NATIONAL DRUG POLICIES

Changing the Status Quo:

A Report from the Philippines

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THE Philippine National Drug Policy evolved in response to the perceived need to give the broad masses of the people access to safe, effective and affordable drugs. It has meant changing the status quo on a broad pharmaceutical front: from regulation to production; procurement to promotion and prescription to education. And by its very nature, change connotes some instability. Unfortunately, undue attention is often paid to the destabilizing effects of change rather than the benefits.

Our efforts to promote the rational use of drugs and to assure better quality control should not be misconstrued or misinterpreted as the "creeping nationalization" of the pharmaceutical industry. The Philippine Government is committed to free enterprise and encourages private initiative in the economic sector. Hence, as our Secretary of Health has said: "Considerations of fairness to private individuals or groups must be harmonized with the need for firmness and protecting public welfare. Intrinsically restrictive regulatory processes required for quality and safety must be balanced by basically promotive efforts to encourage production and growth to ensure availability of drugs."

But it must be stated that we face many difficulties in the implementation of the new policy. The obstacles range from the attitudes of health providers and patients, to the organized resistance of pharmaceutical companies, the pressure of some governments, and the high dependence on imported raw materials.

The market equation in the pharmaceutical system is characterized by a gross imbalance - with a strong supply side, essentially controlled by transnational drug corporations which are almost completely import-dependent for active ingredients and technology; and an extremely weak demand side, comprising an ill-informed public, more than half of whom fall below the poverty line, with the professional health providers who make the decisions and choices for them, overly influenced by the aggressive and expensive marketing and promotional practices of the big pharmaceutical companies. In this equation, prior to the launching of the new National Drug Policy in 1987, the Government - through the Bureau of Food and Drugs - was largely a passive player because of lack of capabilities, logistics and political will.

The new policy has four major components:

- drug safety;
- rational use;
- local production;
- improved drug procurement.

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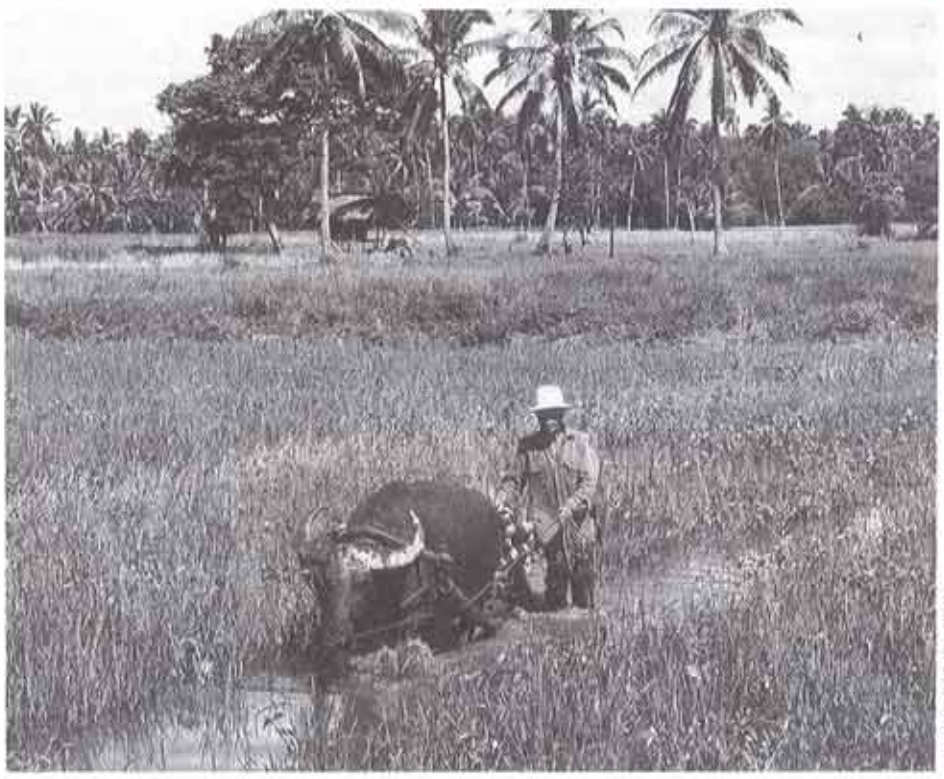

Photo WHO/B. Miller

This Filipino farmer ploughs new land, as does his government with its new pharmaceutical policy.

DRUG SAFETY

The first element is to strengthen the capabilities of the Bureau of Food and Drugs. A new building, with a quality assurance laboratory, has been constructed with financial assistance from the Government of Japan. Systems and procedures are being reviewed and product registration computerized.

