Review Article

# Radiopharmacy education in Brazil

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## ABSTRACT

The number of schools of pharmacy has been increasing each year in Brazil. From 2002 to 2013 over 300 new schools were opened in Brazil with a final number of 415 schools of pharmacy in operation around the country. Of these schools, only 28 schools offer a course in radiopharmacy (7.77%). However, the demand for such trained professionals has grown exponentially in Brazil, especially following amendment 49 (February 2006) that broke the monopoly on the production, distribution, and marketing of short half-life radiopharmaceuticals, and the recent constitutional amendment project 517/2010, which was approved in the last instance and is waiting for final approval by the President. Thus, in this scenario, there are a total of 417 radiopharmacy services across the country waiting for qualified professionals to fill posts. However, while there are insufficient trained professionals, radiopharmacy services under the aegis of Agencia Nacional de Vigilancia Sanitaria – Brazilian Health Surveillance Agency allow biomedical scientists and biologists to perform specialized functions as developed in radiopharmacy services without the presence of radiopharmacists.

## INTRODUCTION

Brazil has been considered a recently industrialized country with profound social, economic, demographic, and epidemiological advances in the last decade, although it still remains a developing country. One of the greatest examples of public policies in the health sector is a national policy to control and prevent cancer, which may serve as a benchmark for other nations less developed in Latin American and/or Africa. This dynamic and innovative national health policy is a consequence of health sector reforms, which have been on-going since the 1980s, and inclusion of stakeholders such as the major churches, civil society and nongovernmental organizations in decision-making processes.[1] The main pillars of the cancer control program are health promotion, prevention, and care considering human rights. This policy forms part of the Brazilian Unified Health System (Sistema Único de Saúde) and is based on technical and scientific evidence by strategic research and epidemiological surveillance over time.[2]

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The burden of cancer affects people worldwide. Today, more than 20 million individuals are living with a diagnosis of cancer. Each year, another 10 million cases occur. As the second most common cause of all deaths, the global mortality from cancer is profound. There is often a misperception that the cancer is associated with wealthy nations and limited to the effects of diet, lack of exercise and smoking. In fact, more than half of new cancer cases occur in developing countries, where it is a leading cause of morbidity and mortality. The scale of the problem confronting developing countries is potentially one of crisis proportions. By 2020, nearly 70% of deaths in the looming cancer pandemic will be in economically disadvantaged countries, reflecting survival rates in these regions that are often less than half those of more developed countries. While poor countries often have high rates of cancers associated with infectious disease, risk factors such as tobacco, obesity, less healthy diets and inactivity are increasing

in prevalence in developing countries. Changes from globalization and economic development are leading to the adoption of these unhealthy lifestyles, diets and behavioral risks in low- and middle-income countries. In addition, the world's population is ageing, increasing the pool of those more susceptible to cancer. The increasing burden of cancer in the developing world is a call for action to protect the public's health. In many developing countries, however, governments and institutions face a wide spectrum of serious health problems, and cancer may not be a priority in limited resource settings. The inability to cope with the growing economic and societal burden of cancer is emblematic of the tremendous global health disparities in which developing countries have only 5% of the resources spent on cancer globally.[1]

Developing countries are many, and considering the breadth of need, it is important to formulate focused policies that will lead to an optimal response. Today, globalization, governmental cutbacks and demand for cost effectiveness drive the increasingly dominant theme of health policy: "Do not try to do everything for everybody." The reality of shrinking health budgets has forced many to confront difficult choices when facing current health problems. Nevertheless, it is important that the cancer pandemic be appreciated now, and priorities for appropriate responses formulated. To this end, many large-scale education, research, prevention, and treatment programs have been gaining momentum in the fight against cancer. While they vary in their specific objectives, the ultimate goal of all these programs is to decrease the incidence of disease and improve the effectiveness of treatment.[3]

## POLICY ISSUES

The discussion about cancer control in Brazil highlights the inadequacy of oncology services and the importance of maintaining a good balance between prevention and therapeutic actions. It also highlights the important role played by human resources, who are still behind the curve on technical–scientific knowledge and epidemic management information; also, they are lacking in quantity and quality.

