Philippine Journal of Public Administration, Vol. XLII, Nos. 3 & 4 (July - October 1998)

Management of Policy Formulation: The Generics Act of 1988

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Drugs play a significant role in the people's healthcare, thus making the formulation of a national drug policy an equally important concern of government. The drug situation in the Philippines, especially prior to 1986, was recognized by the Department of Health (DOH) as one needing attention through the institutionalization of policy reform. The process of policy reform is viewed in an approach that uses stakeholders' analysis, a tool for understanding policy, which focuses on the process and on the role of the social actors in the process. The method by which the policy process is presented is itself a significant contribution of this study. This is an attempt at reconstructing the historical experience in policy formulation by looking at the strategies used by the DOH in managing the formulation of the generics policy as well as the roles and strategies adopted by the different stakeholders. It also dissects how the DOH managed the commonalities and the differences of the stakeholders.

Introduction

The Generic Drugs Law or Republic Act 6675 (RA 6675) is one of the forty-five landmark legislations passed by the Philippine legislature between 1987 and 1992. The so-called Generics Law, or RA 6675, prescribes the use of generic names in manufacturers' and traders' product labels and advertisements, in doctors' prescriptions, and in pharmacies and drug outlets. The law also provides for the use of the Philippine National Drug Formulary (PNDF), or Essential Drugs List (EDL), and the publication of the list of and details concerning all available registered products.

This article offers another lens to view policy and policy reform. It describes the process through which policy reforms in the health and pharmaceutical sector was managed by the Department of Health (DOH). Public policymaking is presented in this study as a participatory exercise that engages players across a spectrum of differing views and interests. As a case study on the management of the formulation of the Generics Act of 1988, it reveals the

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experiences of the DOH in initiating the policy, in drawing the participation of different players in the process of policymaking, in dealing with the stakeholders—their commonalities and differences—in preparing the department toward policy implementation, and in dealing with the legislators. Taking the experience of the DOH in introducing policy reform, the study culls the lessons, which might be valuable to the management of policy formulation.

The Drug Situation: The Context of a National Drug Policy

In developing countries, many people have little or no access to effective and safe medicines. This takes place despite the fact that many poor countries spend 30 to 50 percent or even more, of their health budgets on drugs compared to about ten percent in many industrialized countries (Dag Hammarskjold 1985: 2). Dag Hammarskjold estimates that up to 75 percent of the drugs moving in the market may be outside the control of the health ministries. Pharmaceutical manufacturers are frequently so powerful that it becomes imperative to install official controls to ensure that drugs and their prescription are safe and effective for those who use them. Furthermore, the World Health Organization (WHO) estimates that as much as 70 percent of the drugs in the global market are inessential or undesirable, and despite dangerous drugs being restricted or banned in other countries, these drugs still circulate in the local market (Dag Hammarskjold 1985).

Drug policy represents one of the most important areas of policy in need of major reform especially in poor countries. Drug policy evokes debate about fundamental social values which is a concern of social development administration. The debate also draws in questions concerning the role of the state and the market, of the public and the private sectors, as well as those issues concerning equity, efficiency and participation.

In 1985, there were some 395 drug manufacturing companies in the Philippines producing 90 percent of drugs sold in the market (Bengzon documents 1986). The world's largest companies (Unilab, United American, Medichem, Pediatrica, etc.) were dominant in compounding, packaging and distribution of drugs. On the other hand, Filipino-owned drug companies were smaller in terms of operation and market share. These companies which numbered around 200, shared only about five percent of the market. Most of these local companies were merely distributors or importers. Thus, there was foreign-domination of the local drug market. Local firms were restricted in the conduct of research because of the high levels of capital investments required for personnel and facilities. The market was saturated with brand-named drugs. Approximately 83 percent of registered drug products were branded. But medical research groups found that many of these brand-named drugs are ineffective, expensive and probably harmful (HAIN 1991).

In 1986, the Bureau of Food and Drugs (BFAD) itself discovered more than 200 drug products that were banned in other countries but were still distributed in the Philippines (Bengzon documents 1986). The pharmaceutical industry continued to be predominantly oriented towards products which offered high profit margins over direct costs of production. This approach to production and marketing took place in the face of a largely passive and uninformed consumer base. There was little reliable or independent information on drug products. While information on products was available, it came solely from the drug companies through promotional advertising and the provision of free samples. These features of the market particularly the nature and income of consumer base, the proliferation of expensively marketed brand-named products, and the dearth of objective information, resulted in irrational drug use.

When new administrators took over the DOH in 1986, they were confronted with the discovery of widespread corruption in drug prescription and purchasing. There were no policies governing drug purchase. Since some 10 to 20 percent of the Department's total budget was spent on drug purchases, the new administrators vowed to commit the department to greater cost-efficiency, not only in the use of the department budget as a whole, but also in the use of that portion devoted to drug purchases (Interview with Dr. Alfredo R.A. Bengzon, August 1995).

The Research Problem

Public policy, although largely a feature of the choices made by government, is intended to serve public purposes. In an inclusive society, which recognizes the participation and role of civil society in governance including policy development and administration, nongovernmental entities are summoned to lay their claim on public concerns. As such, public policy becomes a point of intersection between government and nongovernment sectors.

The DOH is a key player, in fact the initiator of the national drug policy, including the generics policy. However, there were many others—from a wide spectrum of the Philippine society—who took part in varying ways and degrees in the formulation and advancement of the national drug policy. In other words, there were various stakeholders in the policy. Due to the multiplicity of stakes held by key players, the process of policymaking was as highly complex as it was political. Policymaking was complex due to the variety of interests and positions claimed by policy players; it was political because policy provides options and choices. Serious disagreements occurred around the policy issue.

Policies are public because they have a broad effect on the social structure of opportunities and choices. Issues between individuals, groups and organizations become public because primary, secondary, or higher-order effects

of a decision, impact upon other actors in ways that require public negotiation and resolution (Freeman 1992: 7). Public policies need to address matters for the affected parties sometimes through hard and controversial choices.

