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PERUVIAN BASIC DRUGS PROGRAM

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INTRODUCTION

In the 1971-1975 intermediate-term plan, the Revolutionary Government established that generic products would be used in order to ameliorate the cost of medicine and make them available to all Peruvians without exception, but to go, fundamentally, to the great majority in the lower socioeconomic scale.

Complying with the above, the Ministry of Health launched the Basic Drug Program under Supreme Decree No. 167 of 16 September 1971, the same decree that approves the Regulations and Official Requisition for Basic Drugs and places the execution, control, supervision, and evaluation of the program under a Permanent Commission; creating at the same time a Requisition Reviewing Commission to be responsible for constantly updating the requisitions in accordance with the latest therapeutic world advances.

Basic drugs are defined as medicines of maximum quality and low cost, approved by the Ministry of Health and destined to help in the promotion, protection, and recovery of the health of the Peruvian population.

With their low cost, the drugs have been made accessible to the people who previously were unable to afford them. The people in the lower economic bracket who were unable to purchase drugs at a high price can get them today, of guaranteed quality and at a lower price, which in some cases comes to 80% and in the great majority of instances to 35% of the price of their commercial counterparts.

The quality of these drugs is under constant surveillance, which constitutes a guarantee both for the individual who prescribes them and for the patient that uses them.

The program was well received from the beginning, as demonstrated by the great increase in consumption from 1972 to date.

Sales were commenced in 1973 in all pharmacies and drugstores which voluntarily affiliated themselves with the program in the departments of Ancash, Ica, and Lima. It is anticipated that the program will progressively be extended to the entire national territory.

The Ministry of Health is continually evaluating the Program of Basic Drugs and proceeding firmly towards the goal of providing drugs of maximum quality and at a price within the economic situation of the entire population, as a matter of their right to health.

1. Background

The Ministry of Health had previously organized and executed the Programs of Popular Drugs and of Social Medicine at the level of its own

services. For various reasons, these were of short duration and they disappeared. On 15 June 1971, through R. M. No. 00093-71-SA/DS, a special commission was appointed to make a complete study of the background and of the existing situation. On 14 July 1971, the Commission submitted a document with its conclusions and recommendations for the execution of a program to lower the cost of drugs, to respond to the objectives and policies on health expressed by the Revolutionary Government of the Armed Forces in its 1971-1975 intermediate-term plan, and which basically would comprise the technical aspects of maximum quality with low cost.

2. Initial Reviewing Commission

At the start, a Commission designed, as first order of priority, the Official Requisition for Basic Drugs, which was composed of 185 items and 265 submission forms. As requested, a consultant from the Pan American Health Organization assisted the Commission in this work.

3. Creation of the Basic Drugs Program

By Supreme Decree No. 167-71-SA of 16 September 1971, the Permanent Commission for Basic Drugs was created and charged with the execution, supervision, and evaluation of the Program of Basic Drugs for the Health Sector. The decree established that the composition and rules of the Commission were to be approved by Supreme Resolution.

The Supreme Decree also provided for the creation of the Requisition Reviewing Commission as an ad honorem consultative organism, composed of representatives of agencies comprised within the Program of Basic Drugs, the Academic Programs of Human Medicine and Pharmacy, the Armed Forces Health Services, the Medical and Chemistry-Pharmacy Schools, and one representative from the Chemical-Pharmaceutical industry.

This Commission will be responsible for the review of the requisition, in the light of the health needs of the country.

The Commission's rules will also be approved by Supreme Resolution.

Subsequently, by Ministerial Resolution No. 000309-72-SA/DS, the Permanent Commission was authorized to organize an administrative office for the Program of Basic Drugs, which will have executive, control, coordination, and maintenance of records functions, as well as any others assigned. This is called the Executive Office.

4. Objectives of the Program of Basic Drugs

The objectives of the Program of Basic Drugs are as follows:

4.1 Restore, preserve, and increase the level of health of the population, in order to reduce morbidity and mortality rates.

4.2 Satisfy with the Program of Basic Drugs the therapeutic needs in the health sector services of government and private agencies, as well as the needs of the population in the rural areas, Rural Cooperatives, Hamlets, Agricultural-Industrial Complexes, Parishes, etc., and, in general, the whole Peruvian population.

4.3 Get the physicians and auxiliary personnel to advertise the program and spread information concerning its scope and benefits.

4.4 Maintain and increase the prestige and efficiency of the Program of Basic Drugs.

4.5 Achieve a degree of self-sustenance.

5. Definition

This is a group of medications, whose main components are the generic products. These medications are indispensable to satisfy the health needs of the population. Their quality is guaranteed and their low cost has been approved by the Ministry of Health. This organism has selected a group of medicines in accordance with the established needs for promotion, protection, and recovery of health.

The Program of Basic Drugs is designed to guard the health and the economy of the Peruvian population and to reach all national territorial boundaries.

6. Structural Organizational Chart

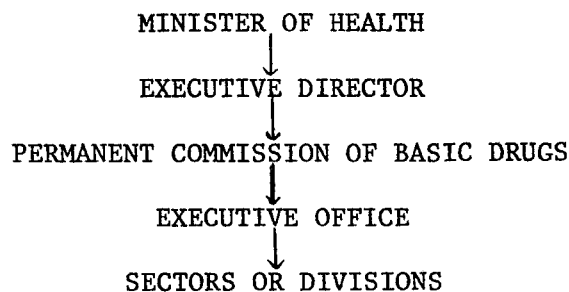
The one presented corresponds to the year 1974.

At mid-year, the data processing and statistics section was transferred to the Office of Information created in the Ministry of Health.

For the years 1975 and 1976, the structure has been modified, eliminating the sections and creating the Technical Division, the Division of Budget and Accounting, and the Division of Supervision.