Drugs banned, withdrawn or restricted in other countries will be progressively removed from the National Drug Product Registry, currently containing some 12 000 items. In an initial effort, 265 products belonging to 14 banned/withdrawn/restricted drug classes in other countries have been identified for probable delisting and their manufacturers given three options: 1) to withdraw voluntarily the item from the market; 2) to modify the formulation, removing the objectionable component; 3) to present scientific evidence supporting continued sale in the market. Such evidence will then be evaluated by an expert panel created for the purpose which will make the necessary recommendation to the Secretary of Health.

RATIONAL USE

The second element is the vigorous promotion of the rational use of drugs, incorporating an essential drugs action programme, the use of generics, improved procurement, and a programme of information, education and communication.

Action programme

There is now a National Drug Committee (NDC) whose primary function is to develop a national formulary appropriate for the Philippines. Using WHO's Essential Drug List as a model, the committee, with the help of several panels of experts in the various specialty fields, is drawing up a list of core or main drugs, and a second list of complementary drugs, to meet the requirements of health providers and patients at the primary, secondary and tertiary levels of health care.

Generics

The generic law of 1988, which both houses of Congress have recently passed on third reading, is a major breakthrough in the effort to promote rational drug use. The salient features of this law are:

- Incentives and other special promotion privileges to producers of essential drugs which use exclusively generic names.

- Government health agencies and their personnel shall use generic terminology in all transactions including purchasing, prescribing, dispensing and administering of drugs.

- Private medical and dental practitioners must indicate the generic name of the drug on their prescriptions.

- Any organization or company involved in the process of manufacturing, importation, repacking and/or distribution of drugs or medicines shall indicate prominently the generic name on the product label.

- All drug outlets, including drugstores, hospital and non-hospital pharmacies, shall post in a conspicuous place the generic and brand names of all drug products and their corresponding prices, so that the buyer may exercise his option on which product to buy.

- Every drug manufacturing company operating in the Philippines shall distribute and make available to the general public the medicine it produces as generically named drugs.

In effect, generic names will have to be used in manufacturing, prescription and retailing.

Information, Education and Communication

This is a critical component of the programme and a campaign is being prepared to address health providers, drug manufacturers/suppliers, policy makers and the general public.

Promotion and Advertising Guidelines

A Pharmaceutical Industry Liaison Group has been established composed of BFAD and pharmaceutical companies' representatives. This group has just completed a review and revision of guidelines on the promotion and advertising of prescription drugs and over-the-counter drugs.

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Under the new policy local production of vaccines will be stepped up.