Thus, law N° 2.439/GM, related to National Oncology Care Policies, determines that all levels of care must be taken into account (basic, intermediate and highly specialized), to ensure the implementation of prevention, diagnosis, treatment, rehabilitation and palliative measures. The law determines that care should be organized in levels of hierarchy, establishing guidelines to guarantee efficient and integral care. It also emphasizes the need to improve human resources and foster permanent education programs for professionals who participate in the implementation of oncology care policies.[4,5]

Besides the awareness of the policies that involve cancer prevention and control, as well as successful implementation of healthcare actions, it is necessary to identify biological, psychosocial and other aspects that are particular to cancer in children and young people. Here, we found that cancer diagnosis and therapeutic processes should begin when symptoms are recognized by parents; often, when diagnosis is confirmed, the disease is already in an advanced stage. Commonly, also, diagnosis occurs by accident during a routine physical examination; this can be explained by the lack of specific signs and symptoms in cancer in children and young people, such as fever, paleness, cephalea, anorexia, bone pain and swollen ganglions, which can be associated with and/or wrongly taken for signs and symptoms of other common childhood pathologies.[6]

The above trends highlight a number of policy deficiencies in developing countries, which we have been trying to address since early 2011 when Brazil quit the announcement of new strategies for cancer. These deficiencies include a lack of effective cancer surveillance and control, but, more fundamentally, a lack of adequate health care, funding and coverage at the national level, as well as a lack of effective preventive policies. Globalization, thought by many to improve economic growth in developing countries, may adversely affect it, thereby also compromising investment in healthcare and health services in individual countries. Of the top four causes of death worldwide, three – cardiovascular disease (CVD), cancer and chronic respiratory diseases – are associated with chronic disease, and CVD, chronic respiratory diseases, cancer and diabetes made up 60% of the 58 million annual worldwide deaths estimated for 2005, with more than three-quarters of these deaths occurring in developing countries.[7]

It is worth noting also that constitutional amendment 49 of February 8, 2006, excludes the federal monopoly of production, marketing and use of short half-life radioisotopes for medical, agricultural and industrial purposes. The most recent amendment to the constitution of 1988 was necessary due to a change in wording of paragraph b and c, adding a

clause to the main clause of Article 23 of 21 and by the wording of the new clause V of the "chapeau" of Article 177.

Originating from the constitutional amendment bill 199/03, which removes the monopoly of union production, marketing and use of short half-life radioisotopes, amendment 49 has facilitated the creation of new nuclear medicine centers that offer this service to the population.

## PRIORITY LEGISLATIVE ASPECTS

### Article 60, § 3 of the federal constitution

The houses of the Chamber of Deputies and the Senate, in accordance with Article 60 of the Brazilian Federal Constitution, promulgate the following amendment to the constitutional text: Article 60 of the constitution sets out the rules for constitutional amendments. Amendments to the constitution are set out in Article 59 as part of the Brazilian legislative process.

Constitutional amendments have been enacted in Brazil since 1992. However, since the constitutional amendment 48 (August 2005) there is no longer a reference to the third paragraph of that article. The paragraph in question states that amendments to the constitution must be enacted by the houses of the Chamber of Deputies and the Senate.

### Article 1°

Article 1º of amendment 49 amends section XXIII, Article 21 º of the constitution. Article 21º deals with the powers of the union. The "chapeau" of paragraph XXIII provides that the union can explore services and nuclear facilities of any type and exercise state monopoly over the exploration, mining, enrichment and reprocessing, industrialization and trade in nuclear ores and their derivatives; this met the principles and conditions which establish the following subparagraphs.

