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# PHARMACEUTICAL POLICY OF THE ANDEAN SUB-REGION

## THE ANDEAN SEMINAR/WORKSHOP ON DRUG POLICIES


Cartagena, Colombia
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## INTRODUCTION

Since Alma-Ata (based on the experience of pioneering countries, such as Peru) the primary health care strategy has involved the adequate supply of essential drugs as a basic component of the delivery of health services. Further developments (e.g. Conference of Experts on the Rational use of drugs, Nairobi, 1985) ratified the relevance of essential drugs within the policies for extending coverage and rationalising the use of resources.

In the Andean region, some important steps have been taken[1] since the Cartagena Agreement (1973-1975) regarding both cooperation mechanisms between countries and the establishment of technical criteria to generate a common Andean drug market. This will require the resolute support of the highest political decision-makers.

(1) Within the framework of Andean health cooperation, based on the Declaration of Caracas (May 1991) and subsequently in Santafé de Bogotá, Quito, La Paz and Villa de Leyva, the five countries have discussed and proposed criteria for the harmonization of policies, health registration, quality control, basic frameworks, pharmacological standards and technical components for international trade, etc. A considerable degree of progress has been made towards the early implementation of these criteria.

The similarities in the patterns of disease and mortality in the countries of the subregion, in the health systems and in the current processes of social and economic transformation, combined with the desire for integration of markets, have made the development of a joint drugs policy for the Andean area a priority. These efforts must be integrated with social and health policies and be consistent with the economic changes, without losing sight of the fact that drugs have health and social dimensions that cannot be ignored and that it is up to the health authorities of each country to regain their natural leadership in decisions affecting the manufacture, marketing and utilisation of drugs.

In tackling the task of defining a pharmaceutical policy for the Andean region, it has to be borne in mind that this policy must be consistent, comprehensive and long-term. Very often, for specific reasons, there is a tendency to give priority to partial aspects such as registration, quality and purchasing but a fragmented approach subsequently reduces the policy efficacy.

It must also be borne in mind that the delivery of curative health services plays an important but limited role in the public health context. Promotion, prevention, community participation and, in particular, living conditions and lifestyles have proved to be determining factors. Within health care, drugs likewise play a limited role. Not infrequently, the best drug is no drug at all.

Moreover, prescription drugs cannot be treated just like any other merchandise. Their market is not transparent and can be distorted. The consumer does not select them, has no basis on which to evaluate his/her satisfaction with their use, and

drugs are the subject of intense publicity that attributes exaggerated properties to them. Health professionals and patients often forget that there is no completely safe drug and that it is by no means certain that the newest or most expensive drug is the best.

## 1. POLICY OBJECTIVES

The role of the state in the pharmaceutical sector, whatever the political ideology may be, is to guarantee availability and equal access by the entire population to effective, good-quality drugs at affordable prices and to ensure their proper use.

> **The availability and accessibility of drugs are parameters for measuring the quality of the health services and constitute social indicators of justice and equity in the distribution of a country's wealth.**

State responsibility for ensuring availability and access is a function that cannot be delegated, although it can be implemented by very different mechanisms and with various forms of participation by the private sector. Far-reaching processes of change are under way in the public sector, involving redefinitions of functions, modernisation, greater administrative flexibility, economic liberalisation, and changes in health systems. It is the task of the health sector to make such changes compatible with policy proposals. Proposals must restore the normative role of the public sector, such as drug registration, but must also identify mechanisms for linkage with the health services, where drug management is critical.

**In the Andean countries a consensus has been reached on promoting two major policy lines: the first is fundamental and concerns the promotion of ESSENTIAL DRUGS as the best approach from the health viewpoint, and this is supplemented by the promotion of programmes of GENERIC DRUG use as the best commercial alternative.**

The selection of essential drugs, those that are the most useful for dealing with the majority of health problems, cuts down the number of products to be manufactured, promoted and marketed, thus making it easier for health professionals and patients to become familiar with them. Their mandatory use in the public sector and their value for the private sector, facilitate the processes of selection, purchasing, storage and distribution, and especially their rational use.

