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UNITED NATIONS INDUSTRIAL
DEVELOPMENT ORGANIZATION

INTERNATIONAL CONSULTATION MEETING*
IN THE FIELD OF ESTABLISHMENT AND DEVELOPMENT
OF PHARMACEUTICAL INDUSTRIES.

Report.

90130.

*This was not one of the Consultations called for in paragraph 61 (d) of the Lima Declaration and Plan of Action and should not be confused with any of the "Consultation Meetings" organized by UNIDO in response to that call.

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Explanatory notes

A full stop (.) is used to indicate decimals.

A comma (,) is used to distinguish thousands and millions.

The term "billion" signifies a thousand million.

References to "tons" are to metric tons, unless otherwise specified.

References to dollars (\$) are to United States dollars, unless otherwise stated.

The monetary unit in Hungary is the forint (Ft). During the period covered by the report, the value of the forint in relation to the United States dollar was \$US 1 = 20.44.

The following abbreviation is used in this report:

GMP Good manufacturing practices

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INTRODUCTION

From 17 to 29 November 1975 a "Technical Consultation on Establishment and Operation of Pharmaceutical Industry in Developing Countries" took place in Budapest, Hungary. The meeting was organized by the United Nations Industrial Development Organization (UNIDO) in co-operation with the Hungarian People's Republic and the Union of Hungarian Pharmaceutical Industry. Its purpose was to discuss the problems and requirements of planning and establishing pharmaceutical factories in developing countries, and to explore the possibility of co-operation among those countries for the promotion of their pharmaceutical industries.

RECOMMENDATIONS

The participants in the consultation meeting took note of the work of the Second General Conference of UNIDO and of its Declaration and Plan of Action. In particular, they paid special attention to the following stipulations of the documents referred to:

(a) In order to promote industrial development, a system of consultations within UNIDO should be established;

(b) The process of applied and scientific research, technological adaptation and innovation, industrial information as well as the elaboration of relevant policies adapted to the needs of the developing countries should be stimulated;

(c) The enterprises of developed countries should be encouraged to participate in investment projects of the developing countries;

(d) National plans concerning science and technology should be elaborated;

(e) Integral industries would give the developing countries the basis on which the building-up of technology will principally rely.

On the basis of the principles embodied in the foregoing stipulations, the participants sought to formulate a plan of action outlining the responsibilities that UNIDO should undertake in order to promote the establishment and development of the pharmaceutical industry in developing countries.

The participants proposed the inclusion in the plan of action of the following recommendations to UNIDO, UNIDO/WHO, the developing countries and the Hungarian Pharmaceutical Industry:

(a) UNIDO is requested:

- (i) To hold further technical consultations on the pharmaceutical industry, especially taking into account the technological aspects of finishing and bulk material production;
- (ii) To assist the developing countries in the preparation of national formulary and drugs acts;
- (iii) To prepare technical films on production, quality control, safety measures etc.;
- (iv) To organize a workshop for an animal laboratory for control and experimental work in pharmaceutical industry;
- (v) To promote the utilization of existing natural resources (plant and animal origin) needed for the production of pharmaceutical drugs in developing countries;

- (vi) To give priority to the assistance of countries which do not have a pharmaceutical industry;
 - (vii) To assist developing countries, wherever possible, in establishing plants for the further manufacture of bulk materials (from raw materials or intermediates);
 - (viii) To allocate more funds for organizing future meetings in order to enable more countries to participate;
 - (ix) To pay attention to supporting activities in the field of pharmaceutical industry, as the supporting activities are the major input to the promotion of this industry in developing countries. Operational activities should be discussed with UNIDO as a follow-up to these activities;
 - (x) To prepare an information booklet on pharmaceutical industry (premises) requirements, quality control etc.;
 - (xi) To have more regular contact with pharmaceutical industries in developing countries, if possible, by organizing meetings or by sending representatives to visit them;
- (b) UNIDO/WHO are requested:
- (i) To be instrumental in establishing an international institute for research and the development of drugs for tropical diseases (see annex I);
 - (ii) To provide documentation on manufacturing, technology and quality control of essential drugs used in developing countries;
- (c) Developing countries are requested:
- (i) To organize training programmes in the field of pharmaceutical industry on a regional basis among themselves. Governments of developing countries should co-operate to establish regional standards for drugs produced locally. It is recommended by UNIDO that the Ministry of Health of Mexico should assist and provide the methodology for establishing such standards (formulated drugs and raw materials);
- (d) The hungarian pharmaceutical industry is requested:
- (i) To train a larger number of technicians in its factories;
 - (ii) To establish industries in developing countries in co-operation with UNIDO or through bilateral assistance;
 - (iii) To facilitate the transfer of technology;
 - (iv) To promote research and studies to meet the needs of developing countries;
 - (v) To expand direct contacts within the industrial circle of developing countries;
 - (vi) To organize more meetings in co-operation with UNIDO.

In connection with the foregoing recommendations to the Hungarian Pharmaceutical Industry, it should be noted that the Hungarian authorities offered to undertake the following action:

- (a) To organize, in co-operation with UNIDO, meetings on veterinary and micro-bacteriological subjects, as well as further consultation meetings in the coming years;
- (b) To delegate experts to developing countries and to accept experts from developing countries for post-graduate training;
- (c) To exchange information on the pharmaceutical industry with developing countries.

