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EVOLVING, CRAFTING AND IMPLEMENTING THE PHILIPPINE NATIONAL DRUG POLICY AND THE GENERICS ACT OF 1988 – A MODEL IN SCIENCE AND TECHNOLOGY POLICY-MAKING

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Introduction

The story of the landmark Philippine National Drug Policy (PNDP) and the ensuing Generics Act of 1988 (G.A. 1988) has all the elements of Science and Technology policy-making. It is therefore important that it be properly recorded and documented so that lessons applicable to other fields of Science and Technology can be drawn from it.

The Philippine National Drug Policy (PNDP) was declared by Presidential Executive fiat while the Generics Act of 1988 passed through the legislative mill.

This paper describes in detail the process of evolution of both the PNDP and G.A. 1988 so they can serve as models of Science and Technology policy-making in the Philippine contemporary environment.

A. PHILIPPINE NATIONAL DRUG POLICY

IDEATION STAGE

As with many good ideas, the birth of PNDP was the result of the right combination of factors and circumstances. Perhaps the most crucial of these was the installation of a new government and a new management team at the Department of Health (DOH) as a result of the peaceful EDSA Revolution of February, 1986. The second critical factor was the presence of sensitive development managers in the person of Sec. A.R.A. Bengzon, Undersec. Rhais Gamboa and others who were quick to recognize a need and grab the opportunity for a major policy initiative in the pharmaceutical field. The third factor was the strong felt need to provide good quality and affordable drugs to the people. In fact, in all of the President's regional consultation, one of the most frequent issues raised was that drugs and medicines are beyond the reach of the majority of the Filipinos. The fourth factor was the worldwide problem of inadequate access to essential drugs and irrational use of drugs which led to the launching of WHO's Essential Drug Action Program in 1981.

As Sec. Bengzon has described it, the National Drug Policy can be said to have been largely born out of serendipity. Just a few months in office and needing to provide drugs for the health care programs, he asked Undersecretary Rhais Gamboa to look into the existing drug policies. It turned out that there was no

long-term comprehensive drug policy. Drugs were procured as needed on an *ad hoc* basis. Procurement seemed largely based on previous practices carried over from one administration to another. Worse, there was lopsided favoring of a single group of companies close to the former President, giving credence to the rumor that grease money changed hands when drugs and medicines were procured by government.

It became obvious to the DOH management that graft and corruption and the lack of a long-term comprehensive drug policy could be solved with a new National Drug Policy. Sec. Bengzon can be best described as the architect of the New Philippine National Drug Policy as well as of the Generics Act of 1988.

THE EVOLUTIONARY PROCESS

As soon as the imperative for a new National Drug Policy was accepted, preparatory work began with the creation of a special Task Force on Pharmaceuticals composed of:

Mrs. Milagros S. Castro	--	Chairman
Dr. Antonio Gonzaga	--	Member
Dr. Natividad de Castro	--	Member
Mrs. Lina Esquivel	–	Member
Mr. Federico Gonzales	–	Member
Dr. Antonio Perlas	–	Member
Dr. Estrella Paje-Villar	–	Member

The Task Force was to gather as much primary and secondary information through research, interviews, consultations, solicited position papers seminar-workshops and conferences. Work started in mid-1986, initially to determine the scope of policy formulation. The actual conduct of research and consultation continued all the way up to April 1987. The research included local studies and publications on the Pharmaceutical System done in other countries or by the World Health Organization or other International Bodies. One such study was by the UN Asia-Pacific Development Institute (UNAPDI) -- a commissioned study on the pharmaceutical Industry in the five ASEAN Countries in 1980. Aside from these studies and publications, interviews and consultation and position papers were submitted by various sectors such as Academe, the Professional Health Providers in government and private sector the Pharmaceutical Industry, – Government Organizations, Non-Governmental Organizations and Consumer Groups. All these were analyzed and synthesized by the Task Force resulting in the identification of the following 7 areas of concern: 1.) essential drug list 2) use of generic name, 3.) advertising and promotions 4.) procurement and self-sufficiency 5.) self-medication 6.) registration of pharmaceuticals and 7.) pricing. These 7 areas of concern were then discussed in depth in seminar-workshops and conferences. All in all, there were 25 position papers, 2 national seminar-workshops or conference

participated in by 99 individuals and resource persons representing 61 different organizations.