The first point to item XXIII established the principle whereby all nuclear activity within the national territory shall only be admitted for peaceful purposes and with the approval of Congress. Item b, modified by amendment 49, established that by concession or permission, the use of radioisotopes was allowed for research and medical, agricultural, industrial and similar activities (Son, 2006).

From the enactment of amendment 49, item b states that trade in and use of radioisotopes for research and medical, agricultural and industrial purposes are allowed under permission only. The withdrawal of the concession is relevant. In a place of administrative law it should be noted that the granting of public service or anything of competence of the state is an instrument used by the government for public or private companies performing or providing that service.

The same happens with permission. The difference between concessions and permissions is relevant. Concessions are granted for larger, more enduring, and in the main, high value activities. Permissions are granted for shorter-term services of less monetary value, and more importantly, these can be withdrawn (Son, 2006).

### Article 2º

Article 2º of amendment 49 amends the wording of section V of the "chapeau" of Article 177º of the constitution. Article 177 establishes monopolies, and subsection V declared that monopolies included the union's activities in research, mining, enrichment, reprocessing, industrialization and trade of nuclear ores and minerals and their derivatives. Henceforth, section V, within the European Union monopolies, provides for research, mining, enrichment, reprocessing, industrialization and trade of nuclear ores and minerals and their derivatives, with the exception of radioisotopes whose production, marketing and use may be allowed under permission, pursuant to subparagraphs b and c of section XXIII of the "chapeau" of Article 21º of the constitution.

It should be noted that the change in the competence of the union generated a change in the article that provides the federal government's monopoly on some activities. Henceforth, production, marketing and use of radioisotopes may be held under permission.

## CONCESSIONS AND PERMISSION

The meaning of the word "permission" is broad and can express the meaning of an administrative act unilaterally, without the contractual nature, discretionary and poor, free or not, by which the government provides to the individual performing the service public or private use of public property by third parties. The permission object is running a public service or the private use of public property, called, respectively, granting of public service and permission to use (Son, 2006).

Article 175 of the constitution states that "incumbent upon the government, under the law, either directly

or under concession or permission, always through bidding, the operation of public services."

The main form of distinction and granting of permission are precisely that the award is contractual in nature, and permission is unilateral, discretionary and precarious, therefore, devoid of any contractual character.

Mello (2001) defines the permission of public service as "the unilateral act and precarious, personal intuition, through which the government transfers to someone the performance of a service and its scope, providing, stylish, which makes the grant to possibility of charging fees from users "and even" the state, in principle, to avail itself of the permission would not wish to be just when the particular rights against him, but only in the face of others.[8]

For its precarious character, it would use it normally, when the grantee does not allocate large capital needed for the performance of the service or when could mobilize to a different destination without further problems, the equipment used, or even when the service does not involve deployment physical rigging sticking to the ground, or, finally, when the risks of insecurity to be assumed by the grantee would be offset by the extreme profitability of the service, either in the short-term to be held longed economic satisfaction."

Continuing the distinction between concession and permission, the following issues arising from the instability of the latter should be highlighted. Precariousness means that the act is revocable at any time without compensation on the initiative of the public administration, as it is granted without establishing terms. Besides these initial characteristics of permission, there are other characteristics such as:

a. Precarious act and delegation
b. Contractual adhesive (contract of adhesion)
c. Unilateral revocability by the grantor
d. Whether the permit is made to individuals, which the grant does not provide for
e. The possibility that the public service is preceded by a public work is planned for only in the case of a concession given the incompatibility of the institute's permission for public works.

When it comes to public service authorization, the Federal Constitution, Article 175° is incomplete when referring solely to concessions and permits. However, Article 21° paragraph XII, lists the services that the union may execute directly or through authorization, concession or permission. Furthermore, in ordinary legislation, authorization is mentioned next to the permission and the grant as a form of delegation of public services. This is a unilateral and discretionary act by which the government provides for the individual performance of material activity or practice of this act requiring consent to be legitimate, that is, it is the authorization to act performed in the exercise of police power.