Part one. Report of the Meeting

I. ORGANIZATION OF THE MEETING

The meeting was attended by 25 participants from 21 different nations, 23 of whom were assisted by UNIDO travel grants, while the remaining two, those from Nigeria and Mexico, travelled at government expense.

All participants had a strong scientific and technical background with experience in the pharmaceutical industry. All of them spoke and wrote English fluently.

A. Programme of activities

The programme of activities was organized as follows:

<u>Activity</u>	<u>Time spent (hours)</u>
Lectures	15
Technical discussions	25
Visits to pharmaceutical plants	10
Viewing industrial films	4
Opening and closing sessions	5
Round-table discussions of pharmaceutical projects	6
Presentation of background papers by participants	8
Panel discussions and case-work	5

All participants attended the same lectures and made the same plant visits. The participants were requested to describe their problems in production and quality control and to obtain advice from Hungarian experts in these fields or from the UNIDO representative, in order to find the best solutions to their problems. Whenever required, technical discussions were extended, and this was warmly welcomed by the participants.

Lectures

Lectures were given on the following subjects:

- (a) Tasks, production structure and several characteristic features of the pharmaceutical industry;

- (b) Conditions of establishment and development of pharmaceutical industries in developing countries;
- (c) Role and effectiveness of pharmaceutical research;
- (d) Problems of planning and siting of pharmaceutical factories;
- (e) Profitability of invested capital in the pharmaceutical industry;
- (f) Veterinary pharmaceuticals and long-term animal health programmes;
- (g) Protection of industrial property in the pharmaceutical industry;
- (h) Modern documentation forms in the pharmaceutical industry, including computerized information research;
- (i) Pesticides and the pharmaceutical industry;
- (j) Possibilities of training chemical engineers in the Hungarian People's Republic;
- (k) Training facilities for skilled workers and technicians in Hungary;
- (l) Social insurance, health services and furnishing the population with pharmaceuticals;
- (m) Epidemiological organization and methods of control of communicable diseases in Hungary;
- (n) Health and safety in the pharmaceutical industry;
- (o) Drug registration and regulatory drug control;
- (p) Tasks of quality control in the production of pharmaceuticals;
- (q) Demographic problems and family planning;
- (r) Feasible forms of co-operation between the pharmaceutical industries of the developing countries and of Hungary.

Plant visits

Two pharmaceutical industries in Budapest were visited by the participants, who were divided into three groups according to similarity of interests, in particular quality control, research and development, product sterilization requirements, and formulation and packaging of synthetic drugs. The following factories were visited: Chemical and Pharmaceutical Works Chinoin Ltd.; and Chemical Works of Gedeon Richter Ltd. After each visit, the Director of the factory and the chiefs and experts of different parts of the factory organized discussions with the participants and answered technical questions raised by them during the visit. These discussions at the plant level were very useful and of considerable practical value.

Technical films

Several technical films concerning the establishment of a pharmaceutical industry with reference to different departments, such as research and development, quality control and production, were shown at the Hungarian Chamber of Commerce in Budapest.

Documentation

At the opening session, the participants received a map and the following documentation: copies of the agenda and of all lectures to be presented by Hungarian experts; a copy of the document "UNIDO's Role in the Development of the Pharmaceutical Industry in Developing Countries"; copies of the UNIDO Newsletter; several brochures on industrial novelties and on the industrial plants to be visited; and tourist guides of Budapest.

At the end of the course, participants received copies of their colleagues' background information and project data sheets prepared by the UNIDO representative according to their needs.

B. Opening session

The Union of Hungarian Pharmaceutical Industry

The opening speech was delivered by the Vice-President of the Union of Hungarian Pharmaceutical Industry. He underlined the necessity of co-operation among developing countries in order to solve and identify their own problems relating to the pharmaceutical industry. He also emphasized that the Hungarian pharmaceutical industry, in co-operation with UNIDO or on a bilateral basis, would assist developing countries in all aspects of the pharmaceutical industry, such as the training of technicians and experts for production and quality control, the supply of equipment and machines, materials in bulk or intermediate form etc.

The Deputy Director of the Industrial Operations Division of UNIDO delivered a speech underlining the importance of the pharmaceutical industry and UNIDO's role in the development of this industry in developing countries.

Another opening speech by a UNIDO staff member on behalf of the organization emphasized the importance of developing the pharmaceutical industry in developing countries and the role of this industry in government health care systems. The attention of the participants was also drawn to the fact that, before a pharmaceutical industry can be established, the developing countries should have all the information they need concerning the requirements of, and the

correct way of planning, such an industry. This would help to prevent various problems and difficulties from arising. UNIDO hoped therefore that the meeting would assist the participants in learning more about the industry, its requirements and its planning.

Countries represented at the meeting, such as Ghana, India, Iran, Iraq, Nepal, Sri Lanka, Sudan and Tanzania already had programmes with UNIDO in the field of pharmaceutical industry. The status of these projects was discussed with the participants during the meeting.

Presentation of background papers

After the official working hours, the UNIDO representative organized sessions for the presentation of the participants' background papers. During these sessions it became clear that developing countries could solve many of their difficulties among themselves, and it was obvious that programmes of technical co-operation among developing countries could be very helpful in the development of pharmaceutical projects.

