media outlets and retailers skip one of the legal requirements (the obligation to show the medication's counter-indications in the advertising piece) and show only the message that the product is "counter-indicated for people with a hypersensitivity to the formula's components". As these components, as well as their risks, are unknown to the majority of the population, the risk of self-medicating with a dangerous product remains.

In his thesis "Globalization and sanitary regulation: the directions of Sanitary Surveillance in Bra-

zil", Lucchese⁸ states that depending on the efficiency of sanitary controls, we can have thousands of products put up for consumption the quality, efficacy or safety with respect to health of which is questionable. Some contain substances the cost-benefit relation of which is narrow and which could only be used in a rational manner by those who really need them, with the risk of generating problems as dangerous as those which they could help resolve, as is the case with medications. Many contain substances – used in their processing – that are potentially toxic and that can only be consumed in specific concentrations. Other substances have a cumulative effect and generate chronic problems with constant use; while the toxicology of others is not perfectly known⁹.

With the aim of balancing marketing acts with correct usage of medication policies, various countries have been trying to regulate these actions. The term *regulation* has been the object of an intense global debate, with various lines of thought resting on a theme that has been growing in complexity, accompanying the process of economic globalization and the gradual substitution of traditional state control structures with entities with a new legal-judicial form, generally identified as regulatory agencies. In this work, we chose to adopt Boyer¹⁰'s definitions, considering the term *regulation* as a contract of adherence to a common set of norms (technical, ethical, moral, legal, economic, etc.) capable of reflecting the stage of development of that social group in the sense of overcoming or minimizing contradictions between the economic structure and the legal, political and social superstructure. Thus, regulation will be analyzed in this study as an instrument in search of overcoming distortions that arise in the course of a process of accumulation within capitalist societies.

The term (social) *manipulation*, according to Bobbio¹¹, indicates a series of relations that are distinguished by a marked difference between the active and intentional character of the manipulator's action, which aims to transform the behavior of the manipulated, and the passive and unconscious character of the latter's behavior. Still according to the author, in Social Manipulation the manipulated subject doesn't know that he is being manipulated and believes he is freely making a decision, while his behavior is, in reality, maneuvered by the manipulator. Especially in relation to Information Manipulation, the author says the simplest example is the lie. Besides the lie, suppression of information is another generic technique of Informative Manipulation, according to the author. Suppression of information does not involve lying;

simply, some news, interpretations or evaluations are not published. In this case, Manipulation restricts the base of knowledge, interpretations and evaluations that the receivers of information could dispose of and, consequently, it limits the choice alternatives that are offered to him, both in terms of belief and behavior.

The regulation of pharmaceutical advertising in Brazil

The regulation of medication advertising in Brazil has its first rules published as part of Law 6,360 of 1976, regulated by Decree 79,094 of 1977. In the year 2000, Anvisa publishes Collegiate Board Resolution (RDC) 102/2000¹², which updates and reaffirms various legal determinations that already existed. A notable part of the Resolution is the requirement for stating, in Portuguese, in a clear and precise manner, the medication's main counter-indication. The rule prohibits, in advertising, making comparisons that are not based on information proved by clinical studies portrayed in registered publications; the practice of provoking fear, anxiety or suggesting that a person's health will be or could be affected for not using the medication; attributing curative properties to the medication when it is intended – as registered in Anvisa – only for symptom control and the control of chronic illnesses. Advertising also cannot suggest the absence of collateral or adverse effects, or use expressions such as: “innocuous”, “safe” or “natural product”.

In the chapter regarding medications not requiring a prescription (the only ones that can be advertised to the general public), RDC 102/2000 prohibits including messages of any kind directed at children or teenagers, “as well as using symbols and images for this purpose”. The rule also forbids using language linking use of the medication to physical, intellectual, emotional or sexual performance or a person's beauty; as well as suggesting that the medication has organoleptic characteristics such as “flavorsome”, “tasty” or equivalent.