In summary, one can say that, classically, by permission and authorization, the Administration also transfers the running of public services to private. Undertaking the substantial distinction between concession and permission for public service is a difficult task, since both involve the provision of public services by private individuals, with compensation provided by the rate that users pay to use the service. As far as, granting permission to admit requirement and a high degree of complexity. The criterion of greater or lesser relevance of the service also does not offer any distinguishing criterion. In the Brazilian legal system, a point of difference between concession and permission lies in the possibility given to dealers to promote expropriations, since an existing prior permission, provided by statute or contract. This possibility follows from Article 3 of decree Law 3.365, of 21.06.41 (general law of expropriation), not extensive, it is notable, to earning an allowance of public service.

Other distinguishing criteria extracted from the mode of expression of the two figures are that grants are made by contract and permissions by administrative act, discretionary, precarious and revocable in principle, at any time. However, the 1988 constitution which required a bidding procedure for both figures, approached permission of contractual form. Finally, Law No. 8.987/95, Article 40, determined that its formalization will be through contract and membership, observed precariousness and unilateral revocability by the grantor.

In response to the authorization, we can conclude that its formalization remains through precarious and discretionary administrative act, recommending its use for services that are less complex, does not always paid through tariff. An example would be the case of authorization for the maintenance of squares, gardens or avenues, in exchange for posting of advertising boards by the company. Still, the authorization is not subject to legal regulation by Law No. 8.987/95.

## OBJECTIVE LIABILITY

The previous subparagraph c predicted that the civil

liability for nuclear damage was not dependent on the existence of fault, that is, it was objective. From the 49th amendment, the subparagraph c has to be determined under a permission that authorizes the production, marketing and use of half-life radioisotopes for 2 h or less.

Subparagraph d, included by amendment 49, inherited the forecast of objective liability for nuclear damage, or liability regardless of fault.

According to the Son (2006) the competence of the union to explore the services and nuclear facilities of any nature and to exercise state monopoly on research, mining, enrichment, industrialization and trade of nuclear ores and their derivatives stems from the importance and danger of issues related to nuclear power. The first principle of note is that all nuclear activity within the national territory shall only be admitted for peaceful purposes and with the approval of Congress. This is an issue of paramount importance to world peace since, as we are witnessing, unstable nations attempting to develop nuclear energy are prevented from doing so under pressure from the League of Nations. The threat of destruction and contamination from misuse of atomic energy justifies such normative predictions.

The easing of the federal monopoly on production, marketing and use of radioisotopes authorized under permission must be performed under safety criteria in view of the relevance of nuclear material.

Thus, the EC 49 created a system which is ambiguous and potentially dangerous, as well as frustrating and desperate with repercussions for the production sector. We saw a hostage situation announced previously. Such conjecture enabled hostile intervention by various professionals in the field of radiopharmacy in Brazil [Figure 1], which had expressed its guilt legally when it published the RDC 38/2008 dealing with nuclear medicine services in Brazil and institutionalized the carrying out of radiopharmacy activities by any senior professional. This showed complete disregard for resolution 486 from the Federal Council of Pharmacy, which classifies the activity as private to pharmacists, as well as Article 2° of decree 20.377/31, which approved the regulations of the pharmaceutical profession in Brazil.

This situation will change dramatically after the publication of PEC 517/2010 that will exclude the entire monopoly of the union. Conservative analysis predicts an increase in the number of radiopharmacy services to 900 across the country, with a demand for 1800 radiopharmacists; related to this, there is still an increase in demand for nuclear medicine investigations, due to the growth in the number of cancer cases in Brazil [Figures 2-4] and the consequent increase in demand for radiopharmacists in radiopharmacy to perform the doses.