II. PHARMACEUTICAL INDUSTRY PROBLEMS IN DEVELOPING COUNTRIES

A. Establishment and operation

Several papers were read on the establishment and development of pharmaceutical industries. Two treated the items that have to be considered when establishing and siting; the subject of two further papers was the carrying into effect of actual investments; and two others reviewed the questions of cadre training and the provision of experts.

With regard to installation and siting, some of the problems requiring special attention are those of storage and transport, power supplies, and the basic production processes in relation to plant design.

Investment economics must also be carefully considered, in view of the sharp rise in costs of execution and machinery during the past 20 years.

Staff training is another question of vital importance to the pharmaceutical industry of the developing countries. Special training courses have been organized in co-operation with various international organizations, and efforts along these lines should be continued.

B. Fields of development

The second topic dealt with during the consultation meeting included some of the characteristic fields of industry development, such as those of pharmaceutical research, pharmaceutical patents and up-to-date documentation.

The years between 1935 and 1965 were a period of great progress in pharmaceutical research and development, largely as a result of the application of such disciplines as physics, chemistry, mathematics and biology to the solution of pharmacological problems. Further great advances in pharmaceutical technology are expected in future with the development of increasingly sophisticated instruments of research and analysis.

Patent protection is another important factor in the development of the pharmaceutical industry, since it helps to generate the substantial resources required to foster the production of new, original pharmaceutical preparations.

In a period of information explosion, the need for an efficient, up-to-date documentation system also becomes essential. In order to meet this need, the registration and compilation of pharmacopoeia must be organized either before the establishment of the pharmaceutical industry, or not later than the quality control of the drugs.

C. Public health

The establishment and the development of the pharmaceutical industry is in close connection with the quality of a country's sanitary conditions. Some important aspects of this group of questions were covered in several papers, with special emphasis on modern public health systems, epidemiological services, family planning policy and health protection regulations in the pharmaceutical industry.

D. Agriculture

The last group of questions covered during the course dealt with the connection between the pharmaceutical industry and agrochemistry. The relationship between the pharmaceutical industry and agriculture is due not only to veterinary medicine, but also to the fact that large-scale agriculture requires premixes for animal feed and modern pharmaceutical resources for the protection of production in ever-increasing quantities.

Part two. Summaries of papers presented to the Meeting

UNIDO and the establishment of pharmaceutical
industry sectors in developing countries

Secretariat of UNIDO

The pharmaceutical industry is a very important one involving many disciplines, including the scientific (pharmacology, biochemistry, quality and efficiency control), technological (synthesis, production, packaging, sterilization, fermentation), economic (marketing costs, pricing, advertising), educational (training, professional staffing), and legal (patents licensing, import and export restriction). Since some of these activities can be very sophisticated, and developing countries usually lack sufficient resources in the various disciplines, it is more practical for them to promote the advancement of a pharmaceutical industry through the growth of individual sectors.

UNIDO can assist developing countries by evaluating the domestic demand for pharmaceuticals, and recommending ways to improve the infrastructure needed to provide a viable basis for the industrialization of such sectors.

One basic task that must be carried out prior to the establishment of a pharmaceutical industry in a developing country is the preparation of a list of the essential drugs required, which will depend on the country's public health needs and patterns, and on the techno-economic aspects of the production of certain drugs, so that the country will become self-sufficient in the production of specific essential drugs selected from the large quantity of drugs available on the international market.

A list of essential drugs prepared for and imported by a particular country out of 2,000 registered drugs is given in annex II as an example. This list will obviously be drawn up according to the country's requirements.

Requirements of the foundation and development of
the pharmaceutical industry

P. Szekely

Year by year world pharmaceutical production is steadily increasing. Production doubles approximately every 5 years. In 1976, annual

production value amounted to \$40 billion, and by 1980 it may reach the figure of \$80 billion. Production and demand, on the one hand, and increased sanitary requirements, on the other, make it necessary for the developing countries to set up their own pharmaceutical industry. According to economic forecasts, developing countries will supply 18% of the world's production in the pharmaceutical industry by 1980. From the point of view of the pharmaceutical industry, developing countries may be classified into the following groups: countries where there is no pharmaceutical industry at all; countries in which finishing activities have developed, including wrapping etc.; countries in which pharmaceuticals are produced on the basis of foreign patents; and countries in which some industrialization has already started and production and development are in progress.

On the basis of their technical level and economic potential, developing countries must elaborate a strategy. Parallel with the development of the pharmaceutical industry, public health problems, such as registration, preventive vaccination, epidemic control, tuberculosis screening etc. also have to be solved.

Tasks, production, structure and several characteristic features of the pharmaceutical industry

B. Mezey

The structure of the pharmaceutical industry differs for differing countries throughout the world. From the point of view of finished products this divergence is not essential, and the technical level as well as the controlling system of the individual countries are approaching one another. Differences are, however, more substantial in the production of agents. In fact, the proportions of some lines of agent production, synthetic or biosynthetic, starting from vegetable and animal raw materials, may be different. With synthetic production the difference appears mainly in its vertical structure. This depends decisively on the development of the organic chemical industry in the respective countries. The structure of the pharmaceutical industry also depends on the share of research activity accounted for by original pharmaceutical agents and pharmaceutical preparations by the industry of the country concerned.

