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UNIDO AND THE ESTABLISHMENT OF PHARMACEUTICAL INDUSTRY SECTORS IN DEVELOPING COUNTRIES [1]

presented by

the secretariat of UNIDO

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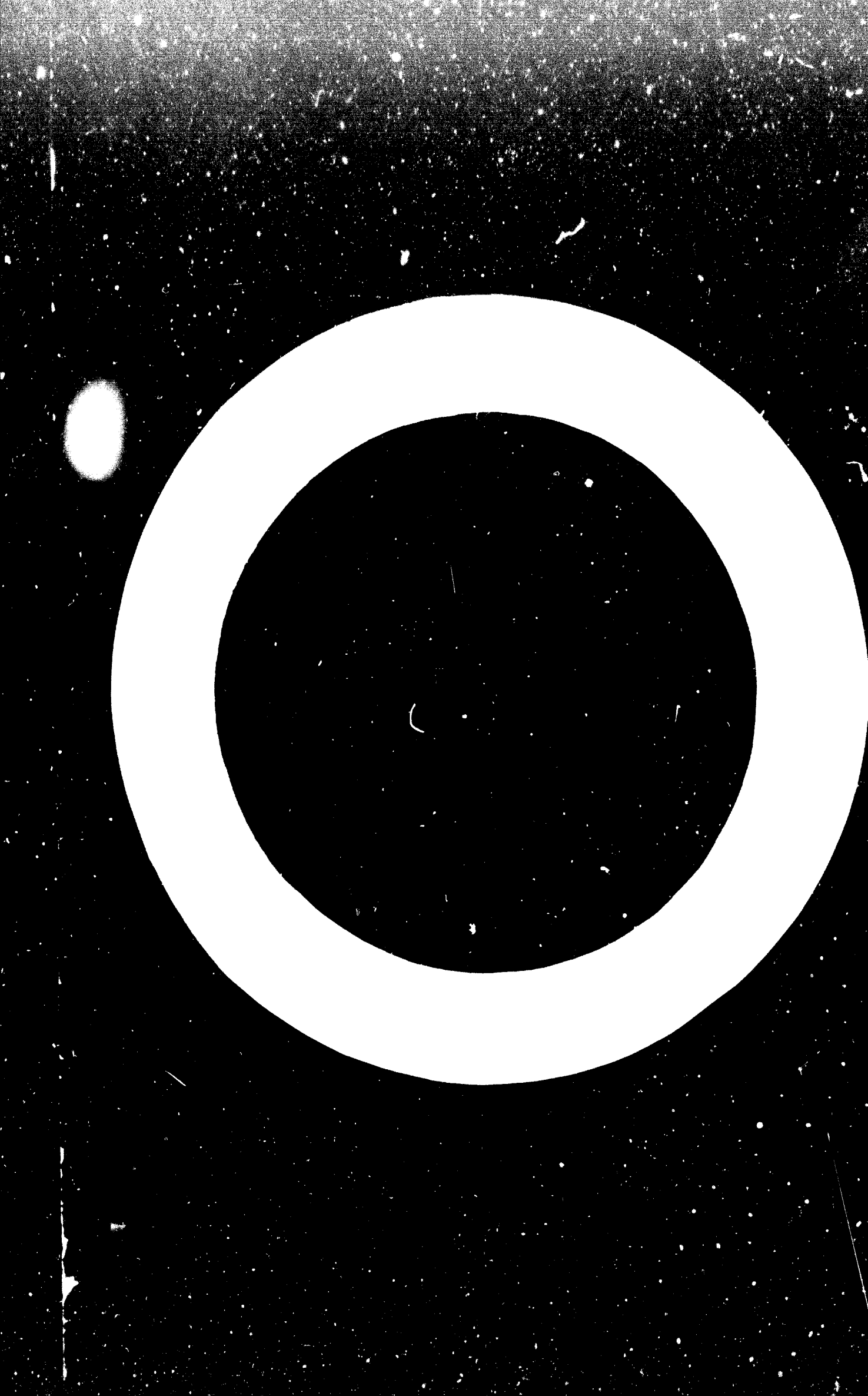


In UNIDO's scope of responsibilities in the support of industrial development in developing countries, a procedure found most adaptable in the preliminary evaluation of a programme is the establishment of terms of reference agreed to by the country concerned, UNIDO, and the United Nations Fund supplying special funds. This procedure assures the assignment of the optimum amount of effort to the most important components of the problem within the budget and time periods involved. Further such agreement on terms of reference permit the early resolution of recommendations to provide the necessary implementation.