Generic drugs, by permitting identification of the product by its scientific name, make it easier for the prescriber, dispenser and user to choose between many alternatives competing in terms of quality, price or convenience. They introduce competition and transparency into a market distorted by the proliferation of brand names and by promotion and advertising practices. Ideally, drugs should be marketed by their international nonproprietary name or generic name, with identification of the manufacturer. In this way, manufacturers can claim parentage for their products and society can see the name of the company responsible. However, whenever a brand name is used it must be accompanied by the respective generic name.

## 2. LEGISLATION

Legislation is the most relevant expression of the role of the state. In the Andean countries, laws and regulations are frequently fragmented, inconsistent (because they are often influenced by economic considerations) and in many respects obsolete. The countries undertake to draw up a consistent, comprehensive and up-to-date body of legislation, of a high technical standard, which reflects commitment to equity and appropriate use (comprehensive drug law).

In keeping with planned government policy regarding Andean integration, standardisation mechanisms must be incorporated. Provisions should be made for mechanisms and resources that guarantee their implementation and management.

## 3. SELECTION

The first component of an overall pharmaceutical policy is selection. This is first expressed in the state's decision as to which products may enter the market and which may not. No health professionals, let alone the patients, can absorb all the available information on the vast number of products manufactured and on the almost infinite range of indications that may be claimed. The state, through expert advisory groups with adequate access to information, evaluates each product and authorises its marketing.

The recent meeting of experts held in Quito[2] highlighted the pressures faced by the registration systems due to various degrees of bureaucratisation and the need to liberalise and internationalise the economy. Administrative procedures need to be more flexible and up-to-date, but this must be done based on a thorough understanding of the essential nature of drug registration, namely the state's obligation to select those products which by virtue of their efficacy, usefulness and safety may enter the market and those which on account of the attendant risks may not. This is a function whose social dimension far exceeds the capabilities of the individual prescriber.

The introduction of PHARMACOLOGICAL STANDARDS is a powerful tool for achieving greater flexibility, on the basis of objective and transparent procedures. The improvement and development of the proposal for a Common Andean Register, the proposal to set up an Andean Review Board and the harmonisation of pharmacological standards, will shortly make it possible to take a very important step towards integrating the pharmaceutical markets.

The task of evaluating which products may enter the market has been refined in order to determine which products are the most suitable (the essential drugs). This will lead to a small group of products that can more easily be handled by each prescriber or by the institutional procurement systems.

(2) WHO-PAHO. *Policies on the authorization of pharmaceutical products.* Document for the meeting of experts of the Andean subregion, Quito, Ecuador, December 1992.

The criteria for determining which drugs are the most suitable from a public health viewpoint are clear: safety, proven efficacy, risk/benefit ratio, and meeting the most common health problems at the lowest possible price.

Both therapeutic and economic rationality in the use of drugs are greatly increased if the use of essential drug lists in health institutions is supplemented by standard treatment regimens (therapeutic protocols for the most common diseases). This not only makes the systems for calculating quantities simpler and more technically accurate but also permits treatment and product follow-up and evaluation.

The Andean Group has made substantial progress in the harmonisation of national essential drugs lists. Their adoption by each of the countries is an additional factor that will facilitate the integration processes.

> **Accordingly, the countries of the Andean subregion undertake to draw up a common list of essential drugs, to harmonise their pharmacological standards and registration requirements, to set up the Andean Review Board and to compile a subregional therapeutic formulary.**

# 4. QUALITY ASSURANCE

A system of drug quality assurance is a prerequisite for the safe and effective use of drugs. It entails a responsible attitude by the manufacturers and the capability for verification and sanctions by the health authorities. In the new economic scenarios, quality is an increasingly critical aspect.