The most important characteristic properties of the pharmaceutical industry are as follows: its dynamic development is considerably faster than the average; product innovation is rapid, although in the last century this was slowed down by increasing requirements for safety and proof of efficiency.

Safety demands are equally prominent in the fields of research, development and production. The international character is stressed, and the importance of foreign trade and the international division of labour is increasing. Research is in the forefront, and the importance of industrial law is also growing.

Two tendencies may be observed in the pharmaceutical industry. The first is the concentration of production, with the number of producing companies decreasing and turnover of individual companies increasing. The second is the decrease in the number of pharmaceutical preparations in circulation in individual countries.

Pharmaceutical agents may be divided into two large groups. The first group contains the well-proven classical agents of long standing and produced in large volumes. The second group comprises agents of a smaller volume, of a shorter life span and of an uncertain future. The latter are more frequent in areas inadequately supplied with pharmaceutical products.

The task of the pharmaceutical industry is not merely of an economic nature, but first and foremost of a social and hygienic nature. Sanitary requirements must be met, at an acceptable and reasonable price and complying with the requirements of safety and efficiency. With this aim in mind, research and development activity must be stepped up. Significant investments are needed to ensure a speedy increase in the consumption of pharmaceutical products. These investments should be at a high technical level, taking advantage of the international division of labour. Countries with a highly developed pharmaceutical industry should assist the developing countries in the foundation and development of their own pharmaceutical industry.

In general, the first stage in the development of a country's pharmaceutical industry is the production of drugs from active agents. After that, in some cases, depending on the available resources, is the production of agents from vegetable and animal raw materials, followed by the realization, with synthetic pharmaceutical basic materials, of the last stages of the synthesis.

Finally, the training of experts has a decisive importance in the pharmaceutical industry.

Problems of settlement and projecting
of pharmaceutical plants

I. Szentpeteri

When establishing pharmaceutical plants questions of siting and designing have to be settled first. Siting requires careful consideration. It is important to start production as soon as possible. In numerous cases production is first centred on drugs, tablets and injections, and only afterwards on raw materials.

The following items have to be kept in mind in the designing and siting of pharmaceutical factories:

- (a) Basic production process in relation to the design of the pharmaceutical plant;
- (b) Storage, transport and conveyance of materials;
- (c) Water and steam supply, distribution and drainage;
- (d) Electricity supply;
- (e) Maintenance of research and control departments;
- (f) Buildings for social care and administration etc.

Economic efficiency calculations of investment
in the pharmaceutical industry

A. Jakabos

Design is followed by execution. In this connection, the economics of investment is a question of vital importance. Here the rate of return must be given very careful consideration, as investment costs have been steadily increasing. In about 20 years the costs of execution have doubled, and those of machinery increased by approximately 50%, while designing costs have remained relatively low.

Specialist training possibilities for the
pharmaceutical industry

T. Meisel

In the establishment of a pharmaceutical industry the solution of the question of the supply of trained staff has vital importance. This is generally

connected with industrialization. Developing countries have to carry out their own training on a large scale. In Hungary, with a population of 10 million, 7%-8% of the inhabitants are attending universities and high schools, and 80% - 90% of the students obtain state grants of some kind. The training of chemical engineers takes place in Budapest and at Veszprem, and 350 students graduate from these universities every year. The Chemical Department of the Budapest Technical University has 13 faculties, the oldest being that of general chemistry, which was founded in 1846, and the most recent that of chemical machinery, set up in 1965. The Institute of Organic Chemical Technology, where the training of pharmaceutical chemists takes place, exists since 1939. Special problems of the pharmaceutical industry are made known in the course of workshop practice, which lasts for one month.

Training facilities for skilled workers and technicians
for the pharmaceutical industry

T. Horvath

In the developing countries, as in Hungary, the training of experts has to be specially organized. Some of the international organizations, such as FAO and UNESCO, and in particular UNIDO, are making a special effort to organize these courses.

Importance and efficiency of pharmaceutical research

L. Pillich

This paper deals with the efficiency of pharmaceutical research and summarizes experience gained in the course of 40 years. Some decades ago, for instance, hormones were extracted exclusively from animal organs, e.g. for producing 5-6 grams of oestrone, 1,000 litres of urine was needed from a pregnant mare. At present, tons of a series of steroids is produced from easily available raw materials, and in some cases even a total synthesis has been achieved. These results are due to a considerable extent to the development of instrumental analytics, chromatography, spectrophotometry, micro-analytics etc. They have led to the sudden development of pharmaceutical

technologies and of large-scale, electronic-controlled, continuous processes. The 30 years between 1935 and 1965 represent the "golden age" of the pharmaceutical industry. In these decades more new drugs were brought into circulation than in all preceding history. As a result of pharmaceutical research, new disciplines such as physics, chemistry, mathematics, biology and pharmacology all contributed to the development of the pharmaceutical industry.

Research has become and keeps growing more and more complex. The Hungarian Pharmaceutical Industry looks back upon 100 years of tradition which has significantly helped its development.