From these discussions was formulated the first statement of the Philippine National Drug Policy and its four component pillars. The statement was enunciated by Pres. Corazon Aquino on April 30, 1987 on the inauguration of the new buildings and laboratories of the Bureau of Food and Drugs of the Department of Health at Alabang.

SUMMARY OF THE PHILIPPINE NATIONAL DRUG POLICY

GOAL

The goal of the PNDP is to provide access for the majority of the population to essential drugs which are safe, efficacious and of high quality.

Towards this end, the following major problems had to be addressed: 1.) the presence of toxic or unsafe, inefficacious, and substandard drugs in the market, 2.) the unnecessary or inappropriate use of drugs, 3.) the high dependency on imported active ingredients and even excipients, for drug formulation, and 4.) the wasteful and inappropriate procurement of drugs by DOH.

FOUR COMPONENT PILLARS

These 4 problem areas required major program initiatives which eventually were known as the four pillars of the Policy. These four pillars are interdependent and they mutually reinforce one another. For easy recall, the pillars were made to start with the letters Q, R, S, and T, the names of the ECG wave pattern familiar to health workers. As renamed, the four pillars are:

Q – Quality Assurance
R – Rational Drug Use
S – Self-reliance
T – Tailored Procurement

Each of the component pillars addresses the four major problem areas enumerated above.

KEY PLAYERS

For the crafting of the policy statement declared by the President, principal credit goes to Undersecretary Mario Taguiwalo. For the refinement and fleshing out of the four pillars, credit goes principally to Dr. Alberto Romualdez, Jr. and later also to Dr. Quintin Kintanar and Manuel Dayrit.

IMPLEMENTATION

Even before the PNDP and its four pillars were fully elaborated, implementation had already been started in late 1986 by the original core group of the task

force, namely Antonio Perlas, Natividad de Castro and Estrella Paje-Villar – then known as the "troika." In early 1987, Dr. Alberto Romualdez,Jr. was named as the official responsible for the National Drug Policy. Simultaneous activities were undertaken to achieve the goal of PNDP through its four pillars

Quality Assurance

Strengthening the Bureau of Food and Drugs (BFAD) – the government's regulatory agency – was the first order of the day. An Advisory Committee on BFAD was created. Its members were Dr. Cecile Gonzales, a pharmacologist, and Dr. Natividad de Castro and Prof. Leticia Gutierez, pharmacists. BFAD policies, standards and procedures were reviewed. In-house and external training of incumbent personnel was undertaken while new personnel were carefully selected to strengthen the human resource of BFAD This training was started in 1987 during the term of Dr. Romualdez as Assistant Secretary In-Charge and BFAD Director Catalina Sanchez, BFAD was further strengthened with the upgrading and revision of standards and requirements under Dr. Q. Kintanar starting July, 1988 and Dr. Cecile Gonzales, who became BFAD director in February of 1989.

Completed by the end of 1988 were the revised rules and regulations for obtaining a license to operate drug establishments and outlets (A.O. 56 s. 1989), the process of Drug registration (A.O. 67 s. 1989), and the process of review and evaluation of Questioned Drugs (A.O. 66 s. 1989). Copies of these A.O.'s are attached for reference as Annex A.

The new BFAD has already produced concrete results. The drug market has been cleansed of unsafe and inefficacious products with the withdrawal of 138 of the 265 banned, severely restricted, or disapproved drugs in other countries. Two manufacturing firms have been closed and the licenses to operate of 26 manufacturers have been suspended for major deficiencies in Current Good Manufacturing Practice Standards (CGMP).

Rational Drug Use

This pillar was tackled in both diagnostic and prescriptive ways. First, an analysis of national drug requirement and sales by Therapeutic Category as part of the RP-UNIDO Pharmaceutical Industry Development Study completed by Oct. 1988, showed a large unfilled gap of $ 44 B worth of drugs, while at the same time documenting an 16% irrational or unnecessary use of drugs such as vitamins, hormones and dermatologicals amounting to ₱1.5 B in 1987 (Table 1)

Then the National Drug Committee developed the first Philippine National Drug Formulary (PNDF), with the active participation of experts and specialists in academe, government, private sector and industry. From the PNDF (which contains 297 Core list Drugs and 262 Complementary List Drugs belonging to 22 therapeutic Sectors and 64 therapeutic Subcategories) have been derived the DOH Hospital Formulary for Secondary and Tertiary Hospitals and the Formulary of Primary Medical Care Drugs for Rural Health Units. These formularies shall

serve as a guide in the procurement of essential drugs by government and provide the best available scientific information and experience to the medical and pharmaceutical professions on the most important safe and effective drugs.