The definition of a "Pharmaceutical Industry" is a broad one and encompasses a variety of "sector" disciplines such as scientific (pharmacology, biochemistry, quality and efficacy control), technological (synthesis, production, packaging, sterilization, fermentation), economics (marketing, costs, pricing, advertising), education (training, professional personnel), legal (patents, licensing, import and export restrictions), and others. Since the degree of sophistication in each of these is high, a developing country with its limited, or total absence of resources in these disciplines, would be hard put to consider embarking in an "across the board" effort. Therefore for practicable purposes the advancement of a "pharmaceutical industry" in a developing country should be via the development and growth of individual sectors.

UNIDO's role is to provide assistance to developing countries in those sectors of the pharmaceutical industry which lend themselves to industrialization. This assistance would include the assessment of the present status of such sectors, detailed evaluation of domestic demand for pharmaceuticals, classes of product, etc. and recommendations concerning the improvement of infrastructures to provide a viable basis for the industrialization of such sectors.

Developing countries want an indigenous production of some pharmaceutical preparations for various reasons. Economically it would save convertible currency, professionally it would permit nationals to develop their skills, and on a national health basis some pharmaceutical active principles or intermediates could possibly be made available without dependence upon outside sources.

It must be realized at the outset that a pharmaceutical "industry" is not analogous to a "leather industry", or a "pulp and paper industry". In pharmaceuticals we are dealing with the health and well being of present and future populations and their food animals. Whereas in other non-allied health industries varying degrees of product quality can be acceptable, this cannot be tolerated in pharmaceuticals.

Upon receipt of a request from a developing country for assistance in the "Establishment of a Pharmaceutical Industry" UNIDO would first embark upon an "assessment of the country's present status of pharmaceutical industry sectors". Since the United Nations responsibilities of pharmaceutical utilization

is vested in the World Health Organization, UNIDO would discuss the following with them:

(a) Therapeutic needs of the country - This covers the principle diseases in the country [illegible], malaria, [illegible] tuberculosis, liver diseases, etc., and the order of their importance in each country in the South Asia. [illegible] problems of less importance but nevertheless contributing to the total [illegible] people may include [illegible] infections of the eye, diseases of the respective system, infection [illegible] and [illegible], etc.

Once these needs are identified and related to the recommendations of WHO and its regional offices an estimation of the relative quantities and types of selected groups of pharmaceuticals needed can be attempted.

Such assessments are usually based on limited data, as records of admittance cases at hospitals in developing countries are often lacking in useful amount and information. Many people are treated in a variety of hospitals and clinics, especially under [illegible], and records are not always available for a study. The detailed diagnosis and recording of diseases is not always possible because of the lack of professional help at clinics, health stations, etc. In addition the number and types of pharmaceuticals distributed by [illegible] and hospitals, clinics, etc. are not always identical.

Whenever possible [illegible] statistics are utilized, mostly in most instances pharmaceutical [illegible] poorly identified and little rationalization can be made, to obtain a clear picture of the needs.

(b) Assuming the therapeutic needs of the country indicate that pharmaceutical products most needed are those for the treatment of malaria, tetanus, liver disease, cysteine and vitamin deficiency, then an assessment (based upon market, production, equipment, people, etc.) would be made of the possibility of making some of these. UNIDO's role would be one of supplying experts [illegible] the economic and economic evaluations. The experts selected [illegible] country and UNIDO are normally assigned to an agency of the [illegible] Government and operates under the Government's direction [illegible] terms of reference of the projects. Should the expert recommend that the most practical immediate implementation would be to import some basic raw materials, and that the country should [illegible] tablets for vitamin deficiency, and for digestive system problems, and certain liquid preparations for skin and eye infection, then the programme can proceed to the next step, how to get these products made.

(c) Upon consultation with the WHO both in Geneva and in Regional Offices and the country's health authorities, UNIDO will provide assistance in regard to the best procedure for the Government to follow to initiate production of selected pharmaceuticals. Since in many cases such initiation is a capital intensive venture, and available capital may be in short supply, the country may wish to consider inviting an internationally oriented pharmaceutical firm to establish a small manufacturing plant to produce quantities of selected pharmaceutical preparations. Since profit is a vital factor to be considered in the

longevity of an industry, specific guarantees must be given. UNIDO can assist in this phase by reviewing the technical business details of suggested agreements.