The Medication Advertising in Brazil Monitoring Project

Anvisa initiates the actions of the “Medication Advertising Monitoring Project”¹³ in 2002, with the purpose of supervising compliance with RDC 102/2000. The project is implemented through agreements between Anvisa and 14 universities. Up to 2004, 6,002 pieces of advertising are collected (54.6%

of them regarding freely-sold medication and 45.4% to prescription-only). Most registered infractions (20.5%) were related to not making the compulsory statement of the advertised product's main counter-indication, followed by the product lacking registration (15.3%), suggesting an absence of adverse effects (10.2%), messages that the product had been “approved” or “recommended” by specialists (10%), suggesting a lesser risk (9%) or making comparisons with no scientific basis (8.8%)¹⁴.

One fact draws attention in the agency's first examination. Even after a wide-ranging debate on the theme and a Public Consultation process that brought together participants from all sectors involved with the question, four years after RDC 102/2000 came into effect, one in five pieces of advertising does not present the product's main counter-indication. And one out of every five advertising pieces aimed at prescribers (for prescription medications) did not contain the precautions and warnings required by law.

Still according to the Partial Results presented by the Agency, 34% went to medication that did not require a prescription and 66% went to prescription-only medication. Anvisa also informs that, according to Law 6.437/77, the values of the fines applied must follow a criteria of light (R\$ 2 million to R\$ 75 thousand), serious (R\$ 74 thousand to R\$ 200 thousand) or extremely serious (R\$ 200 thousand to R\$ 1.5 million).

In 2003, 97 fines were applied in irregular medication advertising lawsuits in Brazil, in a total of R\$ 3.129 million; with R\$ 700 thousand of this being registered in the Union Active Debt. The following year (2004), the highest total volume of fines (222) was applied, totaling R\$ 6.342 million. Effectively, considering the marketing expenditure – relative to 2006 – announced by the Brazilian Pharmaceutical Industry Federation (Febrafarma) itself, R\$ 978.9 million went towards the “Marketing”¹⁵ sector that year. Comparing the value planned for marketing expenses by the industry in 2006 with the fines applied by Anvisa during all of 2004, when the highest volume of fines occurred and they reached R\$ 6.343 million, it can be concluded (even considering that the dates do not exactly coincide) that the punishment of irregularities committed by pharmaceutical advertising equals little more than 0.6% of the sector's annual marketing expenditure.

Research carried out in the same period that Anvisa was doing its monitoring diagnosed that among the main irregularities found in 100 pieces of medication advertising called free sale – gathered

from the media outlets of Rio de Janeiro and Juiz de Fora in 2003 – there was also noncompliance with article 3, Item I, of RDC 102/2000 (which requires the advertisement to state clearly and precisely the main counter-indication of the advertised medication) in no less than 94% of the items gathered. Apart from this infraction, the research found noncompliance, in 52% of the items, of article 10, Paragraph IV of the same Resolution (which prohibits the advertisement to suggest or stimulate diagnosis, advising corresponding treatment)¹⁶.

According to the author, whether in relation to the magnitude of irregularities (100% of the universe analyzed indicates at least one type of infraction) or in relation to the low efficacy of the regulating actions (few advertisements taken off the air and negligible values of the fines applied), the reality of the sector shows that it is not only more rigorous supervision that is needed. The question is broader and is located in the very way that the existing regulating model is structured. Even if Anvisa multiplied its actions many times, the irregular advertisements would continue to be repressed *a posteriori*; the fines would continue to have derisory value; their costs would still be transferred to the costs of medications (and paid by consumers) and the warning placed at the end of each advertisement would continue to stimulate the incorrect use of medications, without a proper prescription.