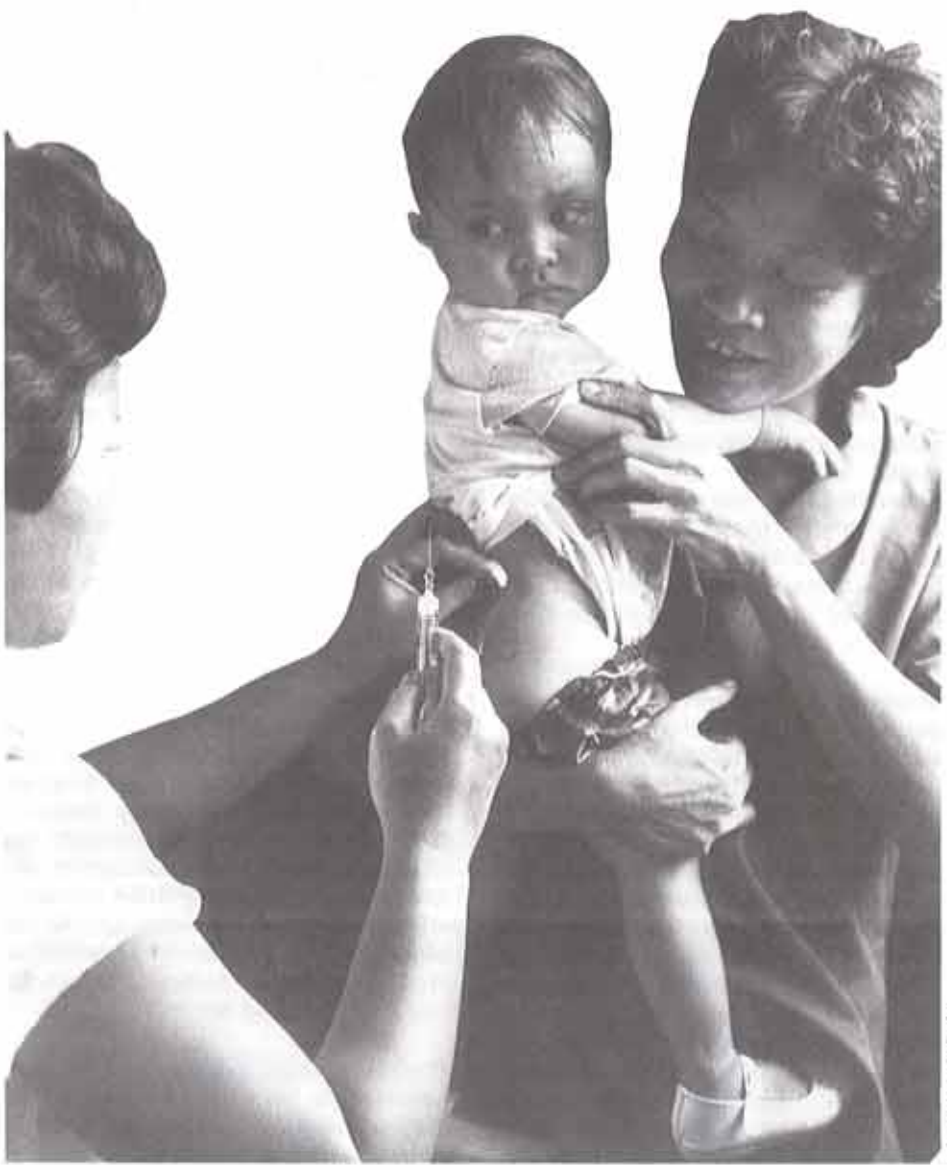

Photo WHO/Zafar

LOCAL DRUG PRODUCTION

The third element consists of developing greater self-reliance in basic drug production. This is an important long-term goal intended to create a national capacity to produce locally selected pharmaceutical intermediates, active ingredients, and finished products. It is particularly significant since 90-95% of raw material requirements are currently being imported. Specific steps will include:

• **Medicinal plants programme:** within the next few months three herbal manufacturing plants will start production of five herbal pharmaceutical preparations for common ailments, such as respiratory complaints, fever, pain and roundworms.

• **Oral rehydration salts:** the Department of Health is now manufacturing packets of oral rehydration salts for diarrhoeal patients. The present remarkable reduction in mortality from diarrhoeal disease in the country is directly attributable to oral rehydration therapy.

• **Local production of USP grade dextrose and sodium chloride:** local research has just been completed which showed that production of USP grade dextrose from local cassava starch as well as production of USP grade sodium chloride from local industrial grade salt is possible. The second phase of the project will be to consider a pilot project to use these locally produced materials to make IV fluids at the hospital level.

• **Production of vaccines and biologicals:** the Biological Production Service of the Department of Health will be expanded and upgraded to support our EPI programme, particularly since foreign donations of vaccines are expected to end within 3 years. We are now producing BCG, DPT, cholera-typhoid, rabies and cobra antivenom serum. In the medium to long term, the production of measles and polio vaccines is also being planned.

• **Philippines-UNIDO pharmaceutical industry development programme:** this study will identify feasible and viable lines of pharmaceutical intermediates or active ingredients for upstream integration. It will also identify appropriate incentives so that entrepreneurs, both local and foreign, can be encouraged to establish manufacturing plants.

IMPROVED DRUG PROCUREMENT

Better government drug procurement procedures, the fourth element, have already generated savings of 30%, and are now based on an approved therapeutic list using generic nomenclature. Bulk procurement and manufacture under licence will be further explored. Recently, the association of privately-owned Philippine hospitals asked to have their requirements included in Government procurement, having seen the low prices obtained. Here we see the possibilities of national bulk procurement in which the private sector volunteers its participation.

Popular support

The Philippines still has a long way to go to implement its National Drugs Programme, but our vision is clear. We want the Government to be a credible guarantor of the safety and efficacy of drugs sold in the market. We want to empower people by providing to them the information that will define the options they have in their drug consumption, and we would like to develop local capability to manufacture certain essential drugs. We know that there are still many obstacles to hurdle and the battle can become discouraging at times. Our consolation is that the great majority of our people, who stand to benefit from these initiatives, are full square behind the movement.

(Part of a presentation to the WHO Second Meeting of Interested Parties in the Action Programme on Essential Drugs, Geneva, 22-24 June 1988) □

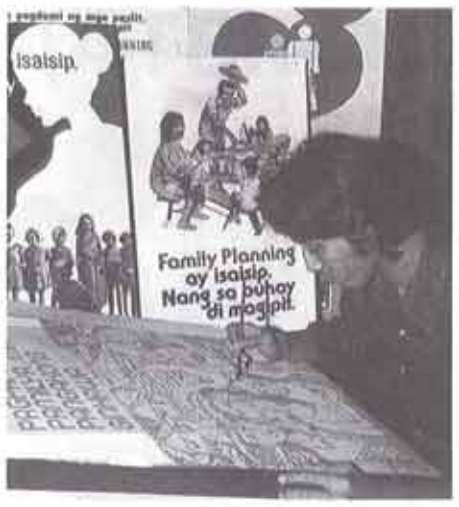

Photo WHO/P. Almasy

Information will be a critical component of the new programme. In Manila the National Media Production Centre creates posters featuring family planning.

Photo WHO/A. Hartfon

A Filipino health worker tends the medical plants in a community health garden: the new drug policy will include 3 herbal manufacturing plants.