Industrial law protection in the pharmaceutical industry

T. Palagyi

If the pharmaceutical industry is to place new, original preparations on the market, 20%-25% of the turnover has to be expended on development. This represents such a large amount that without patent protection it could not be made available.

Patent protection is different in each country. The first international agreement was signed in 1883 in Paris. It was later amended several times, the last being in 1967 in Stockholm. In the pharmaceutical industry it is generally the process which is patented. However, in the developed countries, product patents are used with growing frequency. In some countries the new field of application of a known compound may also be patented. Economic development is fostered by applying brand and trade names.

Modern documentation forms in the pharmaceutical industry and computerized information

I. Kosa

At present we live in a period of information explosion. The largest chemical reference journal records 14,000 periodicals and 530,000 communications. It should also be kept in mind that the amount of information doubles every eight years on the average. A completely new system therefore has to be set up. In 1958 experts of several nations worked out the Ringdoc system,

which processes 40,000 publications annually. Ringdoc operates on the basis of the chemical structure code. Some code-free systems are also known. Data is computer-processed, and registration of patents is carried out in a system called Pharmdoc, based on similar principles, and abstracting 120-140 patents per week. With the help of the computer and the magnetic tapes delivered by the firm, the required chemical structure, therapeutic effect, group of compounds etc. can be quickly traced.

Prior to the establishment of the pharmaceutical industry, or at the latest parallel with the quality control of drugs, registration and the compilation of the pharmacopoeia have to be organized, since only in this way can public health requirements be met.

Organization for drug registration and governmental quality control of pharmaceuticals

I. Bayer

Registration of drugs has been carried out in Hungary since 1927. For this purpose, the National Institute of Pharmacy was established and vested with legal authority. It has 12 departments: biology, registration, analytics, good manufacturing practices (GMP) control, pharmacology etc. When introducing new drugs, one must select from the "materia medica" those drugs which are important from the point of view of public health. For purposes of evaluation, WHO principles are regarded as normative in matters of chemistry, toxicology, pharmacology, stability etc. Production of drugs is based on GMP principles. In the factories, the quality controlling departments - analytics, biology, microbiology etc. - are under the managers' direct control. However, the distributing network for drugs also has its laboratories. Official drug control is a governmental function, and international co-operation, especially with WHO, is extremely important in this field.

Tasks of quality control in the production of pharmaceuticals

J. Zombori

In Hungary the pharmaceutical industry maintains a central controlling laboratory carrying out numerous tests, and the factories themselves also carry

out examinations. Testing of homogeneity, identity, uniform active ingredient content, purity etc. is carried out according to the prescriptions of the pharmacopoeia. The quality of auxiliary and filling materials is also prescribed by the pharmacopoeia, e.g. starch is treated in detail. The countries of the Council for Mutual Economic Assistance (CMEA) publish the "Compendium Medicamentorum" indicating the most important test methods.

Social insurance, health service and furnishing the
population with pharmaceuticals

Gy. Gonda

Circumstances in Hungary may serve as a model for the organization of modern public health systems. The public health system in Hungary has a long tradition of service for the improvement of general health standards. The first health insurance institution was founded in 1905 for miners, and since 1972 free medical and hospital care, sanatorium facilities, thermal baths and dental care have been basic civil rights enjoyed by all, with only 15% of the price of drugs being paid by the insured.

Working places with at least 100 employees have an organized medical service. For 10,000 inhabitants there are 85 hospital beds; by 1990 this will increase to 96, with 50 beds for acute cases, and 46 for chronic ones.

Mothers after childbirth receive 20 weeks' paid leave, which in some justified cases can be extended by a further four weeks. The old-age pension system is also highly developed. The retiring age is 55 years for women and 60 years for men. Since 1950 the supply of drugs is under State control, and as from January 1977 pharmacies allow standard 15% refunds on medicines.

Anti-epidemic measures and organizations

K. Solt

An important part of modern public health systems is the network for epidemiological services. In Hungary epidemics have been systematically fought since 1876, and the present disease-control system, although officially launched in 1975, has been functioning for 20 years.

The Station for Public Health and Epidemics (KÖJAL) has three departments: epidemics, laboratory and the group responsible for disinfection and the eradication of rats and insects. The network of this organization covers the whole country. The experts join the organization after four years' practice. In Hungary protective inoculations are also within the scope of the epidemiological and public health programme. The compulsory protective inoculation of babies goes back over 100 years, having been in force since 1876. Inoculation against diphtheria has been compulsory since 1938; against the bacillus Calmette-Guérin (BCG) and whooping cough, since 1953; against tetanus, since 1954, and against polio, since 1959.

In connection with public health, the Conference dealt with two questions closely related to the pharmaceutical industry, namely population and family planning, which are the subjects of the following paper.

Demographic problems and family planning considerations

Gy. Fekete

Both the number of the world's inhabitants and the population growth rate are steadily increasing - within 2000 years the increase has been about one hundredfold. In the eighteenth century it amounted to 0.3%, in the 19th century, 0.6%, and at present it is about 2%. The growth rate of the population is highest in the developing countries, where it is two to three times higher than in the developed countries.