On the other hand, proceeds Nascimento, it is not an exaggeration to conclude that, from the advertising point of view, to transmit information about risks and possible aggravations is seen by medication marketing as counter-advertising the product. The arguments used most in the advertising analyzed highlight especially the efficacy, the safety, the well-being, the ease of use, the speed of action of the medication, as well as the good humor, pleasure, energy and happiness that they bring, minimizing, or simply excluding, any reference to risks, possible medication interactions or counter-indications. These, when they do appear, are generally shown in minuscule letters, which appear very quickly, in most cases stressing only that that specific medication is *counter-indicated for people with a hypersensitivity to the formula's components*, not determining which demographic groups should not take the medication, such as the elderly, children, diabetics, people suffering from hypertension and others.

The weak points of RDC 102/2000 were also identified by the teams that participated in the Anvisa Monitoring Project themselves. For Soares³, the general results of the Advertising Monitoring

Project for products subject to sanitary vigilance, in its two stages, confirm that there is still an inadmissible situation for the present moment, considering all the knowledge available about the sector, as well as the countless reflections, proposals and recommendations made by the professionals and sectors that defend the health of the Brazilian population¹⁷.

She says that according to existing sanitary legislation and the Consumer Defense Code (...), practically all advertisements analyzed in the area of Niterói and its surroundings over the year can be classified as misleading and/or abusive advertising, according to the definition contained in Art. 2 of Anvisa RDC 102/00.

International statutes that regulate pharmaceutical advertising - the example of the European Union

One of the international standards most used by the countries that opted for regulating advertising and promotion of pharmaceutical products is the "Ethical Criteria for Medicinal Drug Promotion" from the World Health Organization¹⁸, approved at the 41st World Health Assembly, based on the Conference of Experts on the Rational Use of Drugs, held in Nairobi in November 1985.

In the search to improve the quality of sanitary care of UN member countries, through the rational use of medication, the WHO advocates, in paragraph 14 of the "Criteria", directed specifically at medication advertising for the general public, that "the advertisement must contribute to the population being able to take rational decisions on the use of medications that are legally available without prescription. Even if they consider the legitimate right of citizens to obtain information that is of interest to their health, the advertisements must not take improper advantage of people in this respect".

Based on WHO criteria, the 27 countries that form the European Union (EU)¹⁹ regulate medication advertising in two statutes. The first is Directive 84/450/CEE, of September 10, 1984, which deals with "the legal, regulatory and administrative provisions of member states in relation to misleading advertising"²⁰.

When it determines that member states take measures towards prohibiting non-ethical advertising, the EU Council justifies creating these directives because it believes that "misleading advertising can lead the consumer, when he acquires good or uses services, to take decisions that are harmful to him" and for this reason it is necessary to impose limits "for a policy of protection and infor-

mation of consumers”, which sets out “appropriate measures directed at protecting the consumer against misleading and dishonest advertising”.

The need to harmonize national provisions dealing with consumer protection led the European Union to consider that, “in certain cases, it may be desirable to forbid misleading advertising even before it is made public”, leaving, however, each member state the choice to “adopt regulation that plans the prior and systematic control of advertising”.

In relation to the self-regulation of advertising, the directives consider “that the voluntary controls carried out by autonomous bodies to suppress misleading advertising may avoid recourse to legal or administrative action and should, therefore, be encouraged”. The text defines as “misleading any advertising that, in any way, including its presentation, induces error or is susceptible to inducing error in people to whom it is directed or that it affects, and whose economic behavior it may affect, as a result of its misleading character”.

To determine if advertising is misleading, the Directive considers some elements and indications of the advertised product or service, including *the characteristics of the goods or services, such as availability, nature, execution, composition, manner and date of manufacturing or service, adequate nature of uses, quantity, specifications, geographical or commercial origin or the results that can be expected from its use, or the results and essential characteristics of the trials or controls carried out on the goods or services; as well as information regarding “the price or its form of use and the conditions of supply of the goods or rendering of the services*.