If a developing country does not initially interest a private group to undertake the [illegible] it can, then the next step to consider [illegible] partnership. However, this has definite drawbacks as experience in some developing countries has indicated. [illegible] the major share of the capital, usually [illegible].

(d) In order to encourage the growth of new pharmaceutical industry sectors, the country should have certain incentive policies such as to allow tax free imports of raw materials (not available in the country), machinery, spare parts, packaging materials, see Fig. (2), etc. In addition they could allow fast write off for depreciation, declare a freedom from paying corporate taxes for a several year period, and allow the firm to have a competitive edge on sales to the government provided their products meet all the quality standards of import.
UNIDO through assistance from HQ can arrange for the country to establish a quality control, and possibly an efficacy control laboratory by sending an expert to oversee the implementation of these developments. Fig. (3) is an outline of a suggested government regulatory arrangement. In order to train people to become laboratory assistants, to improve the skills of other pharmaceutical technicians UNIDO can, then with HQ assistance, arrange for fellowships. Fig. (3) outlines the scientific education required for such experts and Fig. (4) outlines the organization of a National Pharmaceutical Control laboratory.

Since it would assist a country considerably to have sources of material within its own boundaries for pharmaceutical processing, UNIDO can provide an expert to evaluate the utilization of botanicals, agricultural wastes, and animal organs as sources of effective active principles for pharmaceutical preparations. Fig. (5) is an example of how to organize a natural products industry. Further UNIDO can contract a marketing survey to determine which of these active principles have export possibilities. [illegible] can be called upon for assistance in the growth cultivation, harvesting and processing of these raw materials. Since many pharmaceutical end preparations are made up of large quantities of inactive materials such as diluents, fillers, etc. many of these can perhaps be made in the country reducing the need for imports.

A pharmaceutical industry sector is a viable enterprise. It cannot remain static, as its development depends upon new drugs, new techniques of medical application of pharmaceuticals, and constant competition from exports. The developing country interested in establishing pharmaceutical industry sectors must be prepared to undertake constant improvement in the education and training of people to staff the sectors, in encouraging the establishment of research and development facilities, in directing capital investment to the sectors, and in the development of confidence in their products both domestically and internationally. A necessary input is entrepreneurship, a quality often lacking in many developing countries. Accordingly it would be in order in this paper to discuss entrepreneurship one of the prime prerequisites for the successful establishment of any industrial sector in a developing country.

[illegible] availability of production equipment, scientific apparatus, and a [illegible] in domestic market are not always enough to assure a successful [illegible].

Businessmen, if they are to be successful as reflected by the growth of their enterprise must be achievement motivated. This is true in both developed and developing countries. David C. McClelland [illegible] Harvard [illegible] article entitled "Achievement Motivation Can be Developed" [illegible] the point that it is not enough [illegible] people in need of [illegible], but [illegible] to sharpen the aspirations for [illegible] process. [illegible] that [illegible] course, [illegible] motivation [illegible] but one that can be [illegible] within a period of two weeks or less. McClelland feels that achievement motive can be an acquired characteristic, developed as part of [illegible] economies, just the way a language skill can be acquired in adulthood. Such training should be [illegible] establishment of pharmaceutical [illegible] in this aspect by providing programme [illegible] to select likely candidates.

UNIDO's role therefore in a pharmaceutical industry Sector Development covers the range from need to conception, from initiation to production, from training to marketing and from motivation to management.

ANNEX I

Investing, licensing, trading and labour

In addition to the technological and cultural aspects of establishing pharmaceutical [illegible] in developing countries considerations concerning [illegible], licensing and labour in the particular country should be aware of as they will play an important part in the establishment of any [illegible].

A state owned industry

Some countries have set aside a number of industries for the state's sector in which no others will operate non-exclusively or in partnership with private firms and others would be left to the private sector. Because of the general nature of pharmaceutical sectors in a country many Governments may wish to participate on a partnership basis.

Nationalization

The threat of nationalization to a foreign investor is, of course, ever present and little guarantee can be granted by the country as the degree of the threat will vary with the political situation. Some countries have granted a 10 - 20 years no nationalization, however, experience is not available as to the ensuring of these guarantees.

Government controls on new investments and operations

In some countries the majority ownership in enterprises may be difficult to negotiate as many developing countries have little restrictions although the government prefers to see some form of association with their nationals.