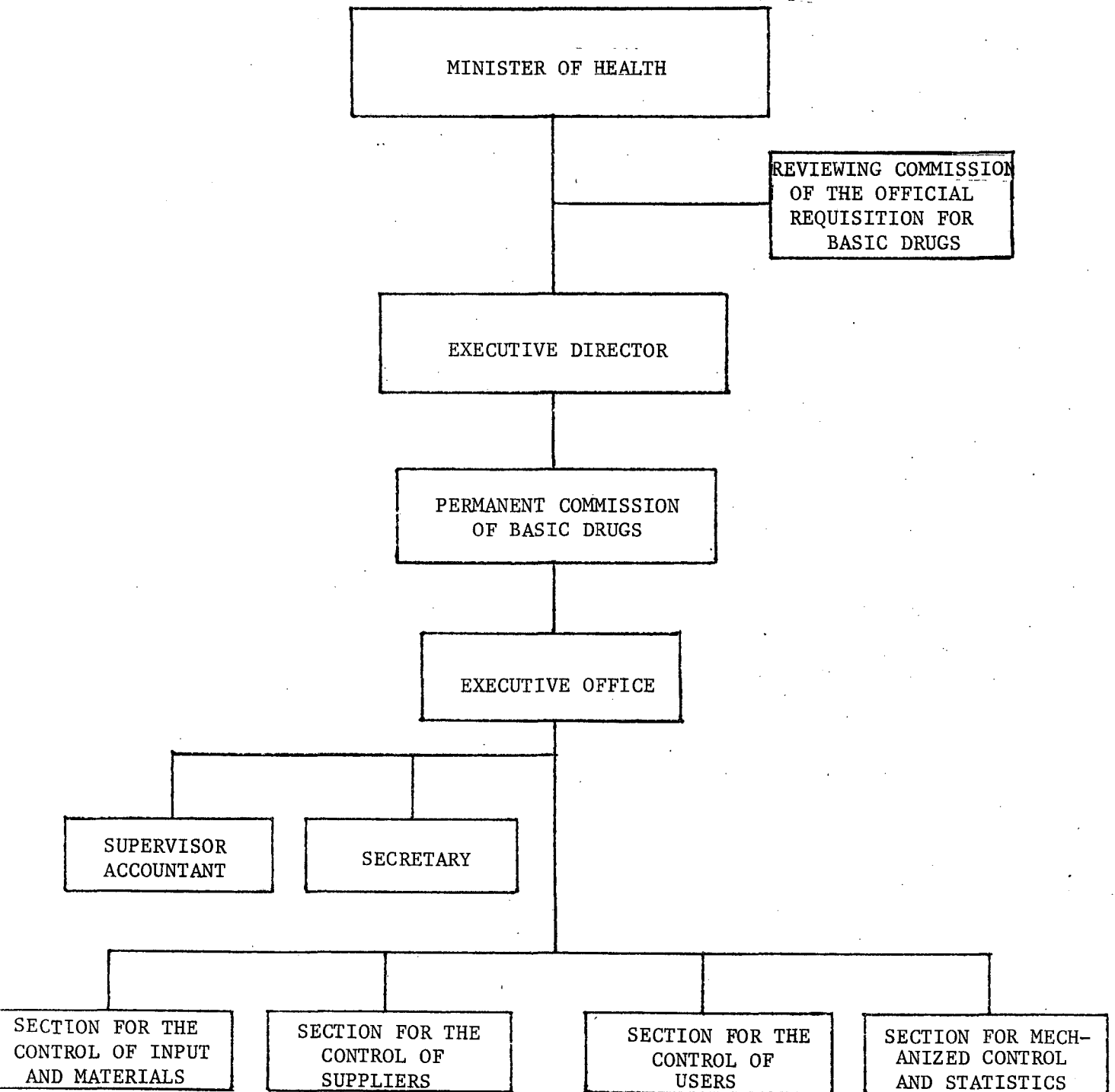
7. Chain of Authority

The chain of authority is as follows:



STRUCTURAL ORGANIZATIONAL CHART
OF THE PROGRAM OF BASIC DRUGS

1974



8. Reviewing Commission of the Official Requisition for Basic Drugs

This is an Advisory Commission of the Ministry of Health, created jointly with the Permanent Commission for Basic Drugs. It is also called Commission on a Wide Basis, due to the fact that it is constituted by representatives from many sectors.

8.1 Composition

The Commission is composed of 12 members, as follows:

One representative from the Ministry of Health, who shall preside;

One delegate from the Joint Command of the Armed Forces;

Four delegates from the Ministry of Health (health sector);

One delegate from the Academic Programs in Human Medicine;

One delegate from the Academic Programs in Pharmacy;

One delegate from the School of Medicine of Peru;

One delegate from the School of Chemistry-Pharmacy of Peru; and

One delegate from the Association of Pharmaceutical Laboratories of Peru.

8.2 Functions

Its principal function is the reviewing of the Official Requisition for the Program of Basic Drugs, according to the health needs of the country, deleting those drugs which are no longer current and introducing new ones discovered at an international level and which, in the judgment of the Commission, should be utilized in the Program.

It reviews the Official Requisition periodically and approves only those drugs requested by Ministerial resolution.

To date, three requisitions have been approved.

In order to serve the users more effectively, the requisition also includes X-ray films, intravenous feeding equipment, rapid diagnostic systems, and optical lenses and frames.

8.3 Suggestions

Months before the review of the requisition is due, a circular letter is sent to all users to elicit suggestions from them.

The replies are studied by the Commission and, in many instances, included in the requisition.

Similarly, any laboratory may request the inclusion of any new drug developed by its company, submitting supporting scientific studies.

Likewise, any member of the Commission can request the inclusion or exclusion of diverse types of drugs.

8.4 Approval of the Requisition

When the Commission completes the review of the Requisition to be used in the next bid, it submits to the Ministry of Health a report which has to be approved by that organism through a Ministerial Resolution in order to put it into effect.

8.5 Projects

To solve the problems of lack of supplies, it is planned to include the following items in the next bid: surgical gauze, cotton, catgut, adhesive tapè, plaster bandages, fixer, developer, laboratory reactives, etc.

8.6 Number of Products

Due to the dynamic character of the Commission, the number of products has been increasing from one bid to the other.

According to the bids conducted, its growth has been as follows:

<u>Bid Year</u>	<u>Items</u>	<u>Submission Forms</u>
1972	185	265
1973-1974	235	333
1975-1976	244	362

Among the drugs included in the requisition are many which are not manufactured in the country and which are imported in their finished state.

9. Permanent Commission of Basic Drugs

It was created by Supreme Decree No. 00167-71-SA.

It is composed of five members, one of whom presides. It is fundamentally composed of physicians, chemists, pharmacists, and one lawyer.

The Commission designates from among its members one coordinator and one secretary.

The Permanent Commission of Basic Drugs is the organism responsible to the Executive Officers for the planning, execution, control, supervision, and evaluation of the Program of Basic Drugs of the health sector.

9.1 Functions

Its functions are as follows:

- 9.1.1 To develop and permanently control the Program for Basic Drugs of the health sector, at the national level.
- 9.1.2 To request, receive, and coordinate the requests for basic drugs from public and private organisms.
- 9.1.3 To coordinate and supervise the strict compliance with the rules governing the program and other additional regulations, both by the public agencies and by the laboratories under contract.
- 9.1.4 To prepare the conditions for the bids and the contracts for the manufacture, supply, and distribution of the products.
- 9.1.5 To participate in the administrative process of the bids for the manufacture and supply of basic drugs.
- 9.1.6 To establish the chronograms of labor, of the delivery of the products, of information, and others that may be needed.
- 9.1.7 To approve the designs for containers and labels submitted by the manufacturers.
- 9.1.8 To establish the selling price of the drugs, as well as recommend to the Executive Staff how to apply the profits for the benefit of the program.
- 9.1.9 To dictate the appropriate norms or directives for the implementation of the program in the entire country.
- 9.1.10 To receive, process, analyze, and evaluate all information, documentation, statistics, needs, and other data related to the Program of Basic Drugs.
- 9.1.11 To control the import of products and materials required for the manufacture and presentation of the basic drugs, endorsing the import documents in close coordination with the Ministries of Industry and of Economy.