The article deals mainly with the strategies and approaches of the DOH in policy formulation on generics. Principally, it tackles the management of policy formulation by devoting substantial discussion to the dynamics and interactions among stakeholders. The study deals with the factors that influenced and shaped the process of advocacy and how these factors were managed by the DOH, in other words, the management of policy formulation.

Objectives of the Study

The article seeks to define and describe the so-called *stakeholders* during the passage of the Generics Act of 1988. The stakeholders' analysis describes the roles of different players in policymaking. The article also aims to describe and analyze the politics of decisionmaking. This means an analysis of the management of policy formulation which is at the same time, cognizant of the variety of stakeholders in the policy.

In particular, attempts are made to answer the following specific questions:

1. What was the context and the rationale that prompted the formulation of the Generics Act of 1988?

2. Who were the various stakeholders in the policy proposal of the Generics Act of 1988?

3. What interests did these stakeholders uphold?

4. What strategies and interventions were utilized by these stakeholders to meet their respective advocacies particularly during the policy formulation phase until the Act was passed into a law?

5. What were the points of convergence and the points of divergence among these stakeholders? How did the stakeholders align themselves under converging advocacy?

6. As the main initiator and proponent of the bill and manager of the generics policy formulation, how did the Department of Health deal with the commonalities and differences of the stakeholders?

7. What factors facilitated and what factors deterred the process of managing the policy formulation?

Scope and Limitations

Looking at the process of the formulation of the Generics Act of 1988 otherwise known as Republic Act 6675, the article is confined to the process of laying the ground for the policy until its formulation and extending to the preparation of the Implementing Rules and Regulations (IRR). It does not include the implementation of RA 6675. An epilogue appears at the end of the article as a way of discussing an overview of the accomplishments and key issues encountered by policy implementors.

In terms of time frame, the study focuses on the years 1986 to 1988, but as it is a study that deals with process, it was inevitable to look back prior to 1986 because much of the context, rationale and preparatory activities by the stakeholders started even before 1986.

The seeds of the Generics Act of 1988 were sown, so to speak, by some policy players even before the formal drafting in 1986. Although 1986-1988 remains most significant for the various policy players engaged in the passage of the Generics Act, the study necessarily finds itself in a crossover of events beyond the set time frame. The drafting and formulation of the IRR, although officially considered as post-legislation, are covered in this study because the interaction among stakeholders continued to unfold even at this stage.

Framework and Review of Literature

The formulation of a policy in the health sector is set against the backdrop of a political environment that is characterized by participation and democracy, resulting from the euphoria of the 1986 EDSA Revolution. Apart from the experiential lesson in contemporary Philippine history, a participatory policymaking is possible, according to different other cases such as in Bangladesh, India and Australia (WHO 1993).

Because policy is *public*, the people, upon whose lives the policy has impact, have a role to play in shaping such policy. The other version of public policy is that it is the domain of government institutions or officials who are accountable to the public (Croft and Beresford 1990).

Although policy and policymaking can be understood in a variety of meanings and perspectives, this article expounds and puts forward the following arguments:

1) public policy is political and as such it is open to differing interests and stakes;

2) stakeholders with varied motives try to influence the outcome of the policy;

3) a view on management of policymaking is that stakeholders/ social actors (including their resources)—both government and nongovernment—contribute to the shaping of policy; and

4) public policy formulation requires not only political keenness but also managerial smartness.

The second point raised herein, namely the presence of stakeholders in policymaking, opens up another dimension to understand policy and policy formulation. Public policy shifts from just being a concern of government, to one which involves the "public," or the various social actors. Hence, there is emphasis on participation and process. This then introduces "stakeholders' analysis" and "actor-oriented paradigm" as constructs of policy formulation. The stakeholders' analysis is an approach adopted by Michael Reich (1990). It is a method of including all "stakeholders" or those players—individuals and groups—who have something to say about a specific policy, because one way or another, positively or otherwise, these players have interests or stakes over the policy. Inasmuch as stakeholders' participation is tied in with the concept of policymaking, the conceptual framework of policy management as practiced by the DOH has been presented.

Delving into another perspective of policy and policy formulation, this article defines "policy and "policy formulation" anew. By referring to the various literature and definitions of policy, the study adds on another perspective on policy and policymaking. John Creighton Campbell refers to public policy as the "politics and theories about decision making" (Campbell 1992: 42). Indeed, because a large section of society is affected by public policy, a lot of politics and "politicking" go into the formulation of any public policy. This means that a range of policy interest groups or those who see stakes in a specific policy, work for and exert efforts to input their respective interests onto a given policy. In this sense, policymaking is political. Because of such complexity, the development of policy is rarely a simple or smooth-flowing process.

But policymaking is also a matter of theory and rationalizing an action that will affect the larger society. Determining a policy is about coming to an intelligent choice after a range of options and a series of activities are considered. Rather than the mere effects of interrelating forces, Smith (1976) affirms that policymaking is coming to a deliberate choice of action. Policy formulation is therefore a matter of making a willful choice—a decision that is

founded on certain aspirations, theoretically motivated by a vision directed at the welfare of the public. Thus, for example, the policy that promotes the utilization of generic drugs is, according to its promoters, in harmony with the larger vision shared by the WHO, namely, to bring essential drugs closer or more available to the people.

Policymaking therefore involves the two dimensions of power and rationality. Power has its origins in office. In large organizations such as government, officeholders more often than not, have the power of initiative which is not available to the rank and file. In policymaking, the power of determination comes as an attribute of the leaders and of leadership. Authority and legitimacy are features of power that allows leaders to carve out policies, or at least to initiate policymaking. The power to initiate a policy centrally lies with the officeholders.

However, there is also the power of groups outside government, which though there may be no use of coercive power, exerts influence through persuasion or pressure. Influence suggests relative rather than absolute power. And in many instances, influences can be competing.