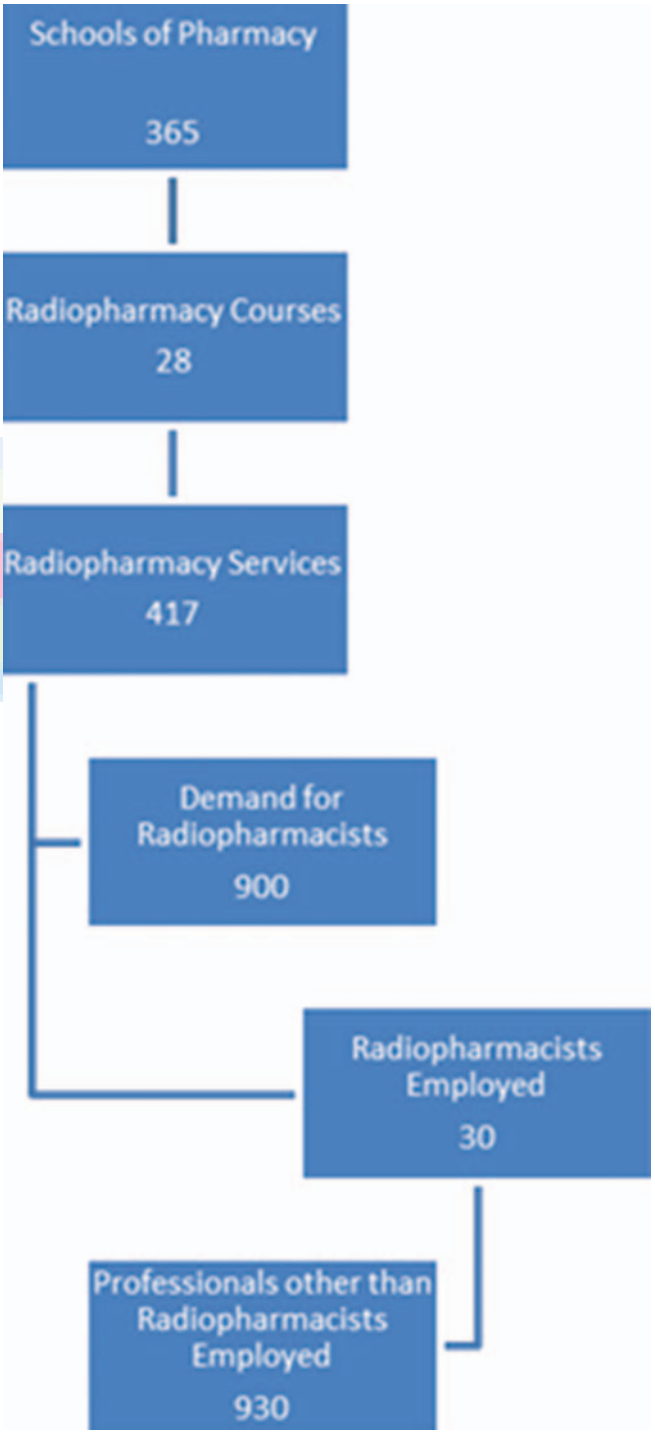


**Figure 1:** Schematic illustration of radiopharmacy in Brazil

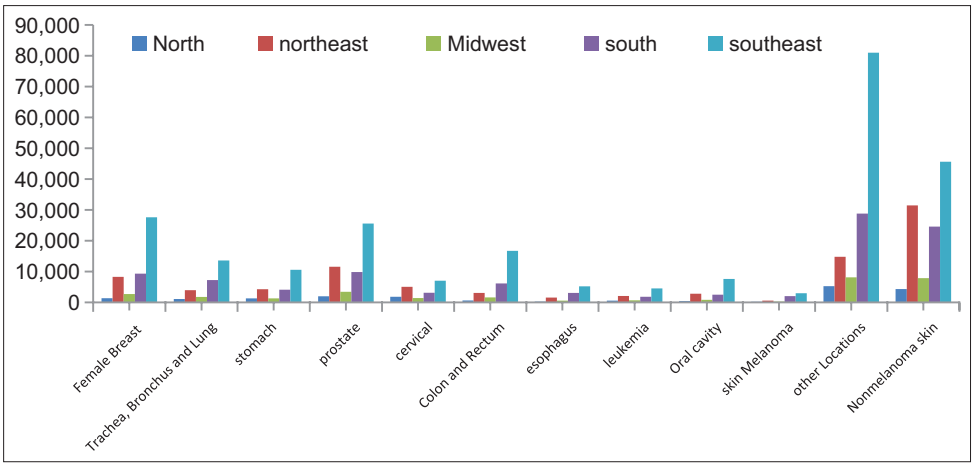


**Figure 2:** Estimates of crude incidence rates per 100,000 and number of new cases of cancer in women, according to primary location, for the year 2010

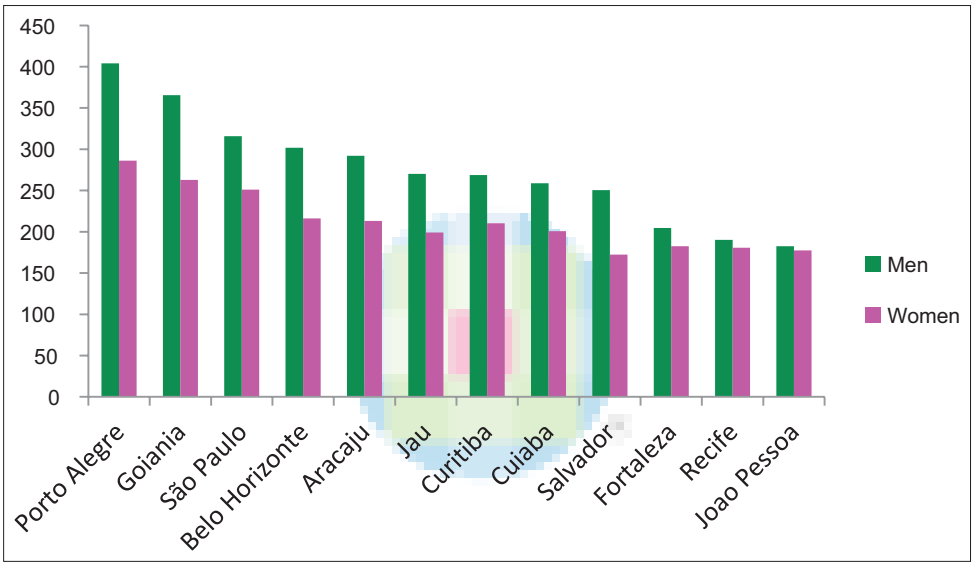


**Figure 3:** Distribution of cases of cancer in regions of Brazil, excluding melanoma cases

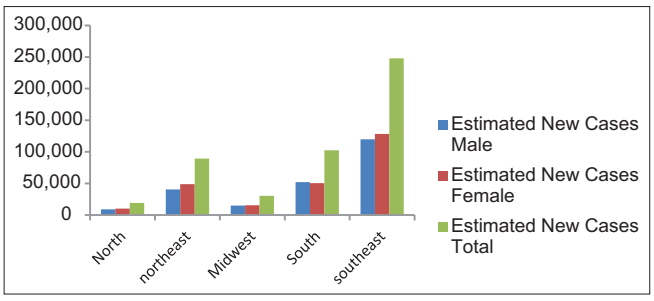


**Figure 4:** Estimation of new cases of cancer distributed by gender and regions of Brazil (*All the data were collected from the INCa)

This whole scenario emerges as a dire and dorsally mistaken situation that requires immediate action by public and private entities to rectify in order to prevent more distortion, putting the Brazilian population at an alarming degree of health risk in radiopharmacy.

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