Lastly, to rationalize and put the use of drugs on a scientific basis, the Generic Acts of 1988 requires the use of the generic name of the active ingredient at every stage of the drug life from production, distribution, advertisement, prescribing, dispensing to consumption.

Self-reliance

This pillar is by its very nature a long-term program. However, some elements geared towards self-reliance had already started when the PNDP was formally declared in 1987.

For instance, there had been for about 10 years a well-coordinated productive R and D on medicinal plants under the National Integrated Research Program on Medical Plants (NIRPROMP) and funded by the Philippine Council for Health Research and Development (PCHRD). By 1987, NIRPROMP had already generated research results ready for commercial application. Moreover the previous Administration had built the infrastructure and bought equipment under a World Bank loan for three commercial processing and manufacturing facilities for medicinal plant products in three different regions. Thus, what we required to operationalize this plank of the self-reliance pillar was only to complete the delivery of necessary equipment, install them, and start the commercial production of medicinal plant products. The Cotabato plant started its operation in November of 1988 with no less than Pres. Corazon Aquino as guest of honor.

The Second Plank under the self-reliance pillar was the expansion and modernization of the Alabang Vaccine Production now under the Biological Production Service of the DOH. A major development plant study had earlier been completed by Intercare Consultancy Firm through PCHRD, funded by US-AID. This study was reviewed by an International Panel of Experts from UNIDO which confirmed many of the findings and conclusions of the Intercare study recommending the establishment of a Biologicals Central Control Authority & Laboratory and the building of a new production facility to replace the largely obsolete present vaccine production facilities at Alabang in support of the country's Expanded Program of Immunization.

The Third Plank of this pillar consists of longer-gestation projects identified by the RP-UNIDO Pharmaceutical Industry Development Study. These projects are for the local production of strategic pharmaceutical products using largely indigenous raw materials. Seven prospects requiring further feasibility or pilot studies have been identified, namely: a) Establishment of a multi-purpose fermentation pilot plant for antibiotics b) Establishment of a production plant for Penicillin and 6APA (6-Amino-Penicillanic Acid) c) Expansion of existing facilities for semi-synthesis of Ampicillin, Amoxycillin, Cloxacillin and Cephalexin d) Establishment of an Erythromycin derivatives & Rifampicin Production Plant e) Establish-

ment of a multi-purpose pilot plant for chemical synthesis f) Cultivation and processing of Cinchona and utilization to produce Quinine g) Upgrading of quality control facility and the Biologicals Production Services at Alabang.

Tailored Procurement

This pillar has been most amenable to immediate implementation and has already generated concrete impact. The Logistics and Procurement Service of the DOH was re-organized and new bidding policies and requirements and procedures were instituted to minimize graft and corruption, and effect cost reduction in drug procurement. In the initial two years of application, a 30% cost-saving in the expenditure for DOH drugs and medicines, amounting to about ₱270 M, was realized. The savings were used to purchase more drugs thereby fulfilling the ultimate goal of the PNDP of providing essential drugs to those who do not have access to them.

Further improvements can still be realized under this pillar by studying the real drug requirements of hospitals through a methodology involving an analysis of morbidity patterns, number of cases treated and applying the current accepted standards therapy on these cases using the essential drugs recommended in the PNDF. This way, the procurement can truly be tailored to the actual needs of patients and hospitals. A study in Sri-Lanka showed that this approach can cut the cost of medicines for in-patients by four-fold and out-patients by eight-fold.

In all these activities, the principle of dynamic flexibility adapting to the exigencies and changing environment as quickly and as much as necessary has been followed. A substantial measure of success has already been achieved in all four pillars of the PNDP.