- 9.1.12 To keep control of all the materials purchased in the country for the presentation of the basic drugs.
- 9.1.13 To coordinate with the National Institutes of Health and other organisms the implementation of a quality control system for the basic drugs from the time of arrival of the products or raw materials in the country to the time they arrive at the place where they are going to be sold.
- 9.1.14 To supervise the punctual payment, by the public agencies, of all the obligations they have contracted for.
- 9.1.15 To approve all additional and complementary orders for Basic Drugs received and order their manufacture.
- 9.1.16 To verify the information related to costs of the basic drugs received from the laboratories.
- 9.1.17 To transmit to the Executive Officers the pertinent reports for the application of sanctions, fines or other corresponding coercive measures for failure to comply with the rules governing the basic drugs.
- 9.1.18 To request from the Executive Officers, at the proper time, application of the measures established in Articles 13 and 15 of the Regulations.
- 9.1.19 To respond to the consultations, requests, clarifications, and other inquiries received.
- 9.1.20 To promote the use of basic drugs at the national level, through the most effective means.
- 9.1.21 To propose to the Executive Officers the necessary agreements for the use and consumption of the basic drugs.
- 9.1.22 To prepare and submit to the Executive Directors projects for the expansion of the program, including pharmacies.
- 9.1.23 To permanently coordinate activities with the Reviewing Commission of the Requisition, receiving and channeling the suggestions they formulate.
- 9.1.24 To perform the other activities within its competence.
- 9.1.25 To perform other activities as requested by the Ministry of Health.

The Regulations of the Permanent Commission of Basic Drugs also contain specific functions to be performed by its president, coordinator, secretary and members.

9.2 Executive Office

This is the administrative office of the Permanent Commission of Basic Drugs and it has the following functions:

- 9.2.1 To direct, coordinate, execute, control, and evaluate the progress of the Program of Basic Drugs at the national level, in accordance with the governing legal requirements and the directives issued by the Permanent Commission of Basic Drugs.
- 9.2.2 To control the consumption of basic drugs by the users.
- 9.2.3 To supervise the compliance with the contracts signed by the suppliers.
- 9.2.4 To control and supervise the faithful compliance, by the users, with the governing directives and regulations.
- 9.2.5 To process users' information through mechanized systems for its analysis and utilization.
- 9.2.6 To permanently evaluate the adherence to the requirements of the General Plan.
- 9.2.7 To recommend the adjustments necessary for the most efficient execution of the Program.
- 9.2.8 To administer the resources of the office wisely.
- 9.2.9 To perform other related duties required by the Permanent Commission of Basic Drugs.

Likewise, each section of the Executive Office has its specific functions.

10. Users

This is the name given to all those organizations using the basic drugs.

Initially, all services of the Ministry of Health and institutions of the public sector subscribed to the Program. Later on this was extended to the health departments of the Armed Forces and of the Police Force.

There are the following types of users:

10.1 In the Ministry of Health

10 Health Regions
56 Hospital Areas
103 Hospitals
343 Health Centers
1,002 Health Units

10.2 Public Service Organisms

These are all those rendering public services and they automatically subscribe to the services of the Program.

They are:

- Health Units of the Armed Forces, the Police Force, and the Police Intelligence
- Social Security of Peru
- Public Welfare
- Provincial and District Councils
- Public enterprises: Petro Peru, Electro Peru, Centromin Peru, Pesca Peru, etcétera.

10.3 Private Sector Organisms

These are those from the private sector who voluntarily request affiliation with the program.

Only the non-profit organisms are accepted.

They are as follows:

- Agricultural and Livestock Cooperatives
- Amazonic Hospital
- Universities, etc.

11. Promotion

This is an extremely important activity which commenced before initiation of the Program and which continues on a permanent basis.

In general terms, this is what was and is being done:

11.1 Distribution of advertising pins and posters, at the national level

11.2 Lectures

Of interest to all:

- Academic Programs in Human Medicine
- Academic Programs in Pharmacy
- Academic Programs in Obstetrics
- Schools of Nursing
- Hamlets
- Agricultural and Livestock Cooperatives
- Councils, etc.

11.3 Communications

Distribution of circulars, directives, etc., to all:

- Medical Staffs
- Pharmaceutical Staffs
- Health Professionals
- Regional Chiefs and Chiefs of Hospital Areas

11.4 Meetings

Meetings have been and will be held with the same groups described above.

11.5 Coordination and Requests for Support

Have been requested from:

- Other Ministries
- SINAMOS
- Local Governments
- Social Security of Peru
- Laboratories

11.6 Interviews, Publications, and Presentations

- Newspapers
- Magazines
- Radio
- Television

11.7 Handbooks

An initial brochure was printed in 1972 and two complementary ones in 1973-74 and 1975-76, which were distributed throughout the country:

- Physicians
- Teaching personnel
- Dental stomatologists

- Chemist-Pharmacists
- Obstetricians
- Nurses
- Health Auxiliaries

12. Bids

Basic Drugs are supplied through public bids, since the State has no direct production of these.

The following steps are followed:

12.1 Consumption Estimates

Well ahead of the bidding, the Official Requisition for Basic Drugs is distributed to the users, in order that they may be able, after proper review, to ascertain their own consumption estimates for the period covered by the bid. Their figures are sent to the Permanent Commission on Basic Drugs, which consolidates them and sets the amount of the bid as the total sum of those estimates. In the first bid, the above system was strictly followed, but in the second and third, adjustments were made in accordance with the average consumption figures presented by each user.

12.2 Invitation to Bid

The Permanent Commission on Basic Drugs announces the bid through notices in local newspapers and in accordance with governing laws. Those notices clearly indicate the conditions for the bidding.

12.3 Conditions and Amount of the Bid

The conditions are established by the Permanent Commission on Basic Drugs, after prior coordination with the competent technical and administrative organisms and final approval by Supreme Decree. The conditions specify the minimum requirements to be satisfied in order to be able to offer products, and without which the bid cannot be entered.

Amounts to be bid are the total sums of all the users' consumption estimates, which in some cases have been adjusted to conform to their consumption averages.

12.4 Consultations

The period between the invitation to bid and the date of opening of the bid is generally 30 days. During the first 15 or 20 days, the Permanent Commission on Basic Drugs can be consulted on any aspects that may need clarification or that had not been taken into consideration previously. The answers are part of the bid and, to avoid unnecessary repetitions, copies of same are sent to all the laboratories.

12.5 Bids Committee

This is the organism responsible for the opening of the two envelopes with proposals for the bid. The first one contains the general requirements, without approval of which the second one, containing the specific requirements, cannot be opened. All the first envelopes (A) are retained by the Bids Committee and all the second envelopes (B) given to the President of the Permanent Commission of Basic Drugs, who puts the offers in proper order and delivers them to the Technical Committee.

12.6 Technical Committee

This Committee is composed of chemist-pharmacists from the Health Departments of the Armed Forces and a physician from the Ministry of Health. Its mission is to technically qualify the offers of the laboratories, taking into consideration their prestige, seriousness, experience in the field and in the product, lack of negative background, etc., and to ascertain that they strictly conform with the requirements of the Official Requisition.

