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Regulatory Impact Analysis: a new tool for better regulation at ANVISA

ABSTRACT

Regulatory Impact Analysis, which is recommended to regulatory departments, aims to improve regulatory quality by providing information about the costs and benefits of regulation as well as solutions to current issues to enhance the decision-making process. This article discusses the importance of Regulatory Impact Analysis in the context of the National Agency for Sanitary Surveillance performance as well as the agency's current phase of regulation improvement and strengthening. Also, the main definitions related to the regulatory field as well as some international case experiences are presented.

DESCRIPTORS: National Health Surveillance Agency. Health Surveillance, economics. Cost-Benefit Analysis. Decision Support Techniques.

INTRODUCTION

The National Agency for Sanitary Surveillance (Agência Nacional de Vigilância Sanitária - Anvisa), created by Law N. 9782 on January 26, 1999, regulates the production and marketing of pharmaceuticals, foods, cosmetics, disinfectants, tobacco derivatives, medical products and equipments, diagnostic reagents, pesticides, blood and blood products and human organs and tissues for transplantation, and it includes the environments, inputs, processes and technologies related to these products. It also exerts control over health services, public health laboratories and ports, airports and borders, and it coordinates the National System of Sanitary Surveillance. Its responsibilities are divided between the federal, state and municipal governments.

The regulation by Anvisa plays a fundamental role in structuring the National Health System. It is considered by the development policy as a tool to increase business investments in innovation and to attract the production, research and development centers of foreign companies.^a Because this institution regulates the industries of the health industrial complex, its importance is strategic. It must reconcile prevention of health risks to the population with organization of the market for social and economic development, seeking to increase access to products and services related to public health.^{1,b}

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^a Ministério do Desenvolvimento, Indústria e Comércio Exterior. Política de Desenvolvimento Produtivo. Complexo Industrial da Saúde. Brasília;2010 [cited 2010 Apr 18]. Available from: <http://www.mdic.gov.br/pdp/index.php/politica/setores/complexoIndustrialSaude/21>

^b Ministério da Saúde. Complexo industrial da saúde. Brasília; 2008 [cited 2010 Apr 18].

Available from: http://portal.saude.gov.br/portal/saude/Gestor/visualizar_texto.cfm?idtxt=32686

Anvisa is aligned with the movement for better regulation in Brazil, which is coordinated by the Presidency of the Republic through the Program for Strengthening the Institutional Capacity for Management in Regulation, established by Decree N. 6062 of March 16, 2007. This movement follows the recommendations of the Organization for Economic Cooperation and Development (OECD),^c according to which there is a clear relationship between economic and long-term social performance and the quality of a country's regulatory framework. The OECD recommends the implementation of Regulatory Impact Analysis as an effective tool for determining regulatory quality.

REGULATORY IMPACT ANALYSIS (RIA)

RIA is a regulatory tool that examines and evaluates the likely benefits, costs and effects of regulations. It is a systematic process of questioning regulatory processes at the beginning and producing an analytical report that can be used to increase the understanding of the problems, evaluate the alternatives, identify possible indirect impacts of government action and to ensure that the action is justified and appropriate. The RIA provides important empirical data and a rational decision-making framework that allows managers to evaluate the regulatory options and the potential impacts of their decisions.^d

Unlike other decision-making processes, which do not involve social participation, RIA exposes the merits of decisions and the impacts of actions through public consultation and review of the documents to establish the objectives and goals of the proposed regulations. This consultation and review enhance the transparency of the regulatory process and consider the response of the public to important information, providing a measure of quality control for the identified impacts and improving the quality of the information on which decisions will be based.

Countries that participate in the OECD have used RIA since 1974, though each country adopts a format according to their own specificities. Despite the diversity, there are ten key elements of good RIA practice: 1) maximize political commitment to RIA; 2) allocate responsibility for RIA; 3) train regulators; 4) use consistent and flexible analytical methods; 5) develop and implement strategies for data collection; 6) focus

the efforts of RIA; 7) integrate RIA into the policy making process as early as possible; 8) communicate the results; 9) involve the public extensively; and 10) apply it to new regulations as well as existing ones.

In 1995, the OECD developed a list of questions to help regulators examine the implications of regulatory options and evaluate whether the chosen proposal will be effective and efficient:

1. Is the problem clearly defined?
2. Is the government's action justified?
3. Is regulation the best form of government action?
4. Is there legal basis for regulation?
5. What is the appropriate level of government for this action?
6. Do the benefits of regulation justify the costs?
7. Are the effects of regulation on society transparent?
8. Is the regulation clear, consistent, comprehensible and accessible to users?
9. Have all interested parties had the opportunity to submit their suggestions/considerations?
10. How will the regulations be implemented and enforced?

The main methods of RIA are: cost-benefit analysis; cost-effectiveness analysis; cost of compliance analysis; business impact analysis; fiscal or budgetary analysis; and risk-risk analysis.

INTERNATIONAL EXPERIENCE WITH RIA

Other regulatory agencies throughout the world with operations similar to Anvisa perform RIA. The processes favored in American (Food and Drug Administration - FDA),^e Australian (Therapeutic Goods Administration - TGA) and Canadian (Health Canada)^f agencies are coordinated by centralized bodies that have been performing quality control of regulations for at least the past 20 years. In these three countries, RIA is part of a broader policy of improving regulations, and the reports are published for public review and consultation.

^c The OECD has existed since 1961, it has 30 member countries, and it aims to bring together governments of countries committed to democracy and market economy to support sustainable economic growth.