THE GENERICS ACT OF 1988

In a similar manner the evolution, crafting and implementation of the Generics Act of 1988 demonstrate the kind of preparation, hard work and meticulous attention to detail necessary in good Science and Technology policy-making.

IDEATION STAGE

Again, the Generics Act of 1988 came serendipitously, even as an afterthought. Initially, it was thought that the PNDP and its four pillars were sufficient to effect the needed reform in the pharmaceutical system. Keen legislators in both the Senate and the House of Representatives, however, saw the need for a law to hasten this transformation as envisaged in the PNDP which the Department of Health quickly supported.

EVOLUTION

From direct legislative mandate to promote or require the use of off-patent cheaper generic and essential drugs for the public sector, the idea evolved into a

broader legislative proposal based on the philosophy of rational and scientific use of drugs and medicines. The Generics Act in its final form gave the patient a role in the choice of the final product he shall buy, without deviating from the doctor's prescription.

CRAFTING OF THE GENERICS ACT OF 1988

With the technical assistance given by the Department of Health, principally through Secretary Alfredo R.A. Bengzon, Dr. Alberto Romualdez Jr., the NDP Management Committee, and the DOH liaison officers in Senate (Dr. Cora Rivera) and the House (Mr. Dante P. Esquejo), the bills passed both houses reasonably smoothly. The principal authors were Sen. Orlando Mercado for the Senate and Congressman Narciso D. Monfort for the House of Representatives. However, a "killer" amendment was introduced in the House version which would allowed the prescribing doctor to write "No Substitution" or words to that effect. Because the law allows the physician to indicate the brand name, if he so desired, allowing the prescriber to write "No Substitution" would have nullified the participation by the patient in the final selection of the product to buy. The versions approved separately by both houses are attached as Annex B for reference and comparison.

Fortunately, alert members of the Joint Conference Committee who saw it, removed the "killer" amendment in the final harmonized version which was passed by the Senate and the House almost unanimously, and signed into law by Pres. Corazon C. Aquino on September 13, 1988 amid demonstrations and pickets for and against the law outside Malacañang Palace.

To show how much care was given this bill in both Houses of Congress and in the Joint Conference Committee, one high-level official or staff of DOH was assigned to each key legislator to explain the rationale of each provision and to ensure his continued support of the bill, throughout the entire legislative process. The Secretary even sent individual notes and called up key legislators. He went to the extent of asking the good offices of the President and the Executive Secretary to help preserve the progressive and reformist provisions of the Generics Act of 1988. Dr. Quintin L. Kintanar provided technical support in the final stages of the crafting of the harmonized version the Joint Conference Committee to ensure the integrity of its provisions.

IMPLEMENTATION

The implementation strategy had to be formulated with the full participation of all affected and interested parties. First, the macro plan was developed in a two-day DOH Top Management Seminar-Workshop in October 1988. At this workshop, the need for thorough and participatory consultation in the preparation of the implementing guidelines of the Generics Act of 1988 was recognized.

STAGGERED IMPLEMENTATION (DOH)

To have some experience with its implementation before applying it to all

sectors, the law was initially implemented in the home front- the Department of Health.

A Task Force headed by Dr. Quintin L. Kintanar prepared the various draft implementing guidelines. The first was the A.O. 51 – Implementing Guidelines for DOH Compliance to Generics Act of 1988. The draft guidelines were first revised and refined through the NDP Management Committee and DOH Executive Committee in October and then processed through a series of three national seminar-workshops held in November, December, 1988, and in January 1989. In turn, DOH National level key personnel, Regional level personnel, Provincial and District level personnel involved in drug transactions or use, were processed in these seminar-workshops culminating in a "Miting de Avance" on January 12, 1989. It was decided that all DOH Regions and units must implement A.O. 51 not later than March 1, 1989.

OTHER GOVERNMENT DEPARTMENTS AND AGENCIES

Letters were sent to the Secretaries of other Government Departments which are significant users of drugs and meetings were held to inform these parties of the plan of implementation. The Commission on Audit later issued COA Circular 298 stating that all drug transactions in government must use generic terminology otherwise they shall not be passed in post-audit beginning March 1, 1989. In effect this meant full implementation of procurement using generic terminology by the entire government system.

