

Sanitary surveillance: recollection of medications in Brazilian legislation

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Abstract The article derives from exploratory and transversal research that gathered data on recollection of medications, action foreseen in the Brazilian sanitary legislation that must be adopted by enterprises in cases of registration cancelling or deviation on the quality of products. The study was conducted between March and October 2005, and this article describes its outcomes from four key-cases, which provided elements for discussion by highlighting the kind of procedure adopted in each. Data show that out of 57 recollection cases started in the period, 22 took place voluntarily (38.6%), six due to registration cancelling (10.5%), and 29 by Anvisa's determination (50.9%). Those 35 featured as non-voluntary (29+6 cases) represented 61.4% of total, regarding which the State was forced to intervene. The discussion uses the principle of beneficence, ethics of protection, responsibility, and the bioethics of intervention. It concludes by indicating that, although there is regulation for voluntary recollection of Revista Bioética 2010; 18(3): 623 – 35 634 medications, this procedure requires responsible intervention by the regulatory agency, aiming at higher good: to benefit and to protect people. It considers that State intervention is ethical in these cases.

Key words: Bioethics. Drug and narcotic control. Health surveillance. Social vulnerability. Beneficence. Liability legal. Social responsibility.

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The principlist bioethics presented by Beauchamp and Childress ¹ describes a principle of beneficence as an action taken on behalf of others, a concept that refers to ethical obligation to maximize benefits and minimize losses. When talking about an act that aims to benefit "others", it is possible to imagine two actors - one who acts with the purpose of benefitting someone and that who is favored by the act. In this sense, it is inevitable to set up the role of superiority of who can act in favor of the other who, by his own condition, already falls in a weaker position. It is from this optics that can be seen the vulnerability of certain individuals, when faced with certain conflicts that may need protection.

The adjective *vulnerable* contains a series of possible interpretations, such as: *the weakest side of a subject of question* or *the point through which someone may be attacked, harmed or injured*. According with such interpretations, the usual meaning of vulnerability leads to the context of *fragility, non-protection, disfavor* and even *desertion* or *abandonment* ². This concept, therefore, encompasses several forms of exclusion of population groups, and the word vulnerable, related to the deviation of medications quality. may reach wide population groups regardless of their social class, acquisition power or intellectual knowledge.

It is useful to incorporate to this study the ethics of protection, an aspect of bioethics which seeks to provide the moral conflicts and dilemmas faced by public health in Latin America, which are not resolved with the tools of the traditional bioethics, particularly

by the principlist bioethics ³. The protection, applied to public health, the second, according to Schramm and Pontes ⁴, requires the specification of what needs to be protected, who should protect and whom protection is aimed to, making it therefore operational.

Leaving the vision preferably individual, reflected by the concepts of benefit and protection, we arrive to the ethics of responsibility, advocated by Hans Jonas, which, according to Zancanaro ⁵, is an acting that precipitates itself to the action and not as a charge or imputation of an already happened act. The moral responsibility, or ethics of the future, is part the sphere of our *power* and *doing*, since the decision defines the space of action in relation to the other and to the fragile as prevention. According to Costa ⁶, Jonas reflects on the importance of valuing the concept of risk and the need of the scientific community to face it with more responsibility; researchers and professionals should, besides informing, safeguard people from possible situations of predicted risks

According to the recent Universal Declaration on Bioethics and Human Rights, UNESCO ⁷, ratified in Paris on 1/19/2005 by acclamation from 192 countries, the social bioethics becomes definitely a part of the public agenda of the 21st century. In this line of ideas, Latin American researchers have been working for a few years with new proposals for bioethics, more focused on daily and collective conflicts in peripheral countries in the southern hemisphere. Accordingly, emerges the proposal of the so-called bioethics of intervention, that defends as morally justifiable, among other aspects, the prioritization - in the public and collective field - of policies and decision making that favor the largest number of people, for the largest possible space of time, bringing better consequences for the whole community, even with prejudice to certain individual specific situations. In the private and individual field it advocates the search for viable solutions and practices for conflicts identified with the context where they occur. Thus, this new proposal suggests a concrete alliance with the historically most fragile side of the society, including the reanalysis of different dilemmas, including: autonomy versus justice / equity; individual benefits versus collective benefits; individualism versus solidarity; omission versus participation; superficial and temporary changes versus concrete and permanent transformations ⁸⁻¹⁰.