Within a predetermined period of time the Committee shall submit the report to the President of the Permanent Commission of Basic Drugs, who in turn will submit it to the President of the Economic Board.

In the bidding on X-ray film, the Committee is composed of radiologists and will be presided by the one with the highest degree; should there be two with the highest degree, the President will then be the older of the two.

12.7 Economic Board

This is presided by the Minister of Health and its mission is to study the report of the Technical Committee. Most of the reports are generally ratified; however, in some cases the awarding is modified. When the revision is completed it is submitted to the Minister of Health as a recommendation.

12.8 Awarding of the Bid

The Minister of Health, following the recommendations of the Economic Board, issues a Ministerial Resolution awarding a bid for each one of the drugs.

The laboratories that are not awarded a bid are allowed three days to file a request for reconsideration of their rejection. The Economic Board reviews same and renders its opinion through a new Ministerial Resolution. This decision is final and cannot be administratively appealed.

12.9 Signing of Contracts

Three days after publication of the awarding or of the decision on a request for reconsideration, the laboratory awarded the bid can sign the corresponding contract, which is ratified by the President of the Permanent Commission for Basic Drugs and signed by the Executive Director of the Ministry of Health.

To protect the national industry, when a laboratory bids with an imported product and another with a similar product of national manufacture, the bid is awarded, de facto, to the latter.

13. Pricing

The Permanent Commission of Basic Drugs, taking into consideration the price established in the bid and in compliance with its fifth objective to avoid being a Government-financed program, increases the price of the drugs slightly, and distributes the difference between the bidding price and the selling price to the public, giving 50% to each one of the users and the other 50% to the Program of Basic Drugs, for its operational expenses at a local or national level, respectively.

14. Laboratories that Were Awarded a Bid

At the beginning of the organization of the Program of Basic Drugs some pharmaceutical laboratories which considered that the execution of the program would represent a competence to their commercial products, issued certain unjustified opinions. Later on, when this image disappeared and to date, the maximum support has been received, to the point that practically all of the laboratories have participated in the bids called.

Of the total number of laboratories operating in Peru, approximately 70% of them have been awarded bids in the program, as follow:

Abbott	Bayer
Ciba Geigy	Colliere
Efesa	Drogueria Kahan
Spedrog	Lilly
Hoesth	Squibb
Merch Sharp Dohme	Ifarpe (Erba)
Glaxo	Parke Davis
Peruano-Germana	Pfizer
Promaco	Quimica Suiza
Roche	Russel
Sandoz	Schering Farmaceutica
Sydney Ross	Refasa
Upjohn	Armour
Merck Peruana	E. Stahl
Bristol	Abeefe

Agfa Gevaert	Alfa
B. Braun	Biosa
Ames	Cipa
Carrion	Esfasa
Farindustria	Hersil
Intherpharma	Lusa
Magma	Perulac
Trifarma	Cofana
Vita	Peikard

15. Approval of Containers and Labels

In compliance with the instructions of the Supreme Decree and of the Permanent Commission of Basic Drugs, the laboratories should submit the design of the containers and labels that will be used for the drugs; these are inspected and, with the approval or necessary changes, returned for final production.

16. Quality Control

We are sure that the backbone of the success achieved by the Program of Basic Drugs is the zeal applied in the control of the quality.

This is exercised on a permanent basis and with the effective action of all means available to us.

In general terms, the following is done:

16.1 Requirement of the Raw Material

If anything is imported for the manufacture of basic drugs, prior to its processing, a certificate from the country of origin of its raw material should be submitted. This certificate should also be endorsed by the respective Peruvian Consul.

All documents are addressed to the Minister of Health and once entered in the respective kardex cards, they are endorsed for removal from customs by the laboratory itself.

16.2 Center for the Control of Drugs and Biologics of the National Institutes of Health

This control center is under the Ministry of Health and is the best control laboratory of the country. The mentioned center controls the quality of the raw material when this arrives at customs, during the manufacturing period in the pharmaceutical laboratories, and, finally, by sampling when it is being sold or used by the consumer.

Likewise, the users, on their own and whenever they deem it convenient, can submit any product for the respective analysis.

The results of the controls performed are transmitted, through the Presidency, to all users and health professionals.

16.3 Foreign Control Laboratories

In some special cases analyses are sent to foreign control laboratories.

The results of the tests performed are received and transmitted to all interested parties.

17. Reduction of Costs

The price of the basic drugs, as compared with their commercial counterpart, is lower, in some cases even 83% less and the average of most of them is near 35%.

The reduction of costs is a consequence of the almost total elimination of marketing expenses, such as advertising, printed, oral, or televised; medical samples; medical advertisers; luxury containers; etcetera.

Likewise, it should be recognized that the laboratories cooperate with the Program of Basic Drugs by reducing their profits to a minimum, inasmuch as when they are awarded a bid they will be signing contracts with the biggest consumer of drugs of the country and they will have the opportunity to utilize to a maximum the personnel hours and the machinery that they have idle.

Besides, the transportation expenses are reduced because the delivery schedules are prepared for three months and, consequently, the excessive expense incurred in the sale of small quantities disappears almost completely.

An objective analysis of the reduction in costs can be seen in the chart on page 18.