Establishment of legal forms and structures

There are a number of forms a subsidiary of a local company or a branch of a foreign enterprise can be established. These cover joint stock companies or corporations, limited liability companies, or general partnerships. Foreign firms overwhelmingly choose the limited liability form as the most suitable one for their purposes. Minimum capital is a requirement since countries will accept the value of machinery as part of the capital requirement. While some countries require that workers be represented on the board, the majority of developing countries do not have this requirement.

Rules of Competition

In many developing countries most companies are considered monopolies because the market is not large enough to support more than one producer, while some countries have limitations on the manufacturer's freedom to sell or set resale prices. The majority of developing countries do not adhere to this business form.

Price Controls

Many developing countries utilize a price control not to prevent the hording or accumulation of capital or consumer goods. However, these controls

will vary with the location of the country to various markets. Some countries use a quasi-government corporation to buy all pharmaceuticals which are then sold at a pre-set profit in order to control high prices.

Trademarks, patents and trade marks

Patents and trade mark protection varies with the country. Some countries will accept an extract from another country, others require the [illegible] while other countries have no protection or extend any [illegible]. Most other countries require the patents and trade mark registration be initiated by their own nationals. Many countries are signatories to the International Patent and Trade Mark Conventions.

Royalties and Fees Paid

There are normally few official limits on the size of royalties or fees which are considered to be private matters. However, income received from the sale of patents, know-how and royalties is in many countries considered as normal income.

Exchange Controls

The controls in this category vary with the country. In some remittability of both profits and original capital is generally easy, while in others it is quite difficult.

Labour

Labour conditions vary with each country. Some Governments require that workers have paid leave for a set number of days in the year, some have minimum wage laws, and others have ordinances against strikes. Fringe benefits in some countries include an annual bonus, provision of housing, etc. Further some countries have a limitation on foreign nationals. In Pakistan for example all employees at present with salaries below R 1000 per month must be Pakistanis, from January 1, 1967 [illegible] of those earning between R 1000 and R 2500 per month must be Pakistanis, and by July 1, 1969 [illegible] of those earning R 2500 per month must be Pakistanis. A foreign firm may permanently maintain a foreigner as its chief executive. Labour is defined as [illegible] pay plus cost of living allowance plus [illegible]. Overseas allowances for non-Pakistani employees are not to exceed one third of their salaries.

Export incentives

Some countries employ a bonus voucher scheme under which exporters of goods can get import entitlement certification covering an amount equivalent to 20 - 30 % of the f.o.b. value of the exports.

