OCCASION

This publication has been made available to the public on the occasion of the 50th anniversary of the United Nations Industrial Development Organisation.

DISCLAIMER

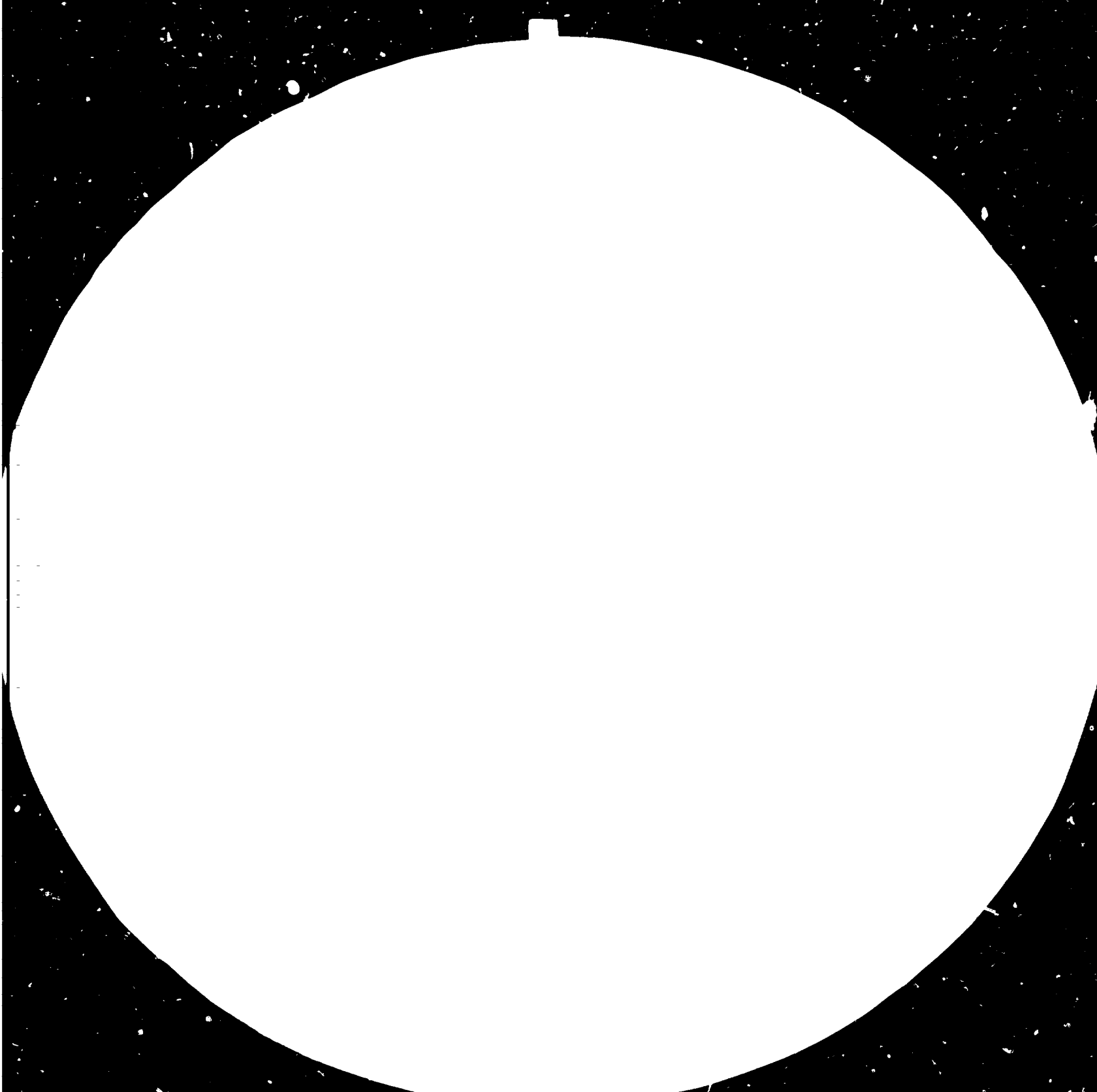
FAIR USE POLICY

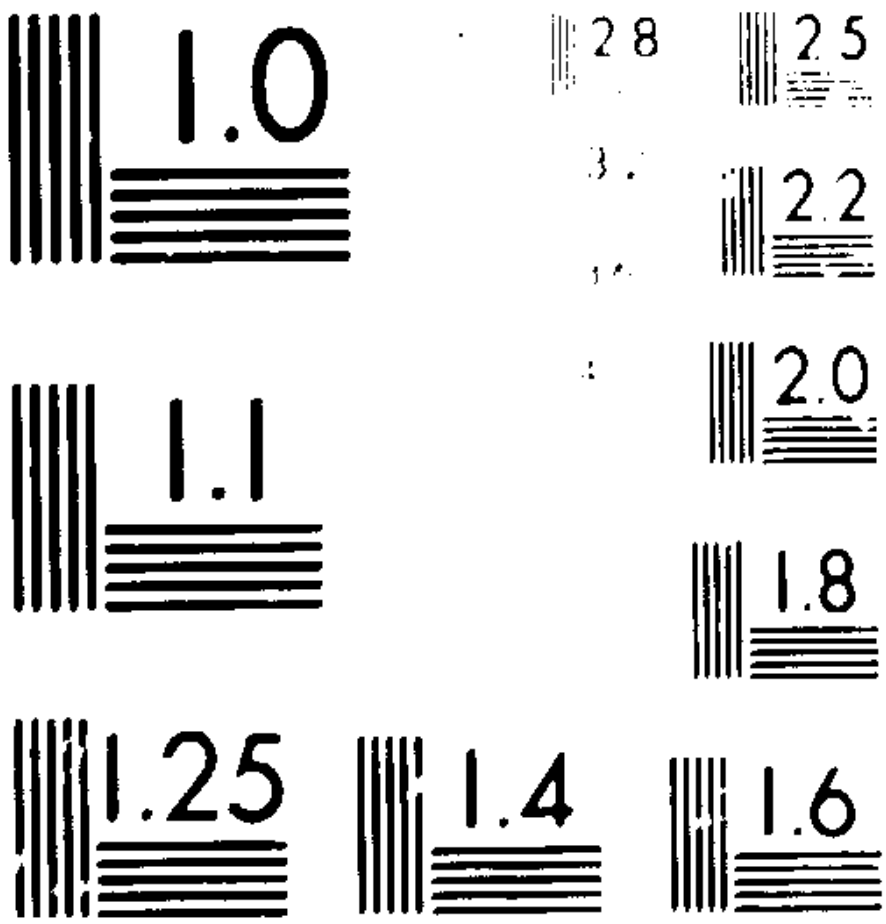
CONTACT

Please contact publications@unido.org for further information concerning UNIDO publications.

For more information about UNIDO, please visit us at www.unido.org

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION
Vienna International Centre, P.O. Box 300, 1400 Vienna, Austria
Tel: (+43-1) 26026-0 · www.unido.org · unido@unido.org





12794-E

Distr.
LIMITED

ID/WG.393/12/Rev. 1
2 November 1983

ENGLISH

United Nations Industrial Development Organization

Second Consultation on the
Pharmaceutical Industry
Budapest, Hungary, 21-25 November 1983

THE MANUFACTURE OF VACCINES IN DEVELOPING COUNTRIES

Issue paper*

prepared by

the UNIDO Secretariat

1120

* This document has been reproduced without formal editing

V.83-63524