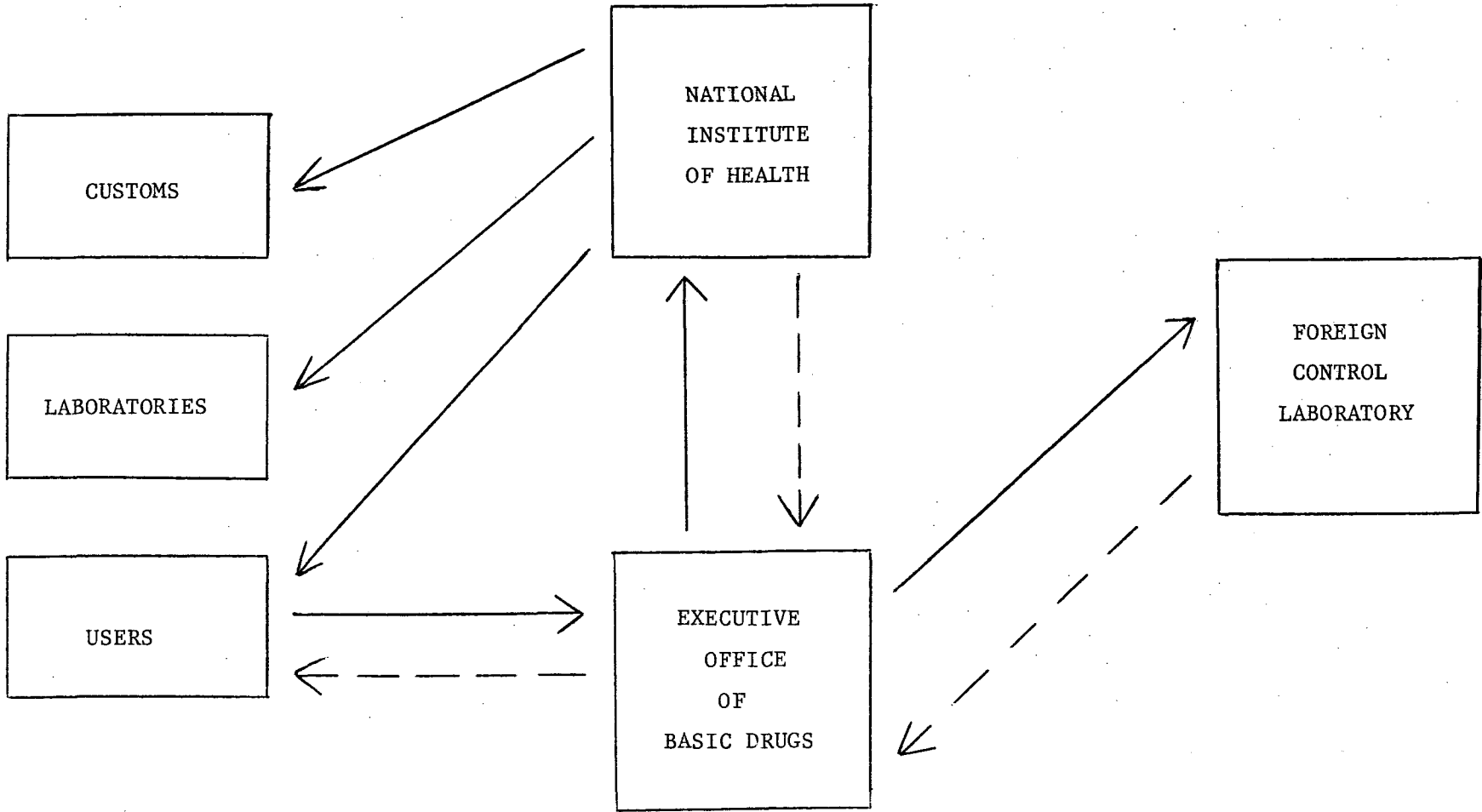
18. Directives

For the better execution of the Program throughout the country, there are two directives, which are revised for each bid. They are as follows:

Directive MB-10 for the users

This directive details the requirements to be met by the users for the normal development of the Program of Basic Drugs.

MEASURES OF CONTROL OF BASIC DRUGS



PERCENTAGE OF REDUCTION OF THE COST OF BASIC DRUGS

Product	Price at Pharmacy	Price of Basic Drug	Percentage Of Reduction Of the Cost
Erythromycin caps.	S/. 16.50	S/. 3.60	% 78.1818
Chloramphenicol caps.	1.95	1.00	48.718
Ampicillin caps.	9.40	3.50	62.766
Penicillin Benzatinic vial bottle	29.50	9.00	69.492
Benzoate	100.00	17.00	83.00
Corticoid drops	40.50	11.85	70.741
Codein, Phosphate and others	24.00	15.00	37.5
Chloropheniramine, maleate Tab.	0.95	0.45	52.632
Ointment with a base of Heparine	38.50	18.00	53.247
Multivitamins with minerals	106.30	17.50	83.538
Total Items Bid for: 298	12,800.07	8,438.15	34.0774

Directive MB-11 for the Laboratories

This Directive is similar to the one above, but is applicable to the laboratories that supply the drugs.

19. Submission Forms

For the best functioning of the Program of Basic Drugs, there are 11 submission forms which are used by all the consumers at a national level.

They are as follows:

Form MB-01	Monthly Report on the Consumption of Basic Drugs.
Form MB-14	Requisition for Additional Drugs from the Supplying Laboratories.
Form MB-20	To effect transfers among the hospital areas.
Form MB-21	Summary of All the Transfers.
Form MB-24	Information on Spoiled Basic Drugs Indicated in Guidelines.
Form MB-27	Report on Sales by the Laboratories to Pharmacies and Drugstores Affiliated to the Program of Basic Drugs. (Trimonthly)
Form MB-28	Evaluation of the Program at the Hospital Areal Level.
Form MB-29	Evaluation of the Program at the Health Region Level.
Form MB-30	Evaluation of the Program at the Ministry of Health Level.
Form MB-31	Increase or Decrease of Deliveries, sent to the Office of Information.
Form MB-100	Requisition for Basic Drugs requested by the users for two years.

20. Mechanization

A fundamental aspect, and one that greatly contributes to the efficient development of the Program of Basic Drugs, is the mechanized processing of all the information, which, in order to adequately achieve its goal, should be exact and timely.

At the beginning of the Program there was a Mechanization Section in charge of described functions; later, this Section was transferred to the Office of Information, when this was created, at the level of the Ministry of Health.

21. Operating Expenses and Original Capital

The Program of Basic Drugs has a very important characteristic, one which has to be stressed. This is that it is not financed by the state and, consequently, has to be financed at a central and at a peripheric level.

This situation is clearly described in its second objective, which reads:

"Achieve a certain degree of self-sustenance".

An original capital that would allow the payment of contractual obligations entered into with the supplying laboratories was never achieved; however, a way was found to cover the expenses without recurring to the Public Treasury.

To achieve this objective, the bidding price has been increased a percentage to cover the operating expenses at a central and peripheral level.

21.1 Users in the Ministry of Health

At the beginning, all the services of the Ministry of Health retained a percentage to cover their own operating expenses. Later, from 1974 on, and in compliance with governing legal dispositions, they had to deposit the corresponding amount, that is, at present they have an obligation to deposit the amount of the sale in the current account of the Program of Basic Drugs.

21.1.1 Sales

The basic drugs are received by these users as a merchandise requested, on consignment, and at their own risk.

Consequently, they have to deposit in the current account of the Program the total amount of its sales, which enables the Program's Directors to fulfill their contractual commitments with the supplying laboratories, thus complying with the contracts signed between these and the Ministry of Health.

21.1.2 Deposit of 70 and 60% of items 02.08 (X-rays material) and 02.09 (medicines and laboratory material).

When this Program was initiated, there were no stocks of basic drugs for each one of the users in the Ministry of Health; likewise, no original capital was received from the Public Treasury. To solve this problem, a Ministerial Resolution was issued requiring that all health users deposit 70 and 60% of items 02.08 and 02.09, respectively, to the current account of the Program of Basic Drugs, using as point of reference the total amount assigned to the items in each one's current budget.

At first we felt that this was a wise decision, since it permitted the disposal of the necessary funds to comply with the contractual commitments with the supplying laboratories. However, this created administrative accounting problems to the peripheric executive organisms, who could not fully comply with the governing legal dispositions concerning the rendition of accounts.

The mentioned Ministerial Resolution has not been reissued in the present budget.

21.2 Internal and Private Agencies

As explained before, the Program of Basic Drugs serves all health establishments of the public sector (public service organisms) and some of the private sector (private sector organisms). These organisms are benefited by the great reduction in the costs of the drugs and in return, in accordance with Article 29 of Supreme Decree No. 00570-72-SA, of 7 November 1972, they have to pay 50% of the difference between the bidding price and the selling price, to the Program of Basic Drugs to cover their operating expenses.