In this study, the individual foci, represented by the principle of beneficence and by the protection ethics, and collective, by the ethics of responsibility and by bioethics of intervention, will be adopted to analyze the compliance with the legislation related to the collection of medications. It was contextualized an approximation with ethical issues through the accountability of the company to the benefit of consumers, in addition to the protective action of the state, that holds the power of intervention as the legislative body, regarding the recollection of medications and the pharmaceutical industry.

Sanitary surveillance and recollection of medications

Sanitary surveillance is understood in Brazil as a set of actions that can eliminate, reduce or prevent risks to health and intervene in the sanitary problems arising from the environment, production and circulation of goods and provision of services of interest to health ¹¹.

In 1999, it was established the National Agency of Sanitary Surveillance (Anvisa), with the mission of protecting and promoting the health of the population, guaranteeing the sanitary safety of products and services and participating in the construction of their access. Its competencies include: regulate, control and inspect products, substances and services of interest for health and work in special circumstances of risk to health ¹².

The subject under study, *recollection of medications*, is an action provided for in the sanitary legislation since the publication of Law 6360 of September 23, 1976¹³. This procedure, seen as a corrective action imposed by the regulatory body or voluntarily adopted by the companies, had no specific technical regulation and was being practiced on a non-standardized way.

The recollection of medicines refers to the act of withdrawing from the market a product that was made available for consumption, but that later showed a suspicious or confirmed deviation of quality that can pose a risk to the population's health. This action should also be applied to cases where Anvisa determines the cancellation of registration related to problems of safety and effectiveness of the medication.

The term *quality deviation* can be used to make reference to any removal of the established parameters to ensure the safety and efficacy of products, as well as aspects related to the consumer rights. Each medication must follow the parameters and specifications described in official compendiums and scientifically proven studies, whose data are entered in the registration process. All processes for medication registration are analyzed by Anvisa and the commercialization of products is linked to the publication of the approval in the Official Gazette (DOU).

It is possible to classify the actions of recollection in two modes: the voluntary and that determined by the sanitary authority. The action of voluntarily recollection and the one adopted by the manufacturing company, which recollects from the market the products with suspicion or detection quality deviation. The recollection determined by the sanitary authority and that imposed on the holder of the registration of the medication, considering insufficient evidence of deviation or at the time of the cancellation of the registration related to safety and efficacy. Anyway, the medicines recollection is an obligation of the company, clearly established in the sole paragraph of Article 144 of Decree 79.094/77 ¹⁴, which states that the company, being aware of the undesirable change regarding public health, is obliged to undertake immediate withdrawal of the product from consumption, under the penalty of committing a sanitary and penal infraction.

With the objective of monitoring and standardizing the actions for recollection, Anvisa, through the Management of Quality Monitoring, Control and Inspection of Raw Materials, Medicines and Products, started in 2003, the elaboration of a technical regulation applied specifically to the cases of recollection of medicines. This initiative

was motivated by the precariousness of the recollection actions, lack of uniformity of procedures, the need to establish criteria based on sanitary risk and lack of information available to the population.

Accordingly, in the years 2003 and 2004 two public consultations were published^{15, 16} in the Official Gazette, procedures that granted the population and the regulated sector the opportunity to forward criticisms, suggestions and proposals for the amendment to the new regulation that was intended to be published. Whereas many legal devices, the regulation for the collection procedures was published on 03.21.2005, by Resolution of the Board - RDC / Anvisa 55 of March 17, 2005¹⁷. This RDC establishes the minimum requirements relating to the communication of cases to the competent authorities and to consumers, as well as the implementation of the action of medicines recollection for cases of deviation from quality and cancellation of the registration regarding problems of efficacy and safety. The main focus of the resolution is the voluntary recollection of medications, with the maintenance of the right by Anvisa at any time, to determine the recollection of medications that represent an imminent risk to the health of consumers. Although in many circumstances and cases Anvisa has its actions based on preventative activities, in some specific situations it is defined what is called "police power" of the Agency, to intervene in public defense of the collective well-being¹⁸.