The goal of family planning is to optimize population growth by either the promotion or limitation of births. The most up-to-date means of limitation is hormonal birth control, the theoretical and practical foundations of which were laid in the early 1950s. Four different medical hormonal birth control methods are known. Contraceptives in the form of combined progesterone- and gestagen-containing tablets have to be taken for 21 days, and their efficiency is 100%. Then there are sequential drugs, including two kinds of tablets: those with an oestrogenic effect which have to be taken for 12-15 days, and the combined ones which are taken for 6-9 days. They have the advantage of introducing a smaller amount of active agents into the body. The continuous method differs from those previously mentioned, since its effects are revealed through a chemical-biological mechanism, and are less certain. Drugs administered through injections have a long-lasting effect, but medical opinion recommends careful handling because of their possibly harmful side-effects.

Labour health and accident prevention in the pharmaceutical industry

M. Grossmann

In the pharmaceutical industry observance of the health protection regulations is also very important. During production care has to be taken to avoid damages due to inhalation, for example of materials having a hormonal effect, or possible industrial diseases of the skin, including normal chemical damages or contact with caustic materials. This, however, does not apply only to the pharmaceutical industry. In the pharmaceutical industry special stress has to be laid on hygienics, and a means should be provided for the workers to observe hygienic requirements. The GMP programme contains these basic requirements.

Veterinary pharmaceuticals and long-term animal health programmes

T. Vaghy

Modern large-scale animal breeding requires a number of pharmaceutical products - coccidiostatics, anthelmintics etc. - which all serve to maintain a healthy animal stock. Increased meat production can be achieved by applying modern premixes and feed mixtures. Feeds containing antibiotics can only be used if they do not induce resistance.

The pharmaceutical industry also produces modern fattening products, thus increasing the efficiency of agriculture.

Pesticides and the pharmaceutical industry

T. Pfliegel

At present almost all large pharmaceutical factories produce pesticides, since diversification of production has proven economically advantageous. The syntheses of pesticides is analogous to that of pharmaceuticals, and their toxicology is also similar; experience in the pharmaceutical industry may therefore be applied in the production of pesticides.

Annex I

DRAFT PROPOSAL FOR ESTABLISHING A RESEARCH INSTITUTE FOR
TROPICAL DISEASES IN AFRICA OR ASIA AND LATIN AMERICA

A. Objectives

The Research Institute would have the following objectives:

- (a) To carry out research in the field of tropical diseases;
- (b) To discover new and more economical drugs for diseases which are common in tropical regions;
- (c) To identify the causes of epidemics due to biological, chemical or other agents, and suggest preventive measures to Government bodies, WHO, UNIDO and other agencies;
- (d) To promote the manufacture and supply of some of the vaccines and sera or other drugs which are not available on the local market;
- (e) To train technicians from developing countries in the field of research and development in diseases of tropical regions.

B. Location

The Research Institute should be located in a tropical country, preferably in Asia or Africa. The location should be selected with the following factors in mind:

- (a) Need for medical colleges/hospitals;
- (b) Importance of a good technical library;
- (c) Existence of other technical services, such as instrumentation etc.;
- (d) Availability of technical personnel.

Approximately 100 acres of land would be sufficient.

C. Organization

The Research Institute should have the following units:

Medicinal chemistry, chemical analysis
Pilot plant
Bacteriology/parasitology

Microbiology
Virology
Clinical medicine
Biochemistry/biophysics
Pharmacology
Toxicology
Instrumentation (analytical)
Animal house
Library

D. Manpower

The staff of the Research Institute should include 50 scientists in various fields, assisted by 150 technicians. It will be necessary to have another 100 employees for the administration and other departments.

It was suggested that at least one top scientist in each field should be appointed and given authority to build up his own department.

The salaries offered would depend on the location of the Research Institute and the background of the scientists.

Annex II

EXAMPLE OF ESSENTIAL DRUG LIST

A. Tablets and capsules

1	Cap.	Chloramphenicol	250 mg	500,000	Antibioticum
2	Cap.	Tetracycline	250 mg	400,000	Antibioticum
3	Tbl.	Clioquinole	500 mg	600,000	Intestinal-asepticum
4	Tbl.	Nitrofurantcin		100,000	Chemotherapeuticum urinare
5	Tbl.	Ferrous Sulphate		300,000	Antianemicum
6	Tbl.	Digoxine		500,000	Cardiotonicum
6	Tbl.	Acidum Folicum		50,000	Antianemicum
8	Tbl.	Acidum Acetylosalicylicum		2,000,000	Analgeticum
9	Tbl.	Phenobarbital		100,000	Antiepilepticum, hypnoticum
10	Tbl.	Chlorpromazine		160,000	Neurolepticum
11	Tbl.	Prednisolone		100,000	Antiallergicum
12	Tbl.	Hexa-Vitamin		1,000,000	Vitamin
13	Tbl.	Vitamin B complex		500,000	Vitamin
14	Tbl.	Vitamin C		500,000	Vitamin
15	Tbl.	Sulphadimidine		300,000	Chemotherapeuticum
16	Tbl.	Metronidazole oral		500,000	Trichomonacid, amoebiacid
	Tbl.	Metronidazole vaginal		200,000	Trichomonacid, amoebiacid
17	Tbl.	Hydrochlorothiazide		200,000	Salidiureticum Antihypertonicum
18	Tbl.	Reserpine		200,000	Antihypertonicum
19	Tbl.	Glyceryltrinitrate		50,000	Cardiovasodilatans
20	Tbl.	Piperazine		200,000	Anthelminthicum
21	Tbl.	Tetrachlorethylene		100,000	Anthelminthicum
22	Tbl.	Tolbutamide		500,000	Antidiabeticum
23	Tbl.	Thioacetazon + Isoniazid		100,000	Tuberculostraticum
24	Gran.	Para-aminosalicylic acid		400,000	Tuberculostraticum
25	Tbl.	Isoniazid		1,000,000	Tuberculostraticum
26	Tbl.	Dapsone 50 mg		60,000	Chemotherapeuticum for leprosy