22. Delivery Chronograms of the Drugs

These are the documents sent to the users, containing the following information:

- Date of Receipt
- Type of Drug
- Name of User
- Name of Laboratory

22.1 Periodicity

They are prepared every three months.
Eventually they will be prepared monthly.

22.2 Quantities

The type of drug and the quantity to be received are indicated.

22.3 Readjustments

The number of months of the current bid is divided by three and that gives the number of chronograms to be issued.

The estimated consumption of each one of the users is divided by the number of chronograms and it gives the quantity of each one of the basic drugs to be received every three months.

This figure is not static, but dynamic; thus, if in the judgement of the parties responsible for this function in the Program for Basic Drugs, any of the users had a stock of any drug, the figure for that drug can be readjusted decreasing the quantities in the next chronogram.

The public and private sector organisms receive their delivery chronograms in the same manner as the users in the Ministry of Health, but, in order to be served, they should submit a purchase order to the supplying laboratories, with a copy to the Program of Basic Drugs.

22.4 Additional Requisitions

When a situation is the opposite of that described in the previous paragraph, that is, when the quantity received is used up in less time, it is necessary to send more drugs to satisfy the demand.

Each user who desires to submit an additional requisition should do it in Form MB-14, designed for such a purpose; however, it should be noted that this should not be done too frequently, so as not to burden the administrative functions unnecessarily.

The ideal is that the consumption estimates be more realistic and that additional requisitions be used as an emergency procedure.

23. Receipt of Drugs

The users of the Programs should receive the basic drugs on the dates indicated in the chronograms. Any delay should be notified immediately so that, if the supplying laboratory has not requested the corresponding extension, that he may have it approved in accordance with the governing regulations. Upon receipt of the basic drugs, users of the Ministry of Health should send a copy of the waybill to the Program of Basic Drugs so that they may proceed to pay the respective invoice. Likewise, users should notify any anomaly they may find in the order, such as a shortage, a breakage, etcetera.

24. Consumption Report

All users should, no later than the 15th of each month, submit the Consumption Report for the basic drugs used by them during the previous month. This should be done in the Form MB-01.

For the Divisions of the Ministry of Health above is mandatory.

25. Accounting

This is one of the most important aspects of the Program of Basic Drugs and should be accorded the greatest care. This should not be neglected because efficient accounting in the Program makes a good impression on the supplying laboratories.

25.1 Responsible Organisms

From the beginning of the Program and until 31 December 1974, all the accounting-administrative aspects were the responsibility of the General Director of Administration, through the Director of Supplies and Auxiliary Services of that department.

This initial decision created a double line of command, one technical, in charge of the Permanent Commission of Basic Drugs and another accounting-administrative, in charge of the General Directorate of Administration. Since this situation was not the most adequate, on January 1st, 1975, the Division of Budget and Accounting of the Program of Basic Drugs was created. It is at present in charge of all the accounting-administrative aspects.

25.2 Deposits

This refers to all the monies that each one of the users from the Ministry of Health deposit in the current account of the Program, from the sale of the basic drugs.

25.2.1 Paid by the Patient

The total amounts paid by the patients for basic drugs, are deposited the next day in the current account, except on Fridays and Saturdays, when deposits are held over until the next Monday.

25.2.2 Paid Through the Budget

It has been established that the drugs should be paid for entirely by the patients; however, there are people who do not really have the economic means to buy them and to take care of that, a social study is made, paying the corresponding cost from the money assigned to the items in the budget in force of each one of the users of the Ministry of Health. This payment is generally made once a month.

25.2.3 Paid by Other Institutions

The organisms in the public sector, and those in the private sector (non-profit) have credit in the services of the Ministry of Health and make their payments on the date previously determined. It is generally made once a month, except where there are agreements signed between the Ministry of Health and some other organisms or ministries.

25.3 Payment to the Laboratories

In accordance with one of the clauses of the contract, the invoices of the supplying laboratories are paid 90 days after delivery of the drugs to the users of the Ministry of Health. For this, it is mandatory that the waybill of the laboratory, duly signed by each user after verifying receipt of the drugs, be enclosed.

The organisms of the public and private sectors pay the laboratories directly.

25.4 Article 29

In accordance with this Article, all types of users should pay to the Program of Basic Drugs 50% of the difference between the bidding price and the sales price, to cover the program's operating expenses. This is done in the following manner:

25.4.1 Health Users

They deposit the 50% directly to the current account of the Program, after the sale is made, keeping the other 50% for their own operating expenses.

25.4.2 Affiliated Organisms

All the organisms, both from the public and from the private sectors, pay the 50% of the difference based on the total of drugs obtained from the laboratories. Payment is performed upon receipt of invoices through the organisms responsible for the accounting of the Program of Basic Drugs.

25.4.3 Pharmacies and Drugstores

Of the total amount of sales in these establishments, 10% is sent directly to the Program of Basic Drugs through the supplying laboratories.

26. Demand

The Program of Basic Drugs in all its aspects has been very well received at a national level. This is evidenced in the aspects detailed below:

26.1 Number of Items and Submission Forms

In the three bids already held, the number of items and of submission forms have been increased. This can easily be seen in the following table:

	<u>Items</u>	<u>Submission Forms</u>
First Bid	185	265
Second Bid	235	333
Third Bid	244	362

26.2 Amounts in Soles

As in the previous case, the figures of the three bids clearly show its great demand. Thus we have:

First bid plus additional contracts	S/. 483,006,662.07
Second bid plus additional contracts	768,918,893.21
Third bid without additional contracts	1,115,395,422.83

26.3 Additional Requisitions (MB-14)

We should state in general terms that the consumption estimates made by the users, in many cases, do not reflect the real demand; thus the amounts they received in accordance with the chronograms submitted were used up in a shorter time than anticipated. To avoid having low stocks, Form MB-14 was designed, through which any of the users can request from the Program of Basic Drugs an additional amount of those drugs they may need, due to a greater demand.

We believe we should repeat that this system should only be used in case of an emergency; otherwise, the administrative control is unnecessarily burdened.

26.4 Additional Contracts

In the two bids that have been completed it has been verified that the amounts bidded for some of the products was lower than the real demand, which has made it necessary to issue a Supreme Resolution authorizing the Ministry of Health to enter into contracts with the supplying laboratories, without bids and at the same prices, for those drugs that

have had a great demand. This situation already arose in the first two bids and we expect it to present itself in the third bid (75-76), due to the explosive demand of some drugs and to the incorporation in the Program of Basic Drugs of some institutions of great consumption, such as Centromin Peru, etcetera.

27. Requirements to Buy Basic Drugs

In all services of the Ministry of Health that have medical personnel, all that is needed is the presentation of a medical prescription, which can be issued by any physician without exception, either from the public sector or exclusively from the private sector.

In the health units, that is, in the minimal health services installations, which are manned by a health auxiliary, this employee is permitted to prepare a small request for basic drugs, to enable him to take care of minor diseases, for which he has been previously trained.

28. Pharmacies and Affiliated Drugstores

The Program has been established on an experimental basis, in the Departments of Lima, Ica, and Ancash only, at the level of the pharmacies and drugstores which have voluntarily joined the Program.