Quality assurance cannot be confined to laboratory analysis but must extend to the entire process of drug supply and utilisation.

> **All countries are agreed on the joint implementation of Good Manufacturing Practices (GMP) as the most effective mechanism, together with the development of inspection capability. This is the most important requirement for the implementation of the Andean Quality Certificate approved by the five countries[3] to support the proposals for integration.**

Nevertheless, the strengthening of the central reference laboratories, the construction of decentralised networks and the accreditation and validation of independent laboratories for analysis continue to be of vital importance. Selective sampling programmes applying criteria of health hazard (products with a narrow therapeutic spectrum, sterile products, products with potential bio-equivalence problems) and of high

(3) Bogotá. *Seminar on the harmonization of national essential drug lists*, February 1992.

consumption will help to focus activities on those manufacturers (and production areas) that present major problems. Public dissemination of the findings spent will be a powerful tool for cleaning up the market.

Sanctions with respect to adulterated or defective products are currently weak. Unless health authorities develop the capacity to take action when faced by situations that threaten individual and community health, quality assurance loses its most important and effective weapon.

The institutional framework for quality assurance is under discussion, both the sources of funding for the laboratories and the problem of retaining qualified staff. Greater administrative and financial autonomy, a high technical standard and administrative mechanisms to make the laboratories self-supporting by charging for services would seem to be needed.

## 5. SUPPLY, MARKETING AND LOGISTICS

Guaranteed access, especially for the poorest members of the population, is another commitment for the state. It can involve agreement with the manufacturing sector on rationalising the production of the most effective and suitable products for the most common diseases in each country. Industry can not only be an ally of the public sector but also contribute concretely to its social service dimension.

However, while there are distortions in supply, there is also much that needs to be done regarding demand, especially in public sector purchasing systems. Introduction of mandatory

of the essential drugs lists, the development of systems for calculating needs and standard treatment protocols for the most common diseases are areas where tangible results are urgently needed. These measures must be combined with the training of purchasers (such as information on suppliers) and those responsible for storage and distribution.

Experiments with subregional exchange of information on suppliers and prices need to be revitalised and strengthened.

Among the current trends to decentralise the administration and delivery of health services, the most suitable approach would appear to be a balanced combination - in accordance with the specific features of each country - of the advantages of decentralisation (adjustment to needs, timeliness, supervision by the people concerned) with the addition of negotiating capacity (pooled purchasing).

Modernisation and technical improvement of purchasing procedures are also being undertaken by private institutions, which are gradually adopting essential drug lists, treatment protocols and training in purchasing, since such measures can enhance consumer satisfaction and quality of care.

It is also necessary to press ahead with training programmes in good storage practices, an area where there are often great shortcomings.

Important participatory experiments in the form of cooperatives serving the community are taking place, throughout virtually all of the Andean subregion. With the community participation and oversight, essential drugs are offered at

affordable prices and viable mini-companies are being set up. The strengthening of such systems, especially through technical assistance, supervision and training, can increase the availability and accessibility of essential drugs.

## 6. FINANCIAL ASPECTS

The trend in drug prices is towards dismantling administrative control mechanisms. This is not just because of new ideas about the role of the state but also because those mechanisms have not always been free from serious problems. Prices that are inconsistent with the cost structures for political reasons, distortions in the market, corruption, etc., have always been disturbing weaknesses of such systems to a greater or lesser extent.

Under the new policies, the most effective controls should be sought within the market itself; a dynamic and well-supplied market with adequate information, rules governing competition and genuine opportunities for choice, would seem to offer the best guarantees that drug prices match cost structures. In any case, the state should reserve its right to watch over the market and to intervene when necessary to correct any distortions and abuses that may arise. Each country will identify the mechanisms and stages it considers most appropriate to market regulation.