27	Tbl.	Chloroquine Phosphate 250 mg	100,000	Malariachemotherapeuticum
28	Tbl.	Primaquine Phosphate	50,000	Malariachemotherapeuticum
29	Tbl.	Antiasthmatic (Ephedrine + (Theophylline + Phenobarbital)	300,000	Antiasthmaticum
30	Tbl.	Oral contraceptive (Norgestrel + Ethylestradiol)	2,500,000	Contraceptive
31	Tbl.	Methyldopa 250 mg	200,000	Antihypertonicum
32	Cap.	Ampicilline 250 mg	100,000	Antibioticum
33	Tbl.	Griseofulvin	50,000	Antibioticum
34	Tbl.	Oxyphenylbutazone	100,000	Antirheumaticum
35	Tbl.	Diazepam	150,000	Psychopharmacon
36	Tbl.	Trifluoperazine 5 mg	50,000	Neurolepticum
37	Tbl.	Chlomipramine Hydrochloride 10 mg	50,000	Antidepressivum
38	Tbl.	Haloperidol	50,000	Neurolepticum
39	Tbl.	Carbamazepine	30,000	Antiepilepticum
40	Tbl.	Oxytetracycline	500,000	Antibioticum
41	Tbl.	Levamisole	300,000	Anthelminticum
42	Tbl.	Codeine compound	500,000	Cough sedativum

B. Injections

1	Inj.	Penicillin	100,000	Antibioticum
2	Inj.	Streptomycin	200,000	Antibioticum
3	Inj.	Emetine Hydrochloride	40,000	Amoebicid
4	Inj.	Atropine	20,000	Spasmolyticum
5	Inj.	Epinephrine	20,000	Sympathicomimeticum
6	Inj.	Dextrosaline	5,000,000	Hydratation
7	Inj.	Furosemide	100,000	Salidiureticum
8	Inj.	Morphine Sulphate	10,000	Analgeticum
9	Inj.	Pethidine	20,000	Analgeticum
10	Inj.	Hydrocortisone	40,000	Antiphlogisticum
11	Inj.	Chlorphenamine	50,000	Antihistaminicum
12	Inj.	Benzylpenicillin	500,000	Antibioticum
13	Inj.	Aminophylline	60,000	Diureticum, cardiotonicum
14	Inj.	Oxytocin	10,000	Accouchement
15	Inj.	Chlorpromazine Hydrochloride	50,000	Neurolepticum