Effective policy is therefore an expression of legitimated power which in turn is determined by the elements of democracy, representation, majoritarianism, local democracy, and consensus on one hand, and a responsible government on the other. Therefore, as there are Lindblom's (1968) "proximate" policymakers who are the legislators, ministers, officials in government, and so on, there are also those who are farther away from the center of decisionmaking yet may play specialized roles such as initiating, controlling, agitating, theorizing and so on. These roles are played by organized groups and parties, including citizen movements.

While Smith (1976) recognizes the two dimensions of policymaking, it is possible to bring together the two elements which have been kept apart, namely, politics, which involves conflict, ideology and power, and administration which involves planning, analysis and organization.

This article suggests that available definitions and understanding of public policy and its various elements are not necessarily contradictory. It is possible to use power, authority and rationality—characteristics of central decisionmakers—to realize a vision in policy formulation. Decisionmakers and officeholders use their power and authority to define rules and boundaries of policy, as well as to exact accountability on the policy. At the same time, however, the seat of power or the officeholders do not necessarily have to insulate decisionmaking from the public. Policymaking can engage the public (stakeholders and other players) in the process of shaping the said policy.

This also advances an understanding of public policy that has for its trademark, the combination of these two, namely, the use of power and rationality on the one hand, and participation of and interest representation by groups that have no clout on the official decisionmakers, on the other.

The lines are not clearly drawn on the issue of whether public policy is a domain of government or a function of civil society. Precisely, this study offers a definition of public policy and policymaking that lie between government and other social actors, the latter being a central part of a new definition of "public."

The article also posits that the management of policy formulation is about the orchestration of a complex set of political and institutional factors. As a process-focused study, the article unravels the diversity of interests in the policy, capturing the pluralist nature of the dynamics involved in policy formulation. The process expounds on the congruence as well as the dissonance in the policy spectrum, a notion that is well articulated in the interactive model of policy reform (Grindle and Thomas 1991). In such model of reform, the policy agenda and the process are at the center stage of the discourse regardless of whether the players and advocates come from the public or the private sector.

The stakeholders' analysis identifies which of those among the stakeholders favor reform, who are opposed to it and the more subtle differences found between and among them. Central to the management of policy formulation is the blend of institutional and political factors that enhance or diminish the policy at stake. The administrative and political factors as well as their interplay are integral to the outcome of the policy. Management of policy formulation deals with forces that are crucial to the shaping of such policy. These forces are however played upon by stakes which can be diverse at one point, or convergent, at another. Diversity of stakes is highly political. It is in regard to the highly political character of the management of policy formulation that tools for the handling of stakes and forces become useful. The political mapping of stakeholders describes and explains the processes involved in decisionmaking and identifies the strategies employed in changing decisions. Thus, the reform formulation is only viewed as an outcome but also as a process. Reich's (1990) political mapping of stakeholders is an analysis of the cooperation and conflicts among the stakeholders which provides a helpful construct that lays out the forces and the variety of sectors, with their corresponding interests in the policy.

The diversity of positions held by stakeholders and the complex of factors that contribute to the making of such a policy, including the policy context, require a high degree of managerial sophistication for the policy to be effectively orchestrated. The managerial skills include the character of the leadership which handles the policy reform process.

The management of policy formulation is even made more complex by the fact that the officeholder is itself the policy initiator. Again, this requires special skills and competence to rise above interest groups, even as the manager himself is biased in advocating a policy. The policy initiator's interest is to get the policy onto the agenda of the legislators. The study challenges Suleiman's (1974) position on the administration and interest or pressure groups that "the administration ... must resist pressure coming from those who seek particularistic aims" (Suleiman 1974: 329).

The Philippine generics policy advocacy sees the DOH playing the role of both policy manager and advocate. Its dual role emanates from the recognition of the authority and power vested in it as a leader which determines its proactive role in pursuing its vision for reform. Apart from being an advocate, DOH is also the policy manager and must deal with harmonizing the stakes and issues so that the policy would emerge workable and that it would satisfy stakeholders of differing perspectives. The policy manager likewise considers the management of social and environmental forces which are crucial to the outcome of the policy formulation and which require management of expertise, technical knowledge, media, resources and organization.

The management of a policy needs to deal with the following issues:

1. factors instrumental in developing a participatory policymaking process;

2. context, both political and administrative, of the policy formulation;

3. strategies of management that enables it to deal with political interests of stakeholders; and

4. use of resources at its disposal to effectively meet its objectives (Interview with Bengzon, August 1995).

The perspective taken by the management of health reform policy such as the generics policy, must be political as it is technical. Management of policy formulation brings in the strategies that rest on technical analysis, ability to conduct consensus-building, and capacity to oversee the conduct of participation among stakeholders. This includes conflict-resolution, negotiation, contingency planning and adaptation. Furthermore, management of policy formulation that involves stakeholders deals with the power and resource differentials among various participants in the policy process and the recognition of the relationship between participation and conflict among participants.

An important feature of policy formulation management in the Philippine context is the role, the style, and the power base of the manager who is required to develop appropriate techniques for dealing with key policy elites (legislators) and with policy supporters in order to develop sufficient space to maneuver a policy proposal towards a satisfactory outcome. Riggs (1964) and Donor (1992) emphasize the importance of managers being aware of complex interrelationships between values and administrative problems in order to understand the working of bureaucracies and the operation of policymaking.

The context, including the interaction between political and institutional factors within which a policy reform proposal emerges, is of crucial importance to a policy manager. The broader contextual setting of a policy, or the action environment (Grindle and Hilderbrand 1995) is the arena that defines the economic, political and social milieux in which a specific policy is taking place or is proposed to take place. It is the setting in which conditions obtain that determine the outcome of the policy, or the direction that policy and its management will have to take. This context either facilitates or obstructs the pursuit of policy reform.