To make this a reality, the legal dispositions to permit this extension were issued and it has only been initiated with 45 items and 82 submission forms, that is, with a reduced requisition which is sold in those establishments. Depending on the results of the evaluation that is being made of its development, it shall be expanded at a national level or this manner of issuance modified.

Coverage reached is 75%.

29. National Coordination

The Program of Basic Drugs has been extensively diffused in Peru, so much so that a request has been received from high officials of the Ministry of Agriculture asking for all necessary information to study the possibility of adopting a similar program for the products used in agriculture, livestock, etc., which have a great demand at the country level.

30. International Coordination

Likewise, the Program of Basic Drugs has had great diffusion at an international level, so much so that several requests have been received asking for information on the Program of Basic Drugs, to promote them, in some cases, or to study the possibility of adopting it in some countries. Thus, information has been sent to the following countries:

- 30.1 Geneva (requested by PAHO/WHO)
- 30.2 Ecuador
- 30.3 Bolivia
- 30.4 Pakistan
- 30.5 India, etcetera

Likewise, in the meetings of the Andean Agreement (Agreement of Cartagena) held in Lima, it was agreed, in the first place, to study the health legislation which permits the establishment of a Program of Basic Drugs at the level of the Andean Agreement and, later on, to study a basic requisition in each one of the member countries.

Finally, it is necessary to indicate that the PAHO/WHO bought a lot of basic drugs to send to the Republic of Bolivia, with the purpose of helping them in the eradication of some epidemics that had been caused by some floods they had, thus showing how well the Program of Basic Drugs has been received in the highest technical organisms in the world.

31. Supervision

This function so important in all administrations has priority and the maximum support of the Permanent Commission of Basic Drugs.

From the beginning of the Program it was established that the Permanent Commission would delegate supervision of the Peripheric Executive Organisms on the Regional Directors. The chiefs of the hospital areas supervise all the health services under their command, such as hospitals, health centers, and health units. Periodically, the national directors supervise those services, specially, the President of the Permanent Commission of Basic Drugs and the Chief of the Executive Offices.

For the better handling of the functions of the supervisors, a supervision questionnaire has been designed. Based on experience, this document can be modified, if necessary. To achieve an effective development of the Program, supervision should be increased to a maximum.

The supervision questionnaire can also be used to perform the evaluation.

32. Evaluation

The Program of Basic Drugs is constantly being evaluated by the Directors at a central level or by the Peripheric Executive Services, all of them getting together in Lima to perform a joint evaluation.

From the results of the technical and administrative evaluations performed, very important conclusions have emerged, which are improving every day more and more the execution of the Program of Basic Drugs at a national level.

For a good administrative evaluation it is necessary to use mechanization; otherwise, too much personnel would have to be used and there would be more possibilities of error. Likewise, the evaluation should be constant to achieve a better programming and execution of the Program of Basic Drugs.

33. Regulations on Sanctions

To achieve its goals better, the Permanent Commission of Basic Drugs has a set of Regulations on Sanctions which were approved through a ministerial resolution and which contemplate all possibilities of infractions that could be incurred in by the supplying laboratories.

The Permanent Commission may, in accordance with the powers that the by-laws and governing legal dispositions confer on it, establish sanctions to the supplying laboratories, from a fine to the cancellation of contracts and even to the closing of the laboratory.

Up to now, only fines have been imposed on some laboratories for delays in the delivery of the drugs and in other cases, some contracts have been cancelled for different administrative reasons.

34. Sales Programming

At the beginning of the Program, there was no clear and concrete image on the amount of Basic Drugs needed by each one of the users of health, to satisfactorily supply its demand, so much so that the estimates of consumption received were in some cases deficient and in others, exaggerated. Later on, and based on the above, the figure to be used by each one of the users have been calculated and at present they have the apparent real amounts of consumption. Using this information and taking into consideration the increases in coverage anticipated for the present two years, the sales of drugs that the users of health should receive have been programmed, including in said figures those to be paid by the community and those that will be credited through the budget, to take care of the patients of low financial resources or for those that will be distributed free, to fulfill Government programs, such as the one of the Mother and Child, for example.

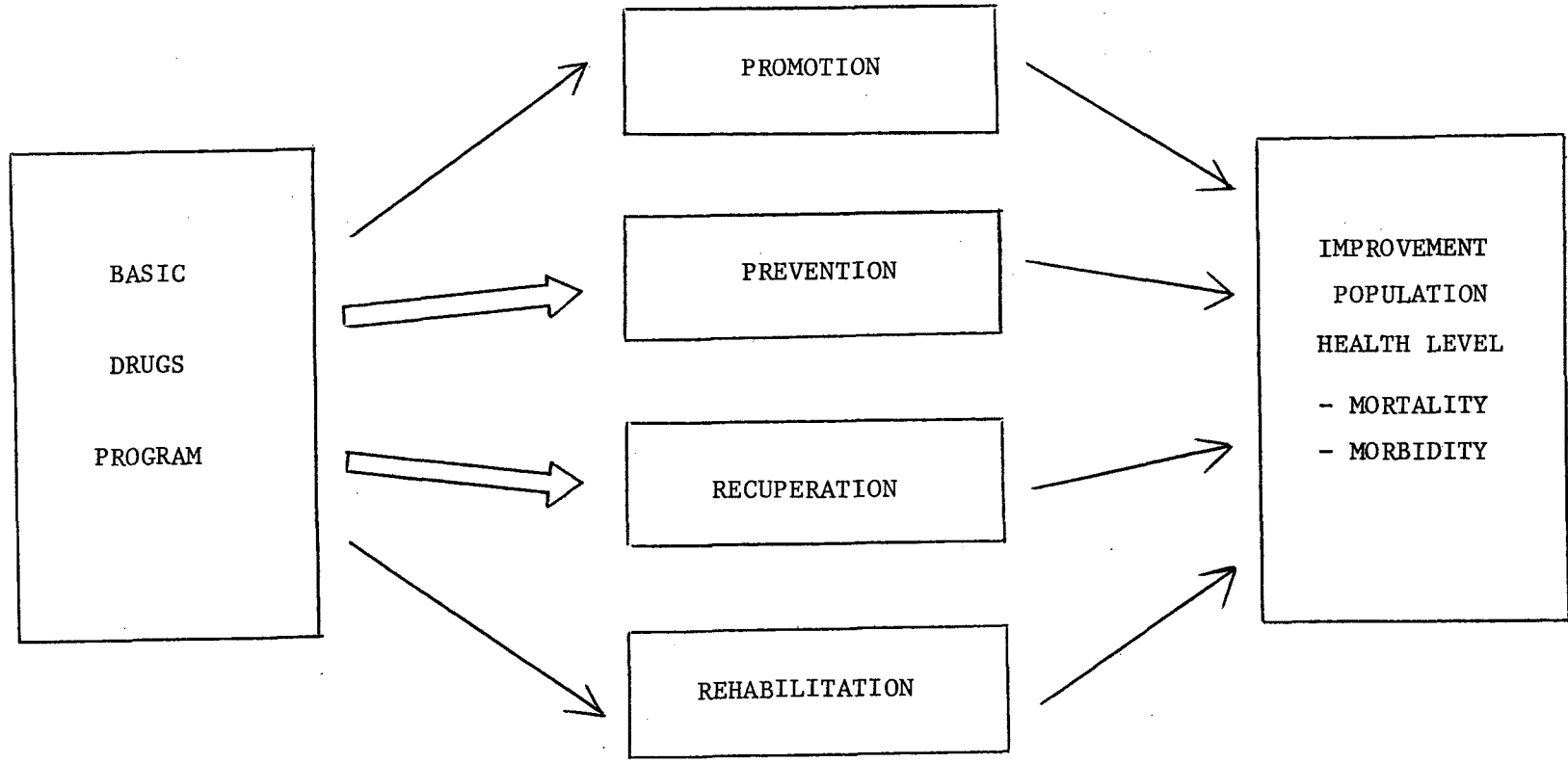
At the beginning, this programming will have some errors in calculation and we are sure that soon those figures will be more realistic.