Recollection of medicaments and bioethics

The withdrawal of medications from the market is a necessary practice since the quality deviations compromise not only the effectiveness of products but, depending on the nature of the deviation, the type of product and its indications, also to the health and the life of consumers. It is important to consider that in most cases the population becomes vulnerable to the extent that visually many deviations are undetectable. Issues related to the content of active ingredient, dissolution and purity of formulations, for example, they can only be identified through methods and laboratory instruments. In this sense, that manufacturers and regulators, the entities that hold the technical and operational capability to control products quality, must act in a responsible way to the benefit of the population that often needs to be protected through interventions by the State, in view of their vulnerability.

From the standpoint of protection, it is the responsibility of the State to ensure that the population has access to quality medicines, with the desired and necessary effects to the promotion and protection of health. The ethics of protection is understood as a specificity of ethics of responsibility, appropriate to the approach of moral problems related with public health. It is an ethics of social responsibility, in which the state should be based to assume its sanitary obligations for human populations¹⁵. From the point of view of ethics of responsibility, it is possible to affirm that the company is no longer responsible for an individual act, but the author of an act with collective consequences. The responsibility reflects on the collective dimension, since Agent, act and effect are no longer the same¹⁹. Thus, it is possible to raise some assumptions In this work, including the relationship between the sanitary surveillance actions and the recollection of medicines, with bioethics searching with this theoretical-practical tool, to minimize the situation of vulnerability to which are exposed the individuals who would use medications with quality deviation. The indicators to be worked will be:

- a. the principle of beneficence and protection ethics: they refer to the individual character of discussion; both the State and the companies have the ethical obligation to maximize benefits, and minimize losses and protect the vulnerable people, which in the case of deviation of quality of medications, and condition that extends to the entire population, without restrictions of social class, intellectual knowledge or purchasing power;
- b. ethics of responsibility and bioethics of Intervention: concepts that refer to accountability of the pharmaceutical industry that, strictly speaking, could not release for consumption medications not complying with the established quality parameters. At the same time, the State cannot exempt itself from its responsibility in the elaboration of standards and to intervene in the fulfillment of the legal requirements seeking the benefit of the population.

Method

The study was the exploratory and transversal type, developed in two stages. The first evaluated, comparatively, from the Anvisa's database, the amount of recollection procedures performed voluntarily by the companies and the amount of procedures performed by determination of Anvisa. Data were collected from 03.21.2005 (the date of publication of the RDC / Anvisa 55) and 10.31.2005 (the date of finalization data collection). Subsequently, it was developed a documentary analysis seeking to identify the cases of recollection ordered by Anvisa that could have been voluntary, in view of the previous knowledge of the deviation by the company.

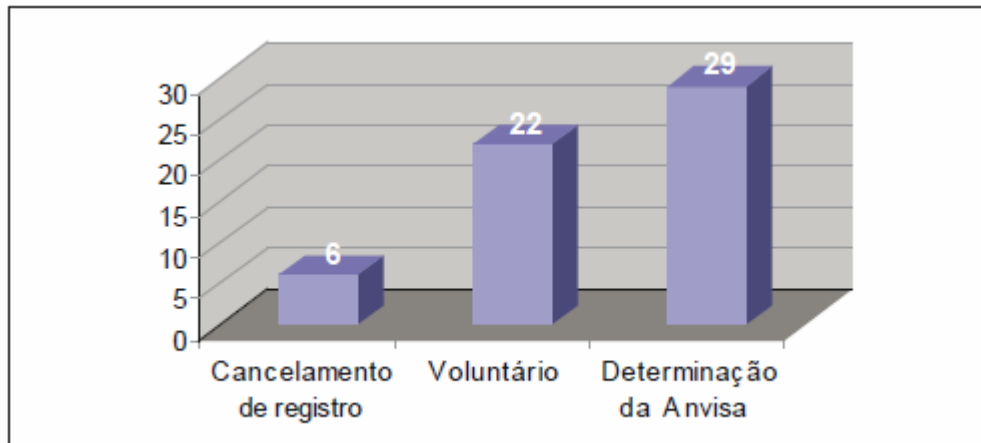
The sources of information considered were the announcements from the companies and notifications issued by Anvisa two documents required to start a recollection at the national scope. Data collection provided subsidies for an initial bioethical reflection focused on the actions taken by the companies: the voluntary aspect of actions, the commitment to public health and the fulfillment with the legal requirements and determinations by the regulatory body.