Article 4 of the Directive determines that member states will ensure “adequate and efficient ways to control misleading advertising in the interest of consumers, as well as competitors and the public in general”, with each state being responsible for deciding which instruments should be applied – considering the legal or administrative channels – with a view to “order the cessation of misleading advertising or start adequate procedures with a view to make this advertising stop” or “prohibit this advertising or start adequate procedures with a view to ordering the prohibition of the misleading advertising, when it has not yet been made public, but when its publication is imminent”.

The second Directive dealing with the theme is 2004/27, of March 31, 2004²¹, which updates Directive 2001/2001/83²². Also approved by the European Parliament and by the EU Council, it creates the Community Code Relating to Medicinal Products for Human Use.

Title VIII of the Directive deals specifically with

medication advertising activity. Article 86 defines medication advertising as “any action of information, search, supply, sale or consumption of medication”, which covers *especially, medication advertising to the public in general, medication advertising to people qualified to prescribe it or provide it, the visit of advertisers to people qualified to prescribe or supply medications, the supply of medication samples, the encouragement of prescription or supply of medications through the concession, offer or promise of pecuniary benefits or in kind, except when their intrinsic value is insignificant, sponsorship of promotion meetings attended by people qualified to prescribe or supply medications, especially in events where the respective expenses for travel and accommodation are the responsibility of its promoters*.

The Directive considers that “the provisions relative to the information of sick people must guarantee an elevated level of consumer protection, so as to allow the correct use of medications, based on complete and understandable information”. But in initial considerations, the Directive determines that “even advertising to the public in general of medications sold without a prescription could affect public health if excessive and unreflected”; and for this reason “such advertising, when authorized, must, therefore, meet certain essential criteria”.

Article 87 of the same statute determines that the advertising message must “instigate the rational use of medications, presenting them in an objective way and without exaggerating their properties”, as well as “not being misleading”. Specifically in relation to advertising medication made for the general public, Article 88 of the Directive stresses that “member states prohibit advertising to the public in general of medications that a) can only be obtained with a medical prescription; [...] and b) contain substances defined as psychotropic or narcotic by international conventions, such as the United Nations Conventions of 1961 and 1971”.

In the chapter referring to “Information and Advertising”, the Directive determines that *all advertising of a given medication to the public in general must: a) be conceived so that the advertising character of the message is evident and the product is clearly identified as medication; b) include, at least: the name of the medication, as well as the common denomination, if the medication contains only one active substance; the information essential for the adequate use of the medication; and an explicit and readable invitation to careful reading of the directions for use or external packaging depending on the case*.

Article 90 establishes that “advertising of a given medication to the public in general cannot in-

clude any element that a) can render medical consultation or surgical intervention superfluous, namely through suggestion of a diagnosis or advocating a treatment" [...]; "b) suggests a guarantee of the medication's effect, without adverse reactions, with results superior or equivalent to those of another treatment or medication"; "c) suggests that a person's normal state of health could be improved through use of the medication"; "d) suggests that a person's normal state of health could be damaged if the medication is not used" (except in the cases of vaccination campaigns); "e) is exclusively or mainly directed at children"; "f) refers to a recommendation made by a scientist, a health professional or a person who, although not a scientist or health professional can, through their notoriety, encourage the consumption of medications"; "g) treats the medication as food, cosmetic product or any other consumer product"; "h) suggests that the safety or efficacy of the medication is due to it being a natural substance"; "i) can induce, through a detailed representation of anamnesis, a false self-diagnosis; and "j) uses in an abusive, frightening or misleading way visual representations of alterations in the human body caused by illnesses or lesions, or of the action of a medication on the human body or parts of the human body".