The general principle of cost recovery in drugs programmes is healthy, provided that the universal right to access is respected and monitored, with special attention paid to vulnerable groups. Free drugs for all may lead to various

forms of black markets, resale, over-prescribing and wastage. In the light of very clear criteria which give priority to attaining an affordable price for drugs, proposals for "flexible recovery" of the cost of drugs may be explored: various levels of discount and proposals for "cost sharing" even in prepayment programmes, to avoid the excessive cost of drugs.

This can still be compatible with mechanisms for partial or total subsidy in accordance with criteria focussing on specific social groups (groups with least resources) or health programmes (the special programmes on communicable diseases run by the health ministries).

Drug donations deserve special mention. All too frequently, they become an opportunity for donors to get rid of products that are irrelevant to local needs, out-of-date and often impossible to use because they are unknown or labelled in a foreign language. Their waste is compounded by the enormous resources that have to be invested in the storage, transport and sorting. Health authorities should draw up lists of drugs that are acceptable as donations.

Pharmaceutical patents have been adopted by the Andean Group. As this policy of intellectual property is in place, the following criteria could contribute to better future policy definition and implementation.

(a) There should be a mechanism for recognising the intellectual property rights of each invention, guaranteeing a fair economic reward for the research undertaken.

(b) This mechanism should guarantee not only the rights of the inventor but also the rights of society to derive the greatest possible benefits from the invention. Mechanisms inspired by the present **compulsory licences** will enable many manufacturers to market their product, awarding royalties to the inventor throughout the duration of the patent.

(c) In the light of the current liberalisation and internationalisation of markets, there is a need to guarantee the right of every product that is legally marketed (i.e. by payment of the respective royalties to the owner of the patent) to move in international commerce; this is the only way to avoid the formation of monopolies at the national level.

(d) The state should reserve the right to intervene on patent matters in cases of health emergency or for serious public health reasons.

## 7. RATIONAL USE

There is plentiful evidence of the inappropriate use of drugs, not only through self-medication or unauthorised prescribing by the retailer, but also inadequate medical prescribing. It should not be forgotten that all drugs involve some risk which must be balanced by their potential health benefit. Risks include those resulting from shortcomings in professional or technical education and consumers' misconceptions and exaggerated expectations about the role of drugs that lead them to demand useless, excessive or even dangerous medication.

Potential educational activities in this field cover a wide range and should encompass all involved. Those directed at users (patients) should aim to change inappropriate ideas and attitudes and also to safeguard the users' right to full information. Self-medication merits special attention, for it is important not just to draw the public's attention to the risks involved but also to explain under what circumstances commonly used products are safe and effective.

Prescribers' education is of greater importance because of their decisive role in the drugs market and in conditions of use. Wide scale distribution of therapeutic formularies has proved to be an effective tool and the standardisation of such formularies throughout the Andean region in the medium term is an important step towards integration. However, prescribers' support for the essential drugs policies and the use of generic names will be crucial, so resolute action to inform, persuade and educate is needed.

Health personnel (physicians, nurses, auxiliaries, pharmacists, and especially health promoters) are a group whose appropriate training has tremendous potential both for improving access to drugs (especially in remote or urban fringe areas) and for optimising their use. Action here should include the reform of undergraduate curricula, the development of postgraduate programmes in clinical pharmacy and pharmacology, and the design of mechanisms for continuing education. Innovative mechanisms of formal education such as in-service training continued education deserve dissemination and support.

Pharmacists have a particularly relevant role to play in drug manufacture (especially regarding quality), and their professional expertise merits support from the state. There is also increasing focus on promoting the better integration and use of pharmacists within the health services (in pharmacy and therapeutic committees, purchasing committees and hospital pharmacy services), in the dispensing of drugs, in information centres and in regulatory activities, thus broadening their health-related professional scope.