35. Basic Drugs and Health Level

The main objective of all the activities performed in the Health Services is to improve the health level of the population.

In the countries that are in the process of development, the health level is measured through negative indicators, such as the mortality and morbidity rates.

BASIC DRUGS AND HEALTH LEVEL



The basic drugs performance is fair in promotion and rehabilitation with its maximum action in the prevention and recovery of health.

Previously, part of the population did not use medicines due to its high cost; others, with some economic capacity, bought part of the prescriptions, which generally were represented by the symptomatics, and not by the antibiotics, etc., which are the ones that really cure diseases. At present, considering the optimum quality and low cost of the basic drugs, the number of people who get cured has increased.

Besides, the Program has not taken the market away from commercial medicines, since it has been proved that the sales of these have also increased, showing by that, that the Program of Basic Drugs has created for them a new market that did not use medicines before now.

Based on the above we can affirm that if the number of persons who get cured is actually higher, the coverage of attention achieved will be higher and, consequently, it shows that there exists a positive collaboration to decrease the mortality and morbidity rates.

Unfortunately, we cannot at present quantify this affirmation, mainly because we are at the moment improving our statistical information, which the same as other countries with similar characteristics, is lacking in data.

36. Basic Drugs and the Economic and Social Development

The countries that are in the process of development have, among others, a special characteristic because of which the great majority of its population expects much from the state paternalism and requests very often from the Government that it satisfy many of the primary needs.

From the beginning of the Program we have insisted, at the national level, that the inhabitants should pay for the basic drugs of optimum quality and low cost which the Government has made available to them.

This request has been broadcasted through the whole country and we requested the active participation of the population in solving its own needs and in this special case, in paying the drugs made available to them at a minimum cost.

The Ministry of Health would not, under any circumstances, allow a person of a low financial condition to go without needed medication, and to that end, after an investigation by Social Services, it would proceed to serve him through monies assigned to the budget of each of the Health Services. The above has had positive results, so much so that we have achieved that in many hospital areas the percentage of basic drugs paid for through the budget has been of under 2%.

In summary we can say that the Program of Basic Drugs is collaborating in changing the traditional mentality of the people who now do not expect the broad support of the Government and who participate actively in the solution of their own problems; consequently, we are helping to change the way of thinking of the people and to achieve one of the objectives of all societies, which is: "Collaborate in the economic and social development of his country."

37. Modifications for the Years 1975-1976

At the start of the Program of Basic Drugs, this was considered from the administrative point of view as a subprogram dependent of the General Directorate of Administration, who, through the Directorate of Supplies and Auxiliary Services, had the responsibility for the accounting and administration of the Program.

In the Budget for the years 1975 and 1976, the Program of Basic Drugs is changed from a subprogram to an Operations Program, with its own accounting service, and creating the Division of Budget and Accounting, which will from January 1, 1975, be responsible for the accounting and administrative aspects of the Program.

Likewise, positions of accountant supervisors are created with the specific purpose that they proceed to increase the supervision of all the Peripheric Services.

Starting with these two years, the Office of Pharmacy has been created in the Ministry of Health, to be a part of the General Directorate of Special Programs on Health.

It has been decided by that Directorate that all aspects and programs of its specialty be centralized and as a consequence, the Program of Basic Drugs will be soon transferred to the mentioned Directorate, being this in the future, responsible for all the functions performed now by the Permanent Commission of Basic Drugs.

38. Conclusions

38.1 The Program of Basic Drugs is fulfilling the objective set in the Peru Plan of 1971-1975 of using the generic products to achieve lowering of the cost of the drugs.

38.2 It has prepared the basic official requisition, which has been frequently revised.

38.3 It has made available to the Peruvian inhabitant drugs of optimum quality and low cost.

38.4 It has received the support of the National Medical Staff and the other health professionals.

- 38.5 It is achieving its autosufficiency.
- 38.6 It has achieved the maximum support from the laboratories suppliers of drugs.
- 38.7 It has given and achieved maximum priority to quality control.
- 38.8 It has achieved an average decrease of 35% of the costs.
- 38.9 Because of its volume, utilization of computerized data processing systems is necessary.
- 38.10 It has achieved a great demand at a national level.
- 38.11 It has achieved a positive promotion at an international level.
- 38.12 It has achieved an efficient supervision, evaluation, and programming.
- 38.13 It is collaborating to improve the health level.
- 38.14 It is motivating the population to participate actively in the economic and social development of the country.
- 38.15 It has received, after three years of execution, the most necessary modifications to make it more effective.
- 38.16 Finally, we affirm that it is a revolutionary Program being executed by the Ministry in the health sector.

39. Recommendations

During the last few years, in some countries, and as a result of the high prices of the existing drugs, the improvement of the health level has not been more efficiently achieved. To serve better the community of countries in the Third World, and using as a model the Program of Basic Drugs of the Government of Peru, it is possible that similar programs be organized in other countries for the utilization of generic medicine, which will enable them to offer their respective populations, drugs of the highest quality at a low cost; to achieve this, the following recommendations can be made:

- 39.1 That in some cases and specially at the beginning, the program be of a vertical type and that it be administratively dependent on the executive offices of the Ministry of Health.
- 39.2 That it be organized with the maximum technical assistance possible.
- 39.3 That it should have a wide promotion and achieve the most complete support from the medical staff and from the other health professionals and the public in general.

- 39.4 That quality control should be given the highest priority.
- 39.5 That it should be a self-sustaining program and that it should have a guaranteed working capital at the beginning.
- 39.6 The necessary counseling and coordination with other sectors should be requested.
- 39.7 Fulfill on time the contractual commitments with the supplying laboratories to create a trustful and positive image for the program.
- 39.8 Evaluate and supervise closely the development of the program making the necessary adjustments.
- 39.9 Program all types of activities.
- 39.10 Have the drugs on sale the 24 hours of the day.
- 39.11 Motivate the population to pay for its drugs and use the payments from the budget for exceptional cases only.
- 39.12 Have available a complete regulation of sanctions, avoiding the use of same as much as possible.
- 39.13 It should adhere to the objectives and goals of each government.