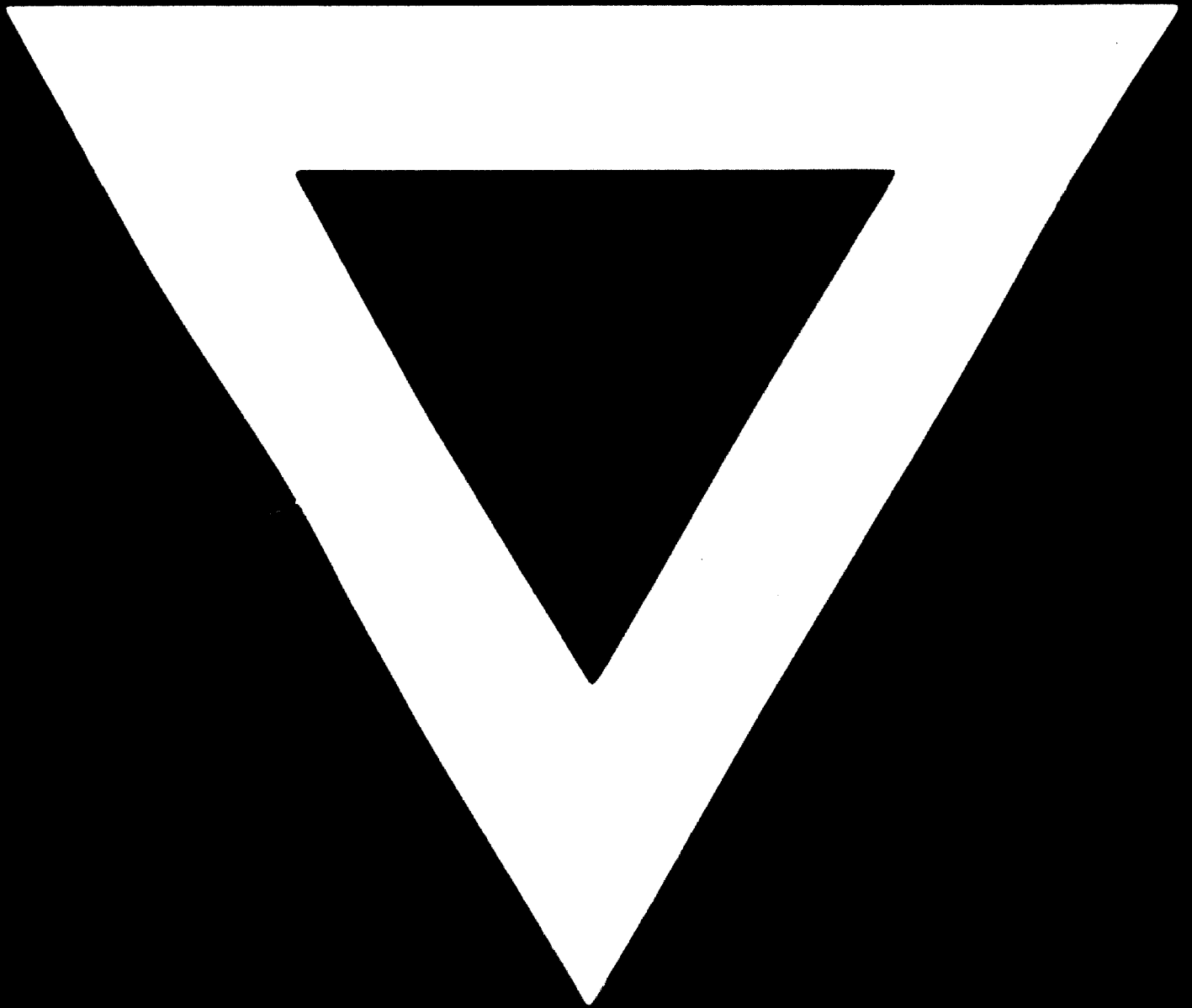
16	Inj.	Pentobarbital-Sodium	5,000	Hypnoticum
17	Inj.	Lidocaine	40,000	Anaestheticum
18	Inj.	Anti-Tetanus Serum, 40,000 units	500	Treatment of tetanus
19	Inj.	Rehydratation fluid	5,000 l	Treatment of cholera
20	Inj.	Glucose 25%, 250 ml	2,000	Perfusion
21	Inj.	Distilled water	1,000,000	Injection treatment
22	Inj.	Phenobarbital-sodium	100,000	Antiepilepticum
23	Inj.	Diphtheria-Pertussis-Tetanus vaccine	50,000 doses	Prevention
24	Inj.	Tetanus toxoid	50,000 doses	
25	Inj.	Anti-diphtheria serum, 20,000 units	500	Treatment of diphtheria
26	Inj.	Insulin Plain	10,000	Pancreas Hormon
	Inj.	Insulin Lente	10,000	Pancreas Hormon
27		Oral Polio Vaccine	70,000 doses	Prevention
28	Inj.	Ampicilline	50,000	Antibioticum
29	Inj.	Chloramphenicolsuccinat-sodium	20,000	Antibioticum
30	Inj.	Glucose 5%	10,000 l	Perfusion
31	Inj.	Solution Saline Isotonic	10,000 l	Perfusion
32	Inj.	Novamidazophen	100,000	Analgeticum
33	Inj.	Butylscopolaminbromide	60,000	Spasmolyticum
34	Inj.	Diazepam		Psychopharmacon
35	Inj.	Strophanthin	50,000	Cardiotonicum
36	Inj.	Vitamin - B (12)	50,000	Vitamin
37	Inj.	Calcium Gluconate	100,000	
38	Inj.	Papaverine	100,000	Spasmolyticum

C. Galenical drugs (syrups, ointments, mixtures, eye drops)

1	Homatropine eye drops	300 l	Mydriaticum
2	Eserine Sulphate eye drops	1,000 l	Parasympathicomimeticum
3	Benzylium Benzoicum emulsion	2,000 l	Scabiosum
4	Acid Carbollic	5 tons	Antisepticum
5	Lysol Creoline	2 tons	Antisepticum
6	Syrup Piperazine	300 kgs	Anthelminticum
7	Tincture Iodine	1,000 l	Antisepticum

8	Extractum Belladonna	2,000 l	Tonicum
9	Chloramphenical	1,000 kg	Antibioticum
10	Tetracycline ointment 1%, 5 gm	10,000 tubes	Antibioticum
11	Syrup Noscapine	1,000 kg	Cough-Sedativum
12	Tetracycline Suspension	1,000 kg	Antibioticum
13	Formaline 40%	500 l	Antisepticum
14	Formaldehyde	10,000	Antisepticum
15	Potassium Permanganate	500 kg	Antisepticum
16	Diethyl Ether	500 kg	Anaestheticum
17	Cetrimonium Bromide lotion	30 kg	Antisepticum
18	Ethyl Chloride spray	5,000	Anaestheticum
19	Boric acid-Alcohol-Glycerol drops		
20	Krushens salt		
21	Neomycine and streptomycine suspension		Antibioticum
22	Syrup Antihystaminic		Antihystaminicum
23	Tetracycline and Neomycine ointment		Antibioticum
24	Heparine ointment		Antiphlogisticum
25	Neomycin and Corticoid Ovules		Antiphlogisticum
26	Tetracycline Ovules		Antiphlogisticum
27	Neomycin and Prednisolone eye ointment		Antiphlogisticum
28	Tetracycline powder		Antiphlogisticum

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