Management of all these factors is not an easy task. It may even be punctuated with failures and frustrations. Crucial to the outcome is the orchestration of the differing elements. The irony in the orchestration of a policy reform is that while policy is highly political and riddled with the interests of the stakeholders, those most actively involved in the formulation of the policy change are technocrats who, at least officially, are supposed to be excluded from political involvement. It is only in rare instances that a policy formulation process may involve the best of both the politician and the technocrat in the manager.

The diagram on "Management of Policy Formulation" (Figure 1) shows a category of social players and their participation in the formulation of the Generics Act. The diagram also indicates the variables referred to as "institutional" factors which include expertise, skills, resources, network and organization, information and technology. The blending and balance of both sets of factors, political (i.e. stakeholders and their vision and motives) and institutional (i.e. resources, network, expertise) is a skill in policy formulation management. The interplay of these factors is described at each stage of the policy formulation.

Methodology of the Study

The article is a historical case. The case study method is used to bring out a description of the process of managing the adoption of the Generics Act of 1988. The descriptive study traces the history and the experiences in

policymaking from the views of the different stakeholders. The management of the process is focused on the DOH's experience and strategies. (See Figure 1.)

The analysis is descriptive and analytical of the events and the roles the different social actors played at the time of the formulation of the Generics Act of 1988. As a case study that discusses the roles played by social actors, the stakeholders' analysis is used to describe the process of policymaking. As a tool for understanding policy process, the stakeholders' analysis highlights the contributions of the social actors, and describes the interventions and type of activities engaged in by these social players. As such, the stakeholders' analysis brings out another focus on policymaking, namely, the actors and their activities.

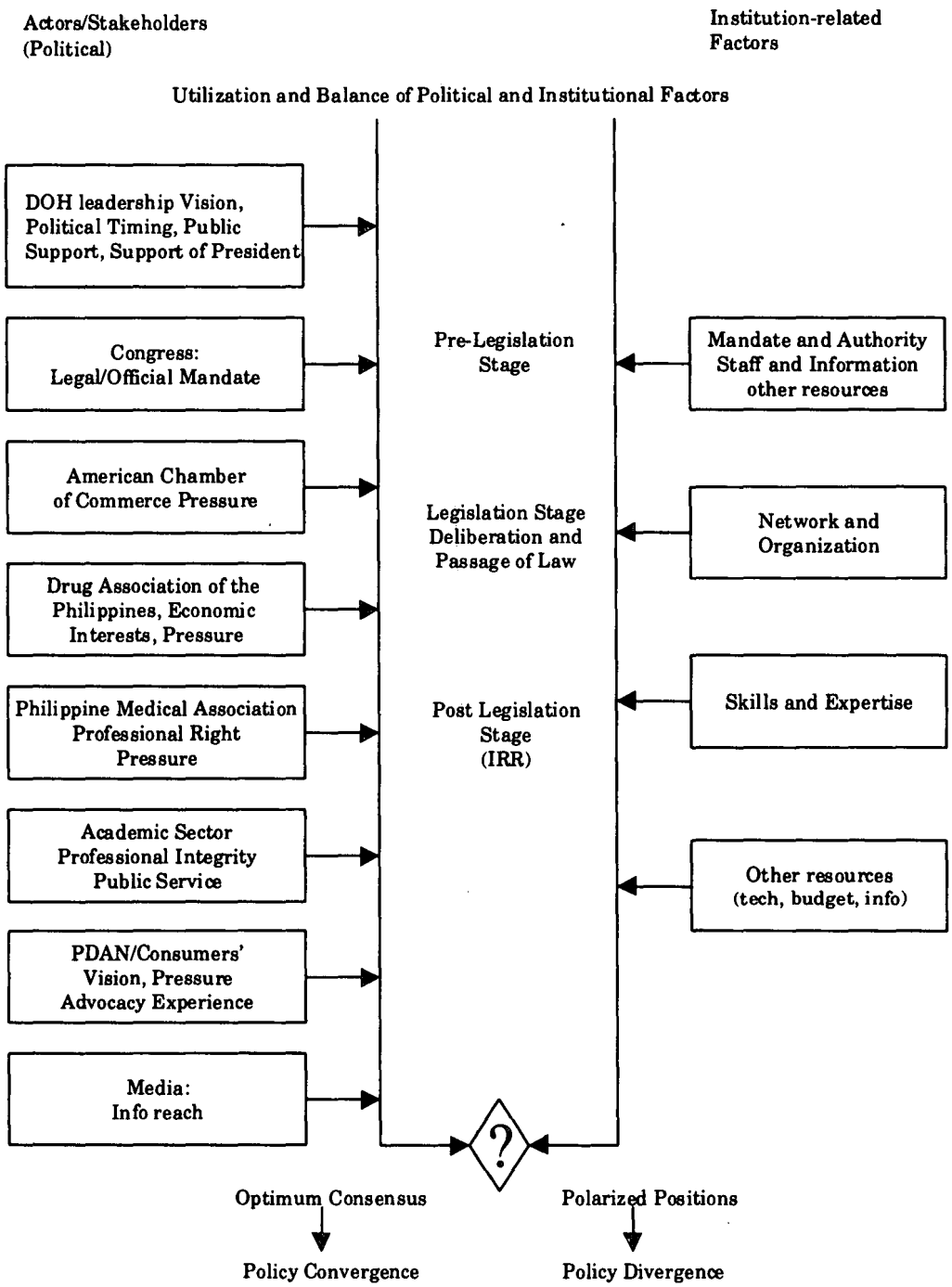
In a stakeholders' analysis, the social players, as well as their interests and motives, their roles, and the means by which they articulated their roles are all identified in the policy formulation. The methodology accounts for the rationale, the strategies, and the interests of different social players that act upon the policy. The tool of stakeholders' analysis therefore views policy formulation not only as an outcome, but also as a process.

Techniques of Data Collection

The study primarily used the interview method. Key informants and resource persons were identified at the initial stage of the study. The informants were selected on the basis of their involvement with and knowledge of the generics policy formulation at various stages of the legislation. A representation of informants on a cross-sectional basis was designed to ensure a balanced input of ideas from both supporters and oppositors of the policy. Most of the informants came from the Department of Health and from major stakeholders, such as the medical profession, the drug association, and the nongovernmental organizations (NGOs).