The analysis of collected data allowed to initially identify some patterns of procedure regarding the recollection of medications. We selected four specific cases for convenience, according with the research objectives in order to illustrate different motives and types of initiative. These models are designed to equip the reader to discuss and reflect on some concrete situations.

The survey of cases of recollection of medicines

According to data available at Anvisa considering the period from 3/21 to 10/31/2005, were identified 57 cases of recollection of medicines, six of which occurred due to cancellation of registration (10.5%), 22 by the initiative of manufacturers (38.6%) and 29 by determination of the regulatory agency (50.9%) according to Figure 1. Among the 29 determined by Anvisa, it was possible to identify 20 cases that could have happened by the initiative of the manufacturers, since they had previous knowledge of the deviation at the time of the performance of the study. The six registration cancellation cases, determined by Anvisa after inspections and investigations, were due to problems related to security and effectiveness of medications.

Figure 1. Number of recollection of medications according to the type of procedure . Anvisa, 3/21 to 10/31/2005



Registration Cancellation Volunteer Determination by Anvisa

Source: Research by the authors

Description of concrete cases

We selected four specific cases related to the recollection of medicines: the first one, volunteer, carried out before the publication of RDC 55/05, showed that the company fulfilled its obligation to recollect a medication considered unsatisfactory; the second one, occurred identically, but after the publication of the resolution; the third one, showed the need for intervention by the Agency in the recollection; and the fourth one describes a case of cancellation of registration.

Case 1. Voluntary recollection of an Intravenous product considered unsatisfactory by the manufacturer itself that, when conducting routine testing, has identified a quality deviation that could compromise the effectiveness of the medication. The product is used in treatment for children and adults of various types of malignant tumors, including brain, under high risk. The result of the recollection was only of 2.98% from total distributed; the company stated that this was the whole amount available at the time of the recollection. Investigative, corrective and preventive measures presented in the company's reports were considered satisfactory. Although the recollection was voluntary, the monitoring by Anvisa was in the sense of requesting additional actions and information, establishing deadlines and demanding the accomplishment of the imposed determinations. Whereas several legal provisions, the Agency intervened booking the company for not ensuring the quality and the safety of the medication, a fact that exposed the population to a risk that could have been avoided by a more rigid quality control . It is worth mentioning that the sanitary measures in relation to the population that made use of the medication were adequately taken by the Agency.

Case 2. Voluntary recollection of voluntary of an antineoplastic product in the form of gelatinous capsules, in which the company has detected a certain deviation classified as Class III, i.e., a slight risk, according to the definitions of RDC 55/05. The procedure reached the recollection of 27.21% of the batch of the medication. The data presented were fairly succinct and easy to analyze based on the fulfillment of the resolution and compliance with its annexes. The company presented investigative, corrective and preventive measures considered satisfactory.

Case 3. A technical complaint referred to Anvisa reports the very serious deviation on an injectable antibiotic. The company was questioned and stated that it was aware of the deviation, but did not presented appropriate investigative, corrective and preventive measures. Bearing in mind the seriousness of the fact, it was the recollection of the product was determined, characterizing the qualification of risk as class I, the most serious one. The company began the procedure for recollection, but considered, without any consent by the regulatory body, that the class of risk was of type III, which exempts the company of issuing a warning announcement to consumers and extends the term for completing the recollection. The company considered the procedure completed 60 days after the initial date, reaching 2.4% of recollection and 95.9% of consumption reported by customers. Notwithstanding the lack of answers relating to 1.7% of total production, the company considered the procedure completed. Considering the facts presented, the company was booked in order the penalties related to offenses were properly applied.