^d Organisation for Economic Co-operation and Development. Regulatory impact analysis - best practices in OECD countries. Paris; 1997 [cited 2010 Apr 18]. Available from: <http://www.oecd.org/dataoecd/21/59/35258828.pdf>

^e Food and Drug Administration. Economic analyses of FDA regulations. Silver Spring; 2009 [cited 2010 Apr 18]. Available from: <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>

^f Health Canada. Regulatory Impact Analysis Statement. Safety of Human Cells, Tissues and Organs for Transplantation Regulations. Ottawa; 2005 [cited 2010 Apr 18]. Available from: http://www.hc-sc.gc.ca/dhp-mps/brgtherap/legislation/gazette1/cto_rias-reir_reg-eng.php

All three agencies conduct cost-benefit analyses, though each country uses different criteria for the mandatory implementation of RIA. At the FDA, the cost-benefit analysis is performed if the proposal is economically significant (i.e., if it has an annual impact of more than \$100 million), if it imposes huge increases in costs for a specific sector or region or if it has an adverse impact on competition, employment, investment, productivity or innovation.

TGA and Health Canada use standard forms for preliminary screening, which must be completed for all regulatory proposals before being sent to the central supervising body. These forms require that the impacts of the proposal be identified and, if the impact is high, further cost-benefit analyses are strongly recommended. This eliminates wasteful expenditure of time and resources on low-impact regulations. In these countries, the RIA includes an evaluation of costs and benefits for each regulatory option, followed by a recommendation of the preferred option.

At Health Canada, when the proposal is controversial, the agency can hire consultants to conduct a Business Impact Test, which uses a methodology that has been jointly developed with the Canadian Industry.⁸ This test is based on research that seeks information on the direct impact on business and includes information about price, quantity of goods or services, market access, supplier relations, investments, regulatory format, costs, benefits and the respondents opinions about the regulation.

According to Hertin et al,^h there are two methods commonly used for RIA documentation: cost-benefit analysis (including variants such as cost-effectiveness) and administrative burden evaluation (especially the Standard Cost Model). Many countries favor economic analysis as the main analysis framework, whereas few mention other quantitative and qualitative methods, such as multicriteria analysis and risk analysis (most notably being the European Union). Checklist tools are also recommended in countries such as the United Kingdom.

A study by Hertin et al,^h with 22 cases, found that there is great heterogeneity in the RIA process, the quality of knowledge produced, the use of this knowledge in the political process, the outcome and the impact. Some RIA reports, while well written and thoroughly researched, have served to justify a decision that was previously made, thus having little impact on any forthcoming or future decision. In other cases, simple RIAs that focused on administrative costs have had considerable influence on changes in policy design.

RIA AT ANVISA

At Anvisa, RIA is in its initial stages of implementation and is one of the actions of the Program for Improvement of the Regulatory Process (Programa de Melhoria do Processo de Regulamentação), established by Ordinance N. 422 of April 16, 2008. This program was created in a context where there was no standardization for the preparation of regulations in the various areas. These regulations, in turn, were developed with little understanding of its impacts. Thus, the RIA aims to qualify the regulatory system, promote transparency, improve the mechanisms of social participation in the regulatory process and improve coordination among the organizational units of the agency.

To achieve these goals, the following initiatives have been developed: the consolidation and revision of legislation on sanitary surveillance; the establishment of a regulatory agenda; the standardization of the regulation process; the training of regulatory personnel; the strengthening of social participation in the regulation and the gradual implementation of RIA tools.

The Regulatory Best Practices Guide document was developed to establish the rules of the program.ⁱ This guide aims to standardize and simplify the regulatory process within the agency, including all stages, consultations and public hearings as well as the RIA. The proposals of normative acts of the agency should be prepared or reviewed following the steps set out in this guide.

The guide has, in addition to standard forms, an instruction report that should be completed as clearly and completely as possible by the concerned areas as this is considered the first step in implementing RIA. This report consists of a questionnaire to encourage technicians from the areas involved to draw up regulations that will promote a structured way to think about the problem, the objectives, the regulatory options and the impacts of their proposals.

CONCLUSION

Despite the differences in procedures and RIA approaches in the regulatory agencies of health surveillance, RIA is a tool that assists decision making by requiring evidence-based systematic evaluation of regulatory options and their impacts. Furthermore, RIA extensively engages stakeholders in consultations, promotes accountability and transparency and contributes to both the process and the result. The result is a more predictable and consistent regulatory environment that increases credibility for both consumers and the productive sector.

⁸ Health Canada. Business Impact Test (BIT). A Survey regarding the Proposed Regulatory Framework for Natural Health Products. Ottawa; 2008 [cited 2010 Apr 18]. Available from: <http://infopoll.net/live/surveys/s19985.htm>

^h Hertin J, Jacob K, Pesch U, Pacchi C. The production and use of knowledge in regulatory impact assessment - an empirical analysis. Berlin: Freie Universität Berlin; 2009 [cited 2009 Sep 13]. Available from: <http://ssrn.com/abstract=1361495>

RIA must be performed early in the regulatory process. It must include broad consultations with stakeholders and seek to disclose evidence of the risks, costs and benefits of regulation prior to the decision-making process. This must be done without removing the necessary protection to society, and it must focus on the consumers' needs, who historically have a small participation in the regulatory process and on the development needs of the productive sector. RIA presents itself as an important tool for improving the quality of regulation, which may help to promote the development of strategies to strengthen social participation and the development of the health industrial complex, which is one of the priorities of health policy.

Given the extent of Anvisa's actions, there is a

challenge to create the appropriate mechanisms and extensively involve states and municipalities in the discussions of the regulatory process while sharing the role of Anvisa and addressing those regulations that must be consensual between different institutions and councils.

Unlike international agencies that have been conducting RIA for the last 20 years, Anvisa is at an early phase of cumulative learning and cultural change with respect to implementation. Thus, the challenge still remains for further development of a deeper methodology, starting with the first step of the implementation process and adapting the theories and methods to the institutional reality.

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