Pharmacies deserve special mention. Training of pharmacy staff, especially on the risks of certain unauthorised prescribing practices and on the commercial advantages of providing genuine pharmaceutical services, has enormous potential for correcting the present shortcomings in the use of drugs. It is also important to win the support of pharmacies for the essential drugs and generic drugs policies, since these policies can benefit pharmacies by reducing stocks, rationalising the range of products and providing a better service for consumers. Whenever possible, the presence of a professional pharmacist in the pharmacy should be mandatory.

Manufacturers and importers also have a role to play that affects the state. This relates partly to the advisability of agreeing on a rational supply, but more particularly to promotion and advertising practices that are of critical importance in determining conditions of prescription and use. Evidence of inaccurate and inappropriate marketing by manufacturers and retailers has led the countries of the region to adopt ethical criteria on the promotion of drugs, but there is an urgent need to seek mechanisms for their practical implementation and to find better control measures.

The role of the consumer organizations in this field is vital. The creation or strengthening of such organizations is highly beneficial, not only because of their natural role of keeping a watch on the marketing, advertising and use of drugs, but because of their experience and skills in the design and implementation of mass education campaigns, an area where they are excellent allies of the health authorities.

Drug information centres have an extremely useful role in rationalising the use of drugs, because they are able to supply timely, objective, reliable and relevant data on specific aspects of drugs (toxicity, most suitable dosages, interactions, side effects, etc.). **Health ministries have the task of promoting such centres at the national level and forming an Andean network of drug information centres.**

Some countries have experience of pharmacy and therapeutic committees within the service-providing institutions and have benefitted from the initiative and participation of prescribers, dispensers, pharmacists, managers and consumer organizations. These committees review prescribing practices and endeavour to track progress towards rational prescribing; they also draw up and revise the institutional or local therapeutic formularies and identify the sources of irrationality. While their aims are basically health-related, they make a positive contribution to improving the use of drugs, and to rationalising purchasing.

The countries of the Andean area are beginning to carry out epidemiological surveillance programmes and studies on the use of drugs. Many are conducted on the initiative of the consumer organizations and tend to highlight the aspect of

irrationality in use (inadequate prescribing, illegal sale of prescription drugs by the retailer, inappropriate self-medication) and non-compliance with the prescription. As yet, very few studies relate to the investigation of side effects. It is most important to promote all these initiatives.

The undeniable existence of curative alternatives to modern pharmaceuticals makes it necessary to seek ways of incorporating these alternatives in the health services. Greater attention should be paid to research on medicinal plants and on the influence of culture on the perception of disease and drugs, especially among indigenous groups.

## 8. INDUSTRIAL DEVELOPMENT

Essential drugs and generic drugs policies make an important contribution to conquering new and wider markets in an area where governments and manufacturers are allies. Industrial complementarity, new possibilities for the transfer of technology and the development of a pharmacochemistry and biotechnology industry are more feasible within an Andean market. The universities have an important role to play in the development of technology in the pharmaceutical sector.

Governments should seek mechanisms for guaranteeing the availability of essential products of low commercial interest (such as certain biologicals).

# 9. ANDEAN INTEGRATION

During the last three years, with the support of the World Health Organization/Pan American Health Organization and the Hipólito Unanue Agreement[5], some important technical instruments have been agreed upon for setting up a joint pharmaceutical market which gives priority to meeting health criteria. This work has entailed a continuous process of discussion, reflection and refinement, in which continuity of the technical human resource input has been essential. The joint experience gained has led to the necessary consensus and commitment to take practical action to implement the agreements. **These include the harmonisation of registration criteria; of essential drug lists; of pharmacological standards; of good manufacturing practices; and the creation of the Andean Review Board and the Andean Quality Certificate.**

Such proposals require political support, collaboration with the economic sectors and detailed drafting and negotiation, to which the representatives of the Andean countries present at this meeting make a commitment in the form of a timetable of short-, medium- and long-term activities.

(4) Special agreement on health issues within the Andean Common Market

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CARTAGENA, COLOMBIA, 24-26 MARCH, 1993.

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