Case 4. Cancellation of registration of medication due to the detection of its indiscriminate use for losing weight. In normal persons, the product could cause serious adverse reactions and even sudden death. The company was notified by Anvisa, who canceled the registration of the product, requested information about the recollection and communicated to distributors, pharmacies and drugstores. In response, the manufacturer sent copies of a correspondence sent to the regional /district managements of the company informing on the removal of the product from the market. As to the information to distributors, drug stores and pharmacies, it claimed that the cancellation of the registration and a public domain announcement, has been published in the Official Gazette, ensuring thus the publication of the information. Of the 31 batches involved in the recollection process, only five had some unit recollected, demonstrating the inefficiency of the process and total disinterest of the company to withdraw the drug from the market. Given the facts, it was initiated an administrative procedures for the application of the appropriate sanitary actions.

Discussion and conclusion

According to preliminary results raised by this exploratory study, companies do not always act responsibly in the fulfillment of the legislation or seek to maximize the benefits for the population, since in most cases studied there was no voluntary action for the recollection of the medications with problems. As consumers represent the vulnerable side of the events of deviation of quality, in many cases it was necessary the formal intervention by the State through the determination of procedures for recollection. In this sense, it was verified that the intervention could have occurred on a smaller scale if , since it was already aware of the facts, the companies would have acted immediately, reducing to the maximum possible public exposure of population to the risks associated with products with deviation of quality.

When analyzing Figure 1, it is possible to realize that certain cases of recollection determined by Anvisa were more expressive than those occurring voluntarily, mainly by considering that the cancellations of registration on grounds relating to security and effectiveness, are characterized as interventions by the State. Thus, 35 cases may be characterized as non-voluntary, which represents 61.4% of the recollections in the period studied.

Comparing the first case - whose recollection was voluntary, in anticipation of even the publication of RDC 55/05 - with the third, when the procedure was determined by the Agency after the resolution, it seems that the actions and posture of the companies are quite distinct and that the exercise of responsibility does not depend only on the norm. Whereas the process of recollection is planned since 1976², the sample studied showed companies responsible and committed that were already acting on a volunteer basis, regardless of the new resolution. However, as described in case 4, it is possible to assume that there are companies that, even before formal solicitations by the regulatory agency, refuse to obey and expose the population to serious risks, which demonstrates their extreme irresponsibility concerning public health.

Sanitary legislation, since Law 6.360/76 until the edition of the RDC 55/05, predicts volunteer actions and the makes companies responsible for the deviations committed by them. The attribution of such responsibility is coherent: if the companies can bear with the costs of distribution of their products, they must also bear with the onus of a possible recollection, upon the detection of quality deviations that may jeopardize the health or life of the population. If the company manufactures, it must necessarily be responsible for what it makes. If social responsibility is the duty of citizenship of the individual it should also be standard for the companies that cannot subsume their responsibility under the mask of the corporate body. Furthermore, if the state and municipal sanitary surveillances were the only ones responsible for seizing all deviated products, the National System of Sanitary Surveillance would be overloaded, and once more the population (and the taxpayer) would have to bear with the onus of such actions. The level of involvement and participation of the population, this sense, is essential not only as a support to the actions of the regulatory agency but also of the very prevention of fraud and abuses in this field and for the smooth functioning of the entire process of surveillance.

It should be also noted that the provisions of the new resolution do not show additional requirements in relation to the law. They only determine deadlines and prioritize the actions, according with the sanitary risk. Considering the wide period of the public consultation, it should be noted that companies cannot claim ignorance or arbitrariness in the requirements, since they were able to actively participate in the construction of the legal text.