PHARMACEUTICAL INDUSTRY

An important element favoring compliance by prescribing doctors and dispensing pharmacists recognized in the Top Management seminar-workshop in October, 1988 was the availability of pharmaceutical products bearing generic names prominently, as provided by GA of 1988. Thus, the implementing guidelines on generic labelling (A.O. 55 s. 1988 as amended by A.O. 64 s. 1989) were formulated in consultation with manufacturers, traders who own the products, and other interested parties. After a lot of negotiations, including the holding of a series of cocktail parties for the Filipino group, the large companies and Transnational Companies (including the Americal Chamber of Commerce), the guidelines on Generic Labelling were published in December, 1988. They were to take effect at first by April 1, 1988, which deadline was moved back later to July 1, 1989 in time for the new BFAD – approved generic labels in production. However, to give time for inventories to be consumed, products bearing present or "old" labels already in the market shall be allowed to be sold up to the end of 1989.

Similarly, a series of consultations with Pharmaceutical Companies, Advertising Companies and other interested parties such as Non-Government Organizations (NGO) and Consumer groups were held to finalize the Implementing Guidelines on Advertising (A.O. 65 s. 1989 as amended by A.O. 69 s. 1989).

PRIVATE PROFESSIONAL SECTOR

This sector had to be given special treatment because of its resistance to the Generics Act, particularly the provisions on generic dispensing on "substitution", and the penalty clauses among the doctors.

This resistance was not entirely unexpected as the doctors felt their turf was threatened. Under the law and the implementing guidelines on prescribing (A.O. 62 s. 1989) and dispensing (A.O. 63 s. 1989), the patient will now have the option to choose from among generically-equivalent products to that prescribed by the doctor. This absolute power to determine what the patient gets in medicine could mean less privileges and material rewards for industry.

To allow for adequate education and information and learning and adjustment time, the implementation for the private professional sector was scheduled in 3 phases:

Phase I – Education & Information Dissemination – March to May 1989
Phase II – Voluntary Compliance with Monitoring but Without Penalties – June to August 1989
Phase III – Full Implementation with Monitoring & Penalties Beginning September 1, 1989

These guidelines considered comments and suggestions coming from all affected and interested parties and were finalized only after a nationwide consultation with prescribers and dispensers in all 13 regions of the country in February 1989.

OTHER PROVISIONS OF GA 1988

There are other provisions of the Law for which the implementing guidelines still remain to be formulated. These are:

Section 4b	–	Systems of incentives for manufacturers of essential generic drugs
Section 8	–	Required Producting of Generic Drugs
Section 10	–	Importation of Raw Materials by DOH for allocation to Filipino-owned or controlled companies for the manufacture of essential generic drugs

An inter-agency committee chaired by the Board of Investment and with members from the Pharmaceutical Industry and other concerned government agencies have been meeting to package these incentives under Section 4b and define the implementing guidelines for Section 8 & Section 10.

For reference, copies of the GA 1988 are attached as Annex B2 and the various implementing guidelines already completed are attached as Annex B3.

ORGANIZATIONAL STRUCTURE

Given the responsibility for the implementation of the PNDP and GA 1988

is the Assistant Secretary (Asec) for Standards and Regulations who has the mandate to create as many Implementation Teams or Working Groups as needed. Besides the NDP and GA 1988, he has also control and supervision over line agencies and program of DOH concerned with pharmaceuticals, such as the Bureau of Food & Drugs, the Biologicals Production Service, the Regional Herbal Pharmaceuticals Program in Tuguegarao, Tacloban, Cotabato and Davao and the Regional Mini Drug Laboratories in all twelve (12) regions. As of May, 1989, the organizational structure of the Asec for Standards and Regulations and PNDP is shown in Figure 1 with seventeen (17) different working groups.

CONCLUDING STATEMENT

We have described the evolution, crafting and implementation of a landmark policy and legislation which have health, human rights and social justice implications as a model for Science and Technology policy-making. This experience points out the importance of a thorough research and study in coming up with an accurate and comprehensive situationer or diagnosis which is a prerequisite to good Science and Technology or other policy-making for that matter. It also demonstrates the need for democratic participation and consultation both during the formulation of the policy and its implementation. The Philippine National Drug Policy and the Generics Act of 1988 experience exemplifies Science and Technology policy-making, a policy with both immediate and long-term impacts on the life of our people.

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