Figure 1

INCENTIVE POLICIES

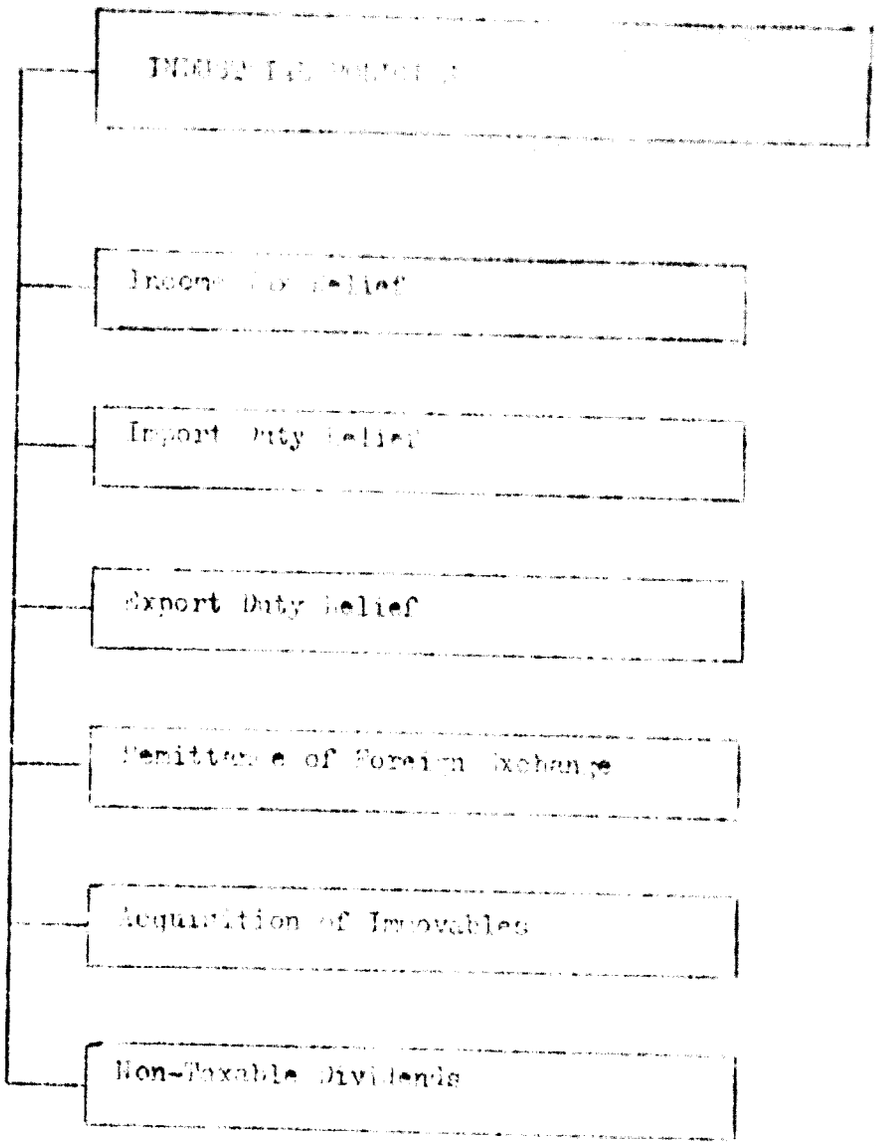


Figure 2

...L AND EXAMINATION OF PHARMACEUTICAL ... PARATIONS

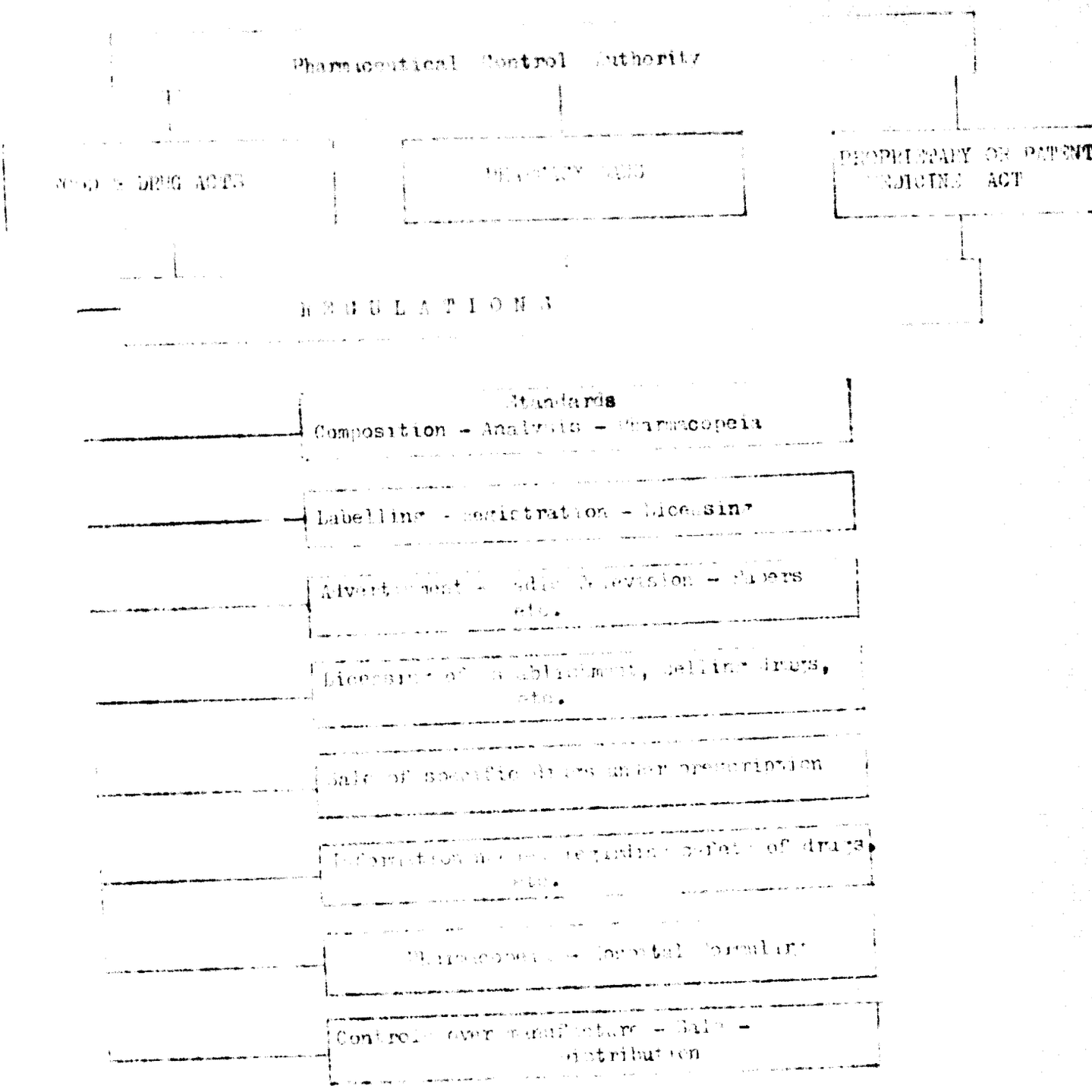


Figure 1

Scientific Education of Experts Responsible for Supervision of Manufacture and Control Operation