Document review and analysis were also employed. As a study that looks back at a historical experience in policy work, the research had to rely on documents and literature for references. The study thoroughly accessed records and files at the Senate Archives (Department of Finance) and at the Legislative Archives of the House of Representatives (Batasan Building). Proceedings and deliberation in Congress, including committee and public hearings, were scrutinized as a major data source. Proceedings of the bicameral committee meeting were also examined. Files and documents at the National Drug Policy (NDP) Program of the Department of Health were scanned and reviewed. The library of the Health Action Information Network (HAIN) was a rich source of valuable information on the drug policy and generics. Personal files and documents of Dr. Bengzon were also made available to the researcher. These

Figure 1. Management of Policy Formulation



were quite important sources of historical knowledge, sometimes even much more informative than the DOH references. The WHO library was also an important source of references.

A focused group discussion (FGD) among women members of a community organization affiliated with the Citizens' Alliance for Consumer Protection (CACP) was conducted.

Findings of the Study

The political context of that period prompted the formulation of the Generics Act of 1988.

The spirit of people power after the EDSA Revolution stirred the formulation of the Generics Act of 1988 with much impetus. The leadership at that time was fired with enthusiasm and inspired by "People Power" and people's participation. The DOH leadership recognized that it was an opportune time to introduce policy reform in the pharmaceutical sector by involving the public in the formulation and adoption of a reform measure in health and drugs.

The study also revealed that the DOH leadership recognized through its consultations and systematic research, that the pharmaceutical industry was heavily dominated by transnational companies that manufactured and aggressively promoted the use of brand-named drugs. According to the DOH, the situation was no longer acceptable, and it believed that reform in this sector was necessarily called for. Thus, nationalism and self-reliance, which again were fueled by "people's power" during the 1986 EDSA Revolution, and still fresh among the Filipino people, catalyzed public officeholders and the popular sectors alike to push for the formulation of the generics policy.

The reading of the situation in the health and drug industry brought the DOH leadership to its advocacy in formulating the Generics Act of 1988. The DOH's reflection and analysis done through a series of consultations and systematic research, established the need for a rational, comprehensive drug policy reform. The DOH study convinced the leadership that a policy needed to be institutionalized through the adoption of a law, rather than through executive orders and administrative proclamations.

The stakeholders in the Generics Act of 1988 are the Department of Health, the Congress which includes both the Senate and the House of Representatives, the American Chamber of Commerce (AmCham), the Philippine Medical Association (PMA), the Drug Association of the Philippines (DAP), different academics and experts, the Philippine Drug Action Network (PDAN), the CACP and the media.

With differing views and concerns, each of the stakeholders upheld their respective interests in the policy. As the formulation progressed, some of these stakes and interests were highlighted to polarize with those of others, while other interests were enhanced as these coalesced with similarly oriented stakeholders.

The study established that only one sector, namely the media, did not prove to have strong and single-minded stakes. Instead, media merely made itself a willing server or channel of other stakeholders.

The interests of the stakeholders varied according to their views, vision, and goals. These interests ranged from economic, business and investment interests, public service and the promotion of people's health, technical and professional integrity, protection of consumers' rights, to the search for and identification of a popular policy.

These interests correspond to the stakeholders as follows:

Stakeholders	*Interests*
1. DOH	public service and the promotion of people's health
2. Congress	search for and identification with a popular policy
3. Amercian Chamber of Commerce	business and investment interests
4. Philippine Medical Association	technical, professional interests
5. Drug Association of the Philippines	economic and business interests
6. Academics and experts	technical, professional integrity and promotion of people's health
7. Philippine Drug Action Network	public service and promotion of people's health
8. Citizen's Alliance for Consumer Protection	protection of consumers' rights

The media did not prove to be a distinct stakeholder although it served as a pliant player in the policy process.

Furthermore, the study discovered that a set of interventions using specific modes of action by the stakeholders were used to advance their

respective advocacies. The interventions, also referred to as strategies, are characterized by the following:

1. Vision

This pertains to a desire for policy reform in the drug industry by altering what was at that time, a status quo in the practices of prescription, labeling, manufacture and purchase of drugs. The vision for reform was a passion and a commitment to introduce changes in these practices through the adoption of a policy that would allow prescription, labeling, manufacture, and purchase of drugs through the use of generics.

2. Competence and Expertise

By utilizing the technical competence, expertise, knowledge and experience of academics and the scientific community and those from the private sector, and by complementing these with the research expertise of the nongovernmental organization (PDAN), the DOH rationalized the policy and the requirements of its adoption.

3. Network and Reach

The link of the nongovernmental organization (PDAN) to the public and its network with some international agencies albeit limited, were an advantage in terms of gaining support on the advocacy and multiple pressures upon decisionmakers.

4. Economic Power and Impact on Public Information

The Drug Association of the Philippines and the Philippine Medical Association used their economic power and capability to pay for advertisements which reflected their advocacy on the policy. By using these strategies, the pressure on policymakers, the public and on the DOH itself was heavily placed by the DAP and the PMA.

5. Pressure on the Leadership and on the Legislators

Pressure politics was applied by the American Chamber of Commerce and the two American senators' pressure upon the DOH and the Philippine Senate, to block off the adoption of the Generics Act of 1988, and in effect, promote their interest in obtaining a liberal policy in the Philippine drug industry. Pressure politics was carried out through the assertion of their position on both the Executive (President and the DOH

Secretary) and the Legislative (Senate) branches of the Philippine government.

The interplay of these modes of action composed a synergy, allowing the DOH strategy of blending interventions by different stakeholders, to be able to manage the formulation of the Generics Act of 1988.