Given the short time elapsed since the publication of the resolution until the deadline for the completion of this study, it was not possible to evaluate with absolute security the effectiveness of this norm, which should be presented in future studies to demonstrate a possible need for adjustments. According with the above results, however, it is noted in the exploratory sample of this study that part of the companies is not concerned with the principle of beneficence, not prioritizing the health of the population. Data suggest that many companies exempt themselves from their responsibility to the population, causing

flagrant contradiction between what they preach - that they manufacture quality medications to promote, protect or restore the health of people – and how they act, refusing to recollect these same medications when their lack of quality is detected. The careful analysis the information obtained indicates that in these situations, if the State does not intervene, fulfilling its ethical and technical responsibility, the population is unprotected and vulnerable. It is indispensable to register that in the specific cases mentioned in this survey, in which punishments were necessary, they were exercised by Anvisa according to the Brazilian legislation. The deepening of this legal and punitive, however, it not part of the objectives of the research.

In parallel, this study points out in the sense that the reasons proposed by bioethical intervention is justified in these cases similarly to other recent studies recently performed¹⁸. As a tool in the field of applied ethics, appropriate for mediating inequities between the State and the market, the intervention proposed by this stream of bioethical thought reinforces and theoretically supports the active, responsible and protective sense of the State with respect to the most vulnerable populations, especially in countries where the legislation is not always taken in consideration.

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Resumo

Vigilância sanitária: recolhimento de medicamentos na legislação brasileira

O artigo decorre de pesquisa exploratória e transversal que levantou dados sobre o recolhimento de medicamentos, ação prevista na legislação sanitária brasileira que deve ser adotada pelas empresas em casos de cancelamento de registro ou desvio de qualidade dos produtos. O estudo foi realizado entre março e outubro de 2005 e este artigo descreve seus resultados a partir de quatro casos-chave, que forneceram elementos para discussão por destacar o tipo de procedimento adotado em cada um. Os dados mostram que dos 57 casos de recolhimento iniciados no período, 22 ocorreram de forma voluntária (38,6%) seis por cancelamento de registro (10,5%) e 29 por determinação da Anvisa (50,9%). Os 35 caracterizados como não voluntários (29 +6) representaram 61,4% do total, em relação aos quais o Estado foi obrigado a intervir. A discussão utiliza o princípio da beneficência, as éticas da proteção e da responsabilidade e a bioética de intervenção. Conclui apontando que embora exista regulamentação para o recolhimento voluntário de medicamentos este procedimento requer a intervenção responsável do órgão regulador, objetivando o bem maior: beneficiar e proteger a população. Considera que nestes casos é ética a intervenção do Estado.

Palavras-chave: Bioética. Controle de medicamentos e entorpecentes. Vigilância sanitária. Vulnerabilidade social. Beneficência. Responsabilidade legal. Responsabilidade social.

Resumen

Vigilancia sanitaria: recogida de medicamentos en la legislación brasileña

El artículo se deriva de pesquisa exploratoria y transversal que levantó datos sobre la recogida de medicamentos, acción prevista en la legislación sanitaria brasileña que debe ser adoptada por las empresas en casos de cancelación de registro o desvío de calidad de los productos. El estudio fue realizado entre marzo y octubre de 2005 y este artículo describe sus resultados a partir de cuatro casos clave, que proporcionaron elementos para discusión por destacar el tipo de procedimiento adoptado en cada uno. Los datos muestran que de los 57 casos de recogida iniciados en el período, 22 ocurrieron de forma voluntaria (38,6%) seis por cancelación de registro (10,5%) y 29 por determinación de la Anvisa (50,9%). Los 35 caracterizados como no voluntarios (29 +6) representaron el 61,4% del total, en relación a los cuales el Estado fue obligado a intervenir. La discusión utiliza el principio de la beneficencia, las éticas de la protección y de la responsabilidad y la bioética de intervención. Concluye apuntando que aunque exista reglamentación para la recogida voluntaria de medicamentos este procedimiento requiere la intervención responsable del órgano regulador, objetivando el bien mayor: beneficiar y proteger la población. Considera que en estos casos es ética la intervención del Estado.

Palabras-clave: Bioética. Control de medicamentos y narcóticos. Vigilancia sanitaria. Vulnerabilidad social. Beneficencia. Responsabilidad legal. Responsabilidad social.

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