Article 97 of Directive 2004/27 determines that "the member states will guarantee adequate and efficient means for the control of medication advertising", clarifying that *these means, which may be based on a prior control system* (our emphasis), *must always include provisions where people or organizations that, according to national legislation, have a legitimate interest in prohibiting the advertising incompatible with the present title, may take legal proceedings against this advertising or submit this advertising to the appreciation of a competent public body, either to study the complaints or to proceed with appropriate legal action.*

Based on what is advocated by the WHO and the European Union's two directives, the prior authorization of medication advertising to the general public is already adopted in countries like Spain, through article 22 of the Royal Decree no. 1416/1994. It determines that advertising messages directed at consumers, in any mass media outlet, will require prior authorization from the sanitary authorities, with this authorization being limited to five years²³.

In France, all advertising directed to the general public is also subject to prior analysis and authorization. The authorization is granted following a report from the commission responsible for advertising control.

The United Kingdom, for its turn, through the Medicines and Healthcare Products Regulatory Agency (MHRA), demands prior authorization for the advertisements of products that have recently been licensed, are subject to intensive monitoring or products that have been reclassified as free sale and the sale of which previously required a prescription.

In Switzerland, prior authorization is required for all medication advertisements on TV and radio. And when these advertisements are displayed in newspapers, magazines, leaflets, posters and audiovisual media, including the Internet, prior authorization is required when they deal with painkillers, tranquilizers, sedatives, laxatives and medication for anorexia.

Even in countries that are not part of the European Union, as is the case with Australia, medication advertisements directed at consumers require prior authorization (granted for two years) when they are transmitted by TV, radio, newspapers, magazines, billboards and in movie theaters.

Mexican legislation, for its part, through chapter II of the General Health Law Regulation in Advertising Matters, requires all advertising of medications and medicines of a vegetable origin directed to the general public to be submitted to prior authorization. In Ecuador, permission is also needed in order to transmit medication advertising to the general public.

Even in the United States and Canada, prior approval is needed in the case of transmitting information that is not widely published in medical literature, or when the use of the medication may cause serious damage to health. In these two countries, sending the sanitary authorities the medication advertisements for the general public is encouraged for a pre-analysis, but this is not compulsory. In Canada, the advertisements are only reviewed by the sanitary authority when they are denounced by consumers.

Conclusion

As can be seen, in several countries medication advertising, as it presents a risk for the collective depending on how it is produced, goes through a prior examination by the state. In these societies, the collective interest is placed above the interests of industrial corporations, advertisers, media and commerce.

By incorporating the question of citizenship to this debate, we can conclude that there are significant weak points in the model of medication advertising regulation in Brazil, originating and manifesting themselves in the following points:

1. The National Sanitary Vigilance System does not seem capable to ensure the fulfillment of its primordial function, which is to protect society from the sanitary risk provoked by the irregular advertising of medication.

2. The Monitoring Project developed by Anvisa's Advertising Management (GPROP) serves only to create an appearance of regulation, which does not exist in practice.

3. The persistent irregularities committed by the sector denote that the current legislation errs by advocating regulation done *a posteriori* to the sanitary offence being committed.

4. The punishments established by the current regulatory model are mild in relation to the seriousness of the offence, not representing any damage to the infractor.

5. Due to the absence of an efficient mechanism, there are no impediments that prevent even the derisory fines applied to infractors from being transferred to the prices of pharmaceutical products, placing a burden on the consumer.

6. What the current regulating model has effectively been able to "impose" on the regulated sector is the display of the phrase "If symptoms persist, consult your doctor", a text that encourages at least the first consumption, through the dangerous practice of self-medication, as it advocates going to a prescriber only after the first use of the pharmaceutical product.

Considering various international statutes, it can be concluded that there are viable solutions for overcoming the deficiencies seen today in the regulatory model for medication advertising for the general public in Brazil. Establishing prior advertising of the advertisements, for example, fulfills the strategic function of preventing the risk to which society may come to be exposed.

In this sense, a debate is imposed on this initiative, which incorporates a sanitary character and imposes the logic of promotion and prevention on a sector fundamental to public health, that of correct and rational use of medication.

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Artigo apresentado em 21/10/2008

Aprovado em 03/12/2008

Versão final apresentada em 21/01/2009