The study established the points of convergence among stakeholders such as:

1. A nationalist perspective on the drug industry among stakeholders

   A nationalist perspective on the drug industry was shared by the stakeholders. This perspective means a preference for a policy that would uphold the manufacture, labeling, distribution, prescription, and consumption of drugs that are locally available and which are in the hands of the local drug industry, rather than by transnational companies. Furthermore, nationalism puts emphasis on the determination of these habits and practices by the Philippine government through the DOH, over a drug industry that remains unregulated yet dominated by transnational companies.

   The stakeholders that rallied behind the issue of nationalism were the DOH, PDAN, the academics, and the Senate.

2. An advocacy to make drugs affordable for all

   The advocacy to make drugs affordable for all specially the poor were shared by stakeholders namely, DOH, PDAN, the academics, Senate and House of Representatives, and the Citizens' Alliance for Consumer Protection.

3. Preference for an informed choice of drugs

   The preference for an informed choice of drugs, rather than a prescription practice that lies solely with the technical expertise of the medical profession, was common among the DOH, PDAN, the academics, and the Senate.

4. The freedom of drug firms to circulate products in the market

   The Drug Association of the Philippines and the Philippine Medical Association vigorously lobbied for the freedom

of drug firms to circulate products in the market. Such advocacy was acceptable to the Senate and the House of Representatives.

5. Regulated circulation of drugs in the market

DOH and PDAN both believed that the circulation of drugs in the market should be regulated. They are convinced that government institutions have a role to play in regulating drugs circulation.

6. The promotion of the Essential Drugs List (EDL)

The promotion of the Essential Drugs List (EDL) as a basis for the acquisition and purchase of drugs was shared by the DOH and the academics.

From the series of consultations among these stakeholders surfaced the points of convergence. The process of interaction among them (stakeholders) made possible an osmosis of issues which initially were viewed from different perspectives. This then enabled stakeholders to coalesce according to the issues which they considered common.

On the other hand, there were also some points of divergence among stakeholders. Some of the stakeholders differed in the following issues:

1. The impingement on the rights of the medical profession to prescribe

The Philippine Medical Association believed that the policy would impinge on the professional rights of doctors to prescribe. The PMA thought the threat was pushed by the DOH through the provisions of the policy.

2. The restriction of opportunities for business and investments

Restriction on business and investments was a point of contention between the American Chamber of Commerce and the Drug Association of the Philippines on the one hand, and the DOH on the other.

3. The possible unrestricted circulation of fake and poor quality drugs in the market

The DAP and the PMA feared that fake and poor quality drugs might circulate in the market. This was hurled by the DAP

and the PMA against the DOH as a controversial issue that the adoption of the Generics Act of 1988 would bring forth.

The management of the adoption of the Generics Act required the combination of skills by the DOH as both advocate and manager. The DOH's ability to manage were exhibited through a participatory and consultative approach to the identification of the policy measure, the inclusion of competent and expert personnel from the private sector into the DOH, a systematic review of the DOH capacities and the requirements of policy formulation on generics through research, study tours and joint planning and reflection prior to action, an enhancement of the content and provisions of the policy through the inputs by the academics and experts, and by using the research and information by PDAN. To enhance the institutional capacity of the DOH and prepare it for the challenges that lie ahead in the policy implementation, the department and the various divisions and units under it geared toward a strengthening of the entire department.

The DOH provided an informed, technical support to the legislators regarding the details of the policy. Even so, the Department continued to link with nongovernmental sectors to establish partnership in information, education, and training and to generate popular support (IEC). The DOH and the NGOs through the PDAN, collaborated to carry out training and information campaign on the issue of generics in some regions of the country. As far as possible, the DOH accommodated differing views about the policy to a point where principles and vision are not substantially compromised. These were carried out through numerous consultations and meetings among sectors and organizations, especially among those who had strong reactions against the generics policy. As far as possible, the DOH tried to accommodate views on the policy and it listened to and interacted with oppositors of the policy. As a manager, the DOH put a time frame to impose a sense of urgency on the policy through memoranda and administrative orders within the department enjoining personnel and units to study the proposed policy and to execute responsibilities that would facilitate the legislators' adoption of the policy. And finally, as if all these were not enough, the DOH solicited unequivocal support from the Chief Executive in the adoption of the Generics Act of 1988.

The DOH showed its ability to advocate for the policy by initiating the process of identification of the policy reform, recognizing the need for policy reform, and by connecting between government accountability and functions on one hand, and the nongovernmental organizations' vision and sense of mission on the other.

The study affirmed that there were two sets of factors that influenced the outcome of the Generics Act of 1988. There were facilitative and deterrent factors.

The main element in the success of managing the formulation of the Generics Act of 1988 was the ability of the DOH to orchestrate the complex environment and the differing positions of the stakeholders involved in the policy formulation. Specifically, the ability to orchestrate the process relied on the following factors:

1. passion and commitment of the DOH to a vision for policy reform;

2. competence to deal with the strengths and weaknesses of the DOH as a department confronted with the challenge to initiate policy reform;

3. supplementation of the in-house capacity (of the DOH) by expertise found outside the Department; and

4. popular support and advocacy on the policy by virtue of the democratic character of the policy proposal.

On the other hand, there were deterrent factors, namely:

1. pressure placed by big business such as the American Chamber of Commerce and the Drug Association of the Philippines upon the DOH and other stakeholders;

2. continued domination of transnational companies in the drug industry; and

3. the prescription habits of the medical doctors in favor of brand-named over generic drugs.

On the whole however, the facilitative factors prevailed over the deterrent factors. The ability of the DOH to enhance the facilitative factors and to blur or dilute the deterrent factors spelled a difference in the management of the formulation of the generics drug policy.

Summary and Conclusion: Management of the Drug Policy Formulation

Policy Context

The policy was borne under a condition ripe for change and for a drug policy formulation. The policy context was also one where the DOH realized that transnational companies dominated the Philippine pharmaceutical industry and therefore, that the status quo was not acceptable anymore. The

rationale and need for the formulation of the Generics Act were clearly established and articulated by the DOH, which was both initiator and manager of the policy formulation. The policy context included the political mood of 1987 when the Filipino people freshly emerged from a victory against the Marcos dictatorship, a political climate just too open for a change in the drug industry. The context is important to policy reform.