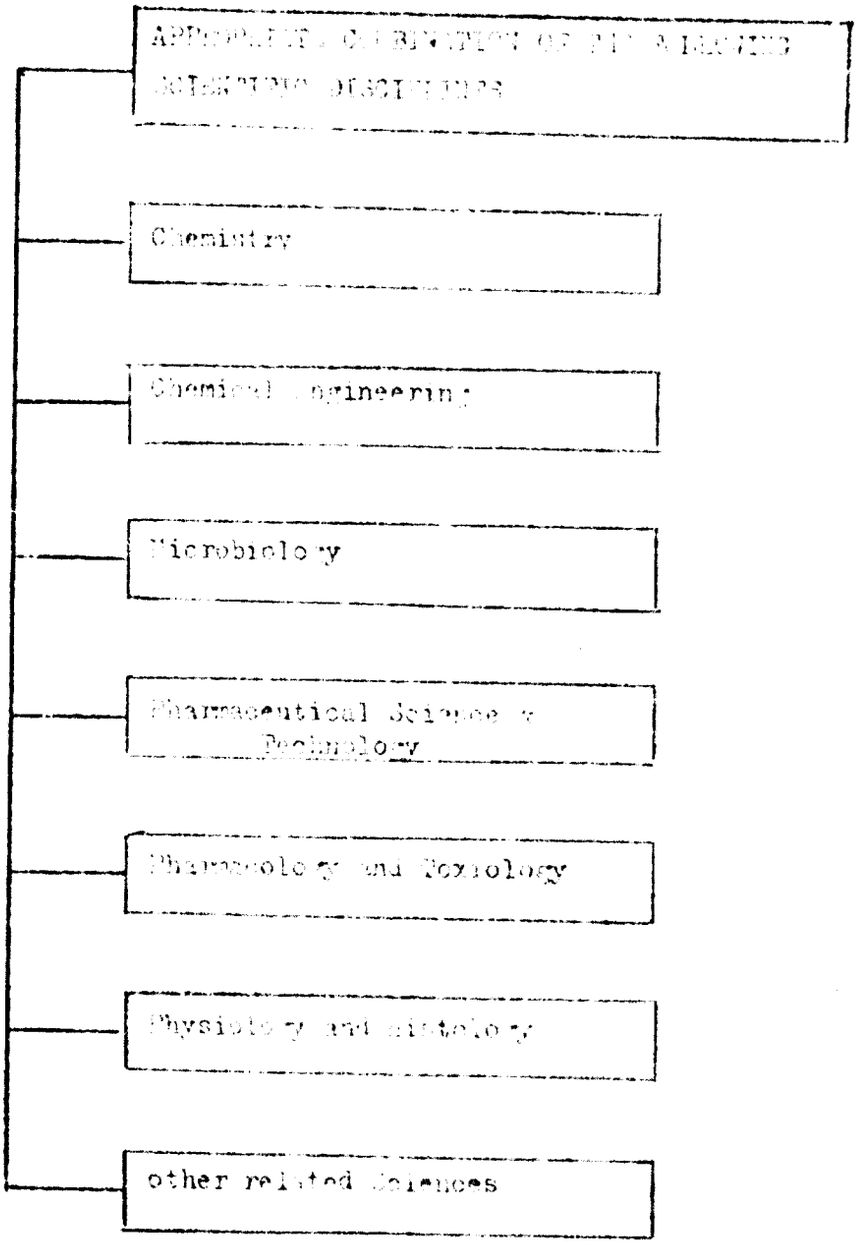


Figure 1

ORGANIZATION OF A PHARMACEUTICAL CONTROL LABORATORY

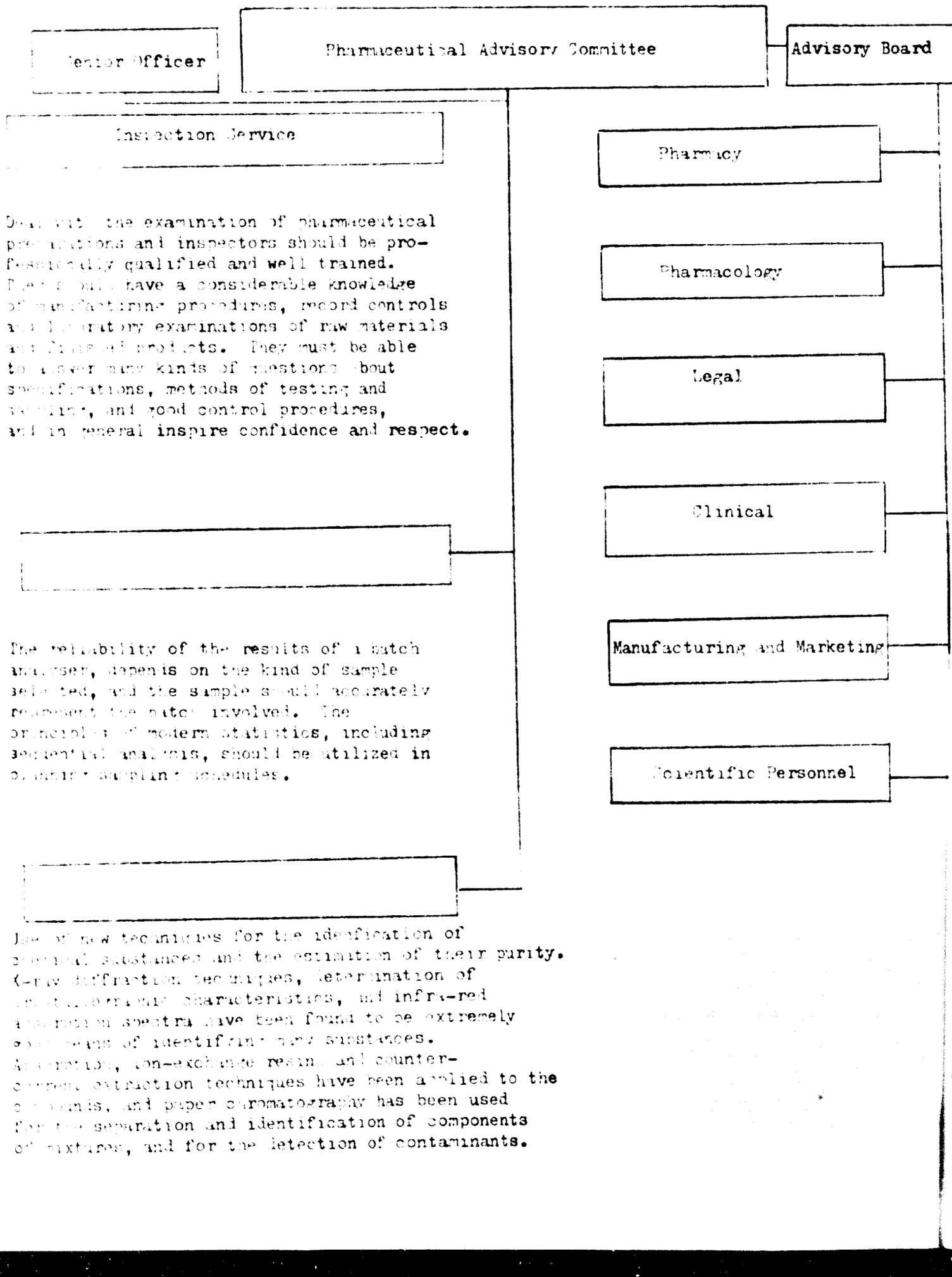
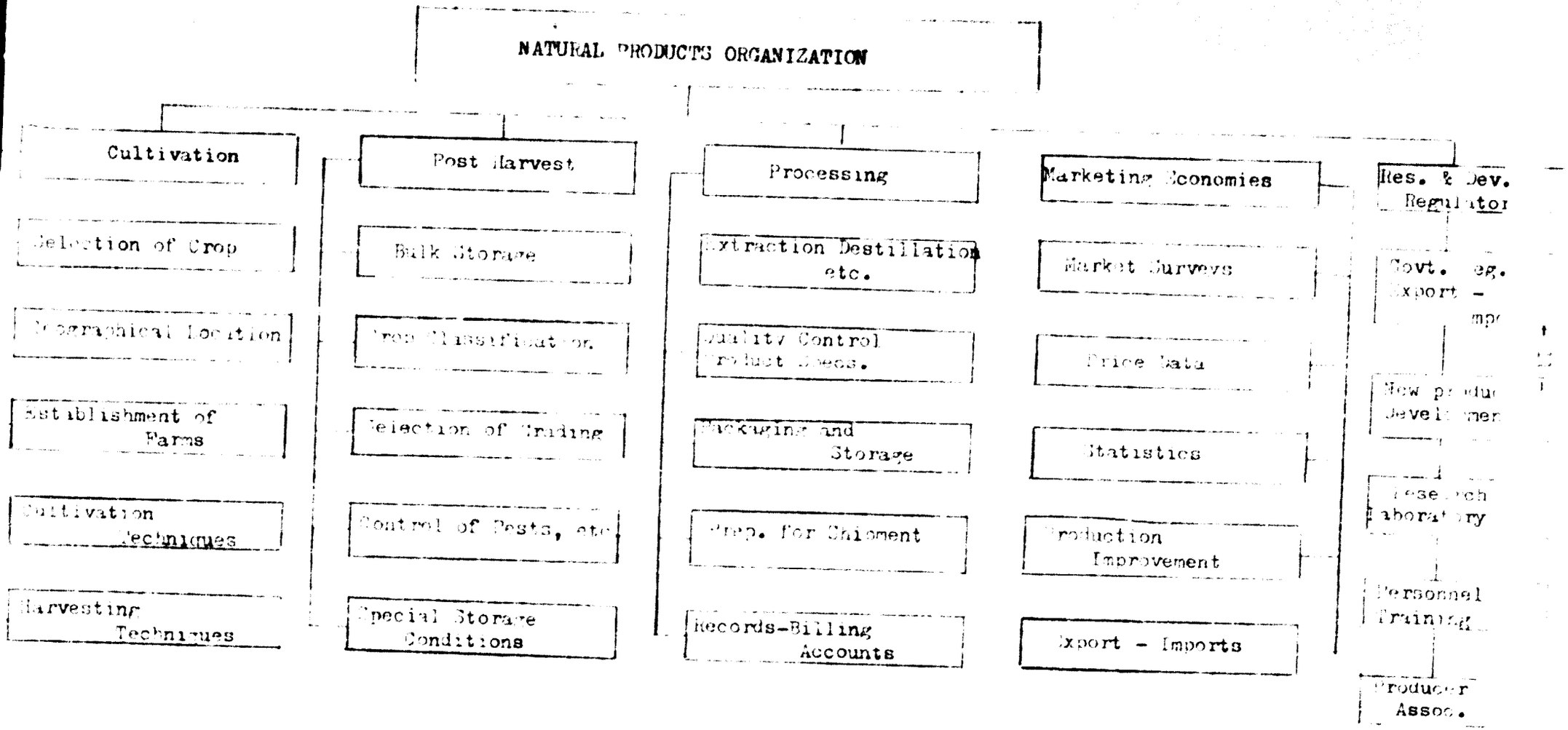


Figure 5


NATURAL PRODUCTS ORGANIZATION
Cultivation
Selection of Crop
Geographical Location
Establishment of Farms
Cultivation Techniques
Harvesting Techniques
Post Harvest
Bulk Storage
Tree Classification
Selection of Trading
Control of Pests, etc
Special Storage Conditions
Processing
Extraction Destillation etc.
Quality Control Product Specs.
Packaging and Storage
Prep. for Shipment
Records-Billing Accounts
Marketing Economies
Market Surveys
Price Data
Statistics
Production Improvement
Export - Imports
Res. & Dev.
Regulator
Govt. Reg.
Export -
Imp
New Product Development
Research Laboratory
Personnel Training
Producer Assoc.

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