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Reforming pharmaceutical regulation: A case study of generic drugs in Brazil☆,☆☆

Elize Massard da Fonseca *

Department of Social Science, National School of Public Health, Oswaldo Cruz Foundation Rua Leopoldo Bulhões, office 913, 1480 Rio de Janeiro, RJ 21041-210, Brazil

Abstract

Brazil is renowned worldwide for its remarkable reforms in pharmaceutical regulation, as the *Generic Drug Act* that have enhanced access to essential medicines while lowering drug costs. In contrast with analysis of pharmaceutical regulation that invokes international guidelines as inspiration for countries to reformulate their norms or argues that regulations emerge in order to serve the interests of powerful interest groups; this paper focuses on actors' preferences and demands to explain how Brazil promoted this large-scale regulatory policy. Paradoxically, the generic drug regulation introduced in the name of patients and opposed by local firms given the high cost to adapt its plants and processes, is today opposed by important patient advocacy groups but solidified by the strong support of local and multinational pharmaceutical firms. The paper concludes that the state still matters for pharmaceutical regulation and that pharmaceutical regulation is only partially influenced by non-state actors.

Keywords: Pharmaceutical regulation; Interest groups; Generic drugs

1. Introduction

Brazil is renowned worldwide for its remarkable reforms in pharmaceutical regulation, which have enhanced access to essential medicines while lowering drug costs. As part of these reforms, Brazilian approved the Generic Drug Act in 1999, which allowed manufacturers to legally produce generic drugs that were identical to innovator drugs. A generic drug is a product that is no longer protected by a patent, and is interchangeable with an innovator drug (World Health Organization, 2001).

Generic drug policies are designed to foster market competition, prompt price declines, and thereby increase access to safe and affordable medicines (World Health Organization, 2001). In Brazil, over 80% of drug expenses are paid for by patients (Cohen, 2000). Studies suggest that generic drugs enter the market with an average price that is 40% lower than their patented counterparts, making medicines more affordable to the Brazilian population and governmental programmes (Vieira & Zucchi, 2006).

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* Tel.: +55 11 55740399.
E-mail address: emassard@gmail.com.

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Although much has been said about the remarkable impact of Brazil's generic drug competition on pharmaceutical markets and price structures (Nishijima, 2008) the process that influenced the adoption of this large-scale regulatory reform has not been well explored. The case of Brazil is paradoxical, as the generic drug regulation that was introduced in the name of patient care and which was opposed by local firms given the high cost of adapting plants and processes, is today opposed by important patient advocacy groups, but now has the strong support of local and multinational pharmaceutical firms. The paper innovates by analysing the policy process of the generic drug reform, demonstrating that pharmaceutical regulation is only partially influenced by non-state actors.

Existing studies provide two partial explanations as why Brazil promoted this reform. First, research points to the influence of international norm-creating bodies, particularly the World Health Organization (WHO). The WHO recommends that generic drug substitution should be a key component of a national drug policy, with two policy instruments to stimulate market competition: the use of a non-proprietary name (INN) and bioequivalence tests. The INN is a unique name that is globally recognised and is public property[1] and facilitates the identification of pharmaceutical substances (World Health Organization, 2010). The WHO also recommends that generic drugs must be therapeutically equivalent to their innovator version, something that can be established using bioequivalence tests.

But these recommendations do not fully explain Brazil's decision to reform. The WHO may influence domestic decision-making by setting and diffusing key norms, but it cannot ensure the capacity for policy implementation. Understanding what regulatory arrangements are necessary to improve access to medicines, it is important to understand how countries go about implementing them – how domestic political institutions (e.g. health surveillance regimes) mediate international guidelines to implement generic drug policy.

Other studies suggest that the Minister of Health and presidential-hopeful, Jose Serra, promoted the reform as a response to a crisis in the sector triggered by a scandal involving fake birth control pills (Dias & Romano-Lieber, 2006). However, because these studies focus only on the critical period of reform, little is known about either the institutional antecedents that channelled this entrepreneurial activity, or the subsequent development of generic drug regulation after Serra's influence waned. This paper attempts to fill this gap by placing the crisis period within the continuity of the longer decision-making and implementation process and exploring the preferences of political actors.

This paper is organised according to three sections, excluding this introduction. The second part reviews the literature concerning pharmaceutical regulation,[2] which usually argues that this relates to the diffusion of international norms or the influence of powerful pharmaceutical corporations. I challenge these two perspectives, suggesting that an in-depth analysis of actors' preferences/strategies, mediated by domestic political institutions, is the most important determinant of the timing and direction of the regulatory policy. The third part illustrates this argument using the Brazilian case. The paper concludes that a more promising avenue is to observe how policy legacies shape the preferences of actors; that is, the preferences of interest groups are constructed within the regulatory policy process.

2. From above or below? Policy diffusion and interest group politics

There are two analytical explanations as to why countries promote large-scale pharmaceutical policies. The first refers to the diffusion of international guidelines that inspire countries to reformulate their regulatory regimes, such as the guidelines of the WHO. Other scholars argue that regulations emerge in order to serve the interests of powerful interest groups, which are usually small and homogeneous. This paper argues against both approaches, as we shall see.

Some scholars claim that international regulatory standards formulated by developed countries inspire developing countries to revise their local guidelines (Carpenter, 2010). This seems plausible as regulators – e.g. FDA – set the rules to enable pharmaceutical firms to access developed country markets. In addition, the scientific expertise of these agencies can encourage other governments to emulate their guidelines. Since the late 1980s, WHO has provided rules to regulate INN, BE and technical specifications of drug registration (World Health Organization, 2001). However, little is agreed between countries on how to formulate these norms to secure public health interests (Pan American Health Organization, 2008).

[1] Medicines have three names: the chemical name describes the product's molecular structure; the INN is a shorter version of the chemical name; and the brand-name is assigned by the manufacturer.

[2] Although not all studies were concerned with pharmaceutical regulatory reforms, they provided information regarding why and how countries adopt regulatory policies in this sector.