Stakeholders' Positions

The generics policy challenged the political viewpoints and positions of the stakeholders involved in policymaking. It opened an opportunity that revealed the different interests and positions, as well as the strategies adopted by the stakeholders as they went through the various stages of the policy formulation. In the beginning, there was an apparent consensus regarding the rationality and need for the generics policy. DOH's vision to legislate a generics policy was shared by all sectors which participated in the consultations. However, interests and motivations became more polarized during the last stage of the policy formulation. The cleavage deepened when the implications of the law and their stakes in the pharmaceutical business dawned on the oppositors.

There was consistency in the alignment of positions among the DOH, PDAN, and the academic sector. These three groups of stakeholders fed on each other's abilities and skills in different ways, such as the academics' expertise on important technical inputs during the various sectoral and multisectoral consultations and skills in the preparation of the national drug formulary. There was also the NGOs' information, education and training support for the DOH. The DOH enhanced the roles of the NGOs and the academic sector by allowing them to contribute to the process of policy formulation.

The consumers, less informed about the issue, did not stand out prominently because they depended on the medical experts and the NGOs for technical information. As a result, the consumers' role was reduced to passive supporters of the DOH.

The DOH fairly involved the potential oppositors to the policy from the early stage of the consultations. As the reaction of the oppositors grew stronger, the DOH strengthened its reliance on technical inputs that effectively argued its position. This then swayed the legislators to the side of the DOH. Technical inputs and experts' knowledge pulled away the DOH from what emerged as self-centered interests of the opposing stakeholders. Furthermore, with a popular support behind it, the DOH redirected the heat of the controversy from itself to the popular movement. The alliance and identification between the DOH and the organized groups gave the DOH another positive weapon.

On the whole, the similarity of positions was consistently and strongly maintained by DOH among its allies. On the other hand, the DOH dealt with the opposition through a counterposition based on well-founded research and technical arguments. Openness was the spirit behind the DOH's accommodation of the oppositors' demands. But openness did not necessarily mean complete accommodation of and acquiescence to the oppositors' demands. By using sovereignty and self-reliance as reasons, the DOH dealt with external pressures exerted by the American senators and the American Chamber of Commerce.

Management of Resources

The resources—technical expertise, personnel and organization, material resources, and information network—were treated by the DOH as elements by which to start policy work and to strengthen its capacity. The DOH carried out a review and overhauling of the department involving the following:

1. stock-taking of the internal capacities and resources available at the department;

2. creation of the Philippine National Drug Policy Programme through which the R (Rational drug use) pillar was given sufficient attention;

3. orientation and reeducation of DOH personnel at all levels of the department regarding the policy;

4. retraining and development by BFAD personnel through short-term training facilities and country exposures;

5. strengthening the BFAD by linking it with experts from the academe and the professional societies by involving academics from the University of the Philippines College of Medicine and the University of Santo Tomas' Department of Pharmacology, in some of BFAD's activities;

6. enhancing the facilities and equipment of BFAD toward effective regulatory functions and operation such as through the importation of laboratory equipment and monitoring system from Australian development agencies;

7. tying in with the NGOs involved in health education and advocacy for the DOH's program on training and seminars regarding generics such as in Regions III and V;

8. study tour by key personnel and consultants on national drug policy experiences in neighboring Asian countries; and

9. research and documentation on the world and national drug situation involving the expertise of medical professionals and practitioners.

The DOH made policy reform a collaborative effort between government and nongovernment sectors.

Strategies and Interventions

A comprehensive approach was used by DOH involving capacity-building, institutional strengthening, information and education campaign, participation at all stages of the policy formulation, and solid defense of the policy position from a technical, medical viewpoint. Research and documentation was integrated into the planning and strategizing thereby linking technical knowledge with management. The formal channel such as the bureaucracy, and the informal one such as the nongovernmental sector complemented each other in the information-dissemination strategy.

A consultative approach to the process set the generics policy apart from any other legislative policies. Expertise and professionalism within the DOH top management and consultants were unequalled hallmarks of the DOH leadership, factors crucial to a decisive management of policy formulation. Harnessing competent people was a strategy of the DOH. There was careful blending and management of political and institutional resources which led to a powerful policy outcome.

Factors that Facilitated the Management of Policy Formulation

A number of factors facilitated the management of the generics policy formulation:

First is *political timing*. There was a political mood after the Marcos dictatorship: openness for policy reform.

Second is the *ability and skills to negotiate with the legislators*. DOH possessed the knowledge and skills to convince and approach the key legislators through formal and informal channels. Through its ability to feed information to the legislators, the latter valued the assistance of the DOH in the deliberation and adoption of the policy. Likewise, the DOH sat in crucial meetings to support the legislators in the latter's decisions, and it persuaded a

number of them, mostly the undecided ones, by attending informal gatherings where interactions were more relaxed and conducive to achieve unity.

Third is the *competence and expertise of the DOH leadership*. This refers to the ability of the DOH to do its homework by shaping up the department's internal capability. The DOH leadership ensured that above all, the personnel of the department were informed and convinced about their own advocacy and proposed policy. The DOH engaged its own staff—seniors and middle-level—in the research and consultation processes as well as in the proactive interface with legislators. The legislators' information and basis for deliberation, were in fact, supplied by the DOH through the latter's research and hard work.

Fourth is the *leadership's vision and personality*. The DOH Secretary was moved by the vision and decisiveness to pursue a drug policy reform. Leadership meant not delinking the role of a manager from an advocate. The DOH Secretary's own personality, as someone close to and trusted by the Chief Executive, was crucial in gaining the endorsement of the President in favor of the policy.

Fifth is *information technology and network*. The in-house facilities for information-dissemination and training and the external resources within its reach, were put to use by the DOH. Its network included the NGOs from where the DOH Secretary came.

Sixth is the *support from the Chief Executive*. As a personal and political confidant of the President, the DOH Secretary himself was a convincing channel for the policy to gain the Chief Executive's support.

Factors that Deterred the Management of Policy Formulation

The deterrent factors include:

1. lack of persistence and resources to pursue information and education campaign—the inadequacy to meet the demand for a thorough and broader reach of the IEC not only in the metropolis but also in the rural areas;

   The advocacy on the generics policy still lacked the information and education campaign enough to cover also the rural areas in the country. The DOH efforts were mostly absorbed by the process of the legislation, after the series of consultations among sectors and organizations.

2. pressure from the US Senate and big business;

The presence of two American senators in the Philippine Senate was viewed by the Filipino legislators as an obstruction to the passage of the generics drug policy, which had caused anxiety and tension among Filipino decisionmakers. The same was true in the case of the American Chamber of Commerce which had an exchange of strongly worded communication with the DOH Secretary.

3. political economy of pharmaceuticals in the Philippines;

The dominance of transnational pharmaceutical industry and its resistance to the policy strained the DOH efforts on policy reform. Through the influence exerted by the pharmaceutical industry via the DAP and the PMA, the strongest resistance to the policy was hurled against the DOH. The shared interests of the industry and the PMA posed as the biggest challenge to the DOH as far as the passage of the policy was concerned.

The DOH experience on the generics policy formulation tells a lesson. It says that the operation of solving a differential equation, through recognition of differing variables, is possible. And in the face of differing motives and interests of stakeholders, policy formulation could be managed by segregating political variables from institutional factors. The orchestration of these variables and factors, along with the timing, is the contribution of the manager. Vision, competence, and ability for negotiation are the hallmarks of an advocate-manager.

Epilogue: Milestone and Key Issues in the Implementation of RA 6675

The formulation of the policy was concluded by the implementation which began in 1990. After almost a decade of its implementation which began in 1988, the DOH commissioned the UP College of Public Administration to conduct an evaluation on the implementation of RA 6675.

The evaluation study noted some key results. Its most salient findings are:

a) The National Drug Committee completed and published five Rational Drug Use Training Modules for use in the training courses for members of the Therapeutics Committees. It also completed the second and third editions of the Philippine

National Drug Formulary (PNDF), Volume 1. At the time of this research, the Essential Drugs Monitor and the Cross Reference Index of Registered Drugs were still in the press for publication.

b) Training for health professionals including pharmacists and pharmacy assistants were conducted in various regions of the country.

c) The National Drugs Policy–AIDAB Project was launched in late 1993 with a Quality Assurance Component and a Rational Drug Use component. The project was expected to provide technical assistance, training and fellowship and some equipment to the National Drug Policy over the next five years.

d) There was an increase in the percentage share of unbranded generics in the total market from less than two percent in 1988 to about ten percent in 1993 in pharmaceutical unit terms (Varela 1997).

The level of compliance by government is observed in these two main accomplishment areas, namely: (a) that there was mandatory use of the current edition of Philippine National Drug Formulary (PNDF) Volume I as the basis for procurement of drug products by the government (EO 49); and (b) that government doctors are required to prescribe in generics. Compliance in this regard is very high as shown in a survey spot checking conducted at government pharmacies and local drug outlets.

Inspite of the program accomplishments, both implementors and policymakers identified key issues such as follows:

a) There is an inadequate utilization of the PNDF due to limited copies and poor distribution system of the PNDF. As a recommendation, copies of the PNDF should be made available to consumers.

b) End users still have a traditional bias for branded drugs. The lack of exposure to alternatives to brand-named drugs explains the perpetuation of the latter. This problem is somehow connected to the limited PNDF availability. The problem is also rooted in uncontrolled expensive multi-media advertisement potency of brand-named drugs by transnational pharmaceutical firms. The practice also stems from sustained habitual use of brand names by doctors prescribing them and also from practices of end-users.

c) Self-medication and use of over-the-counter (OTC) drugs still proliferate due to the high cost of consultation and professional fees. The DOH and the Philippine Information Agency (PIA) are recommended to provide IEC materials on herbal medicines and on rational drug use. According to policy implementors, the Generics Law does not clearly provide for a strong IEC which is important in the rational drug use campaign.

d) There is still an "irrational drug use" because prescribers have not fully observed the law's provision on prescription. There are still inappropriate prescribing practices. Such negative behavior comes from an inadequacy of refresher courses for prescribers.

e) Itinerant vendors and sale of drugs in *sari-sari* stores continue to proliferate. The sale of drugs without prescription by a pharmacist remains a habit.

f) Manufacturers continue to demand for an amendment to the Penalty provision under Sections 6 and 12 of the Implementing Rules and Regulations.

g) Likewise, the PMA urged that professional freedom, i.e. doctor's freedom to prescribe brand-named drugs be strongly considered. In this regard, the doctors intend to lobby in Congress.

h) There is noncompliance of EO 49 and therefore, strict implementation by NDP was urged. As a strategy, the NDP plans to carry out a seminar workshop among auditors regarding EO 49 (Varela 1997).

i) The substitution needs monitoring and in this regard, the BFAD was recommended to deal with monitoring.

Significant achievements of RA 6675 are evident in key result areas, namely, in putting out two volumes of the EDL or the National Drug Formulary which determines the drugs for procurement and circulation by the government, in training medical practitioners on drug formulary and in producing training modules for medical assistants, and an increase in the use of generic drugs from two percent in 1988 to ten percent in 1993.

However, there were problems encountered in the implementation such as: poor circulation of PNDF due to limited copies, end-users tend to stick to brand-named drugs due to flooding of advertisements in multi-media, IEC efforts greatly strengthening on the part of the DOH and the PIA, and finally, prescribers still stick to old prescribing habit and practices which favor brand-named drugs.

In the midst of medical practitioners' demand for liberty on prescription, majority still tend to ignore the provision of the Generics Law regarding prescription. It is necessary for government to campaign harder to solicit wider support for the law through more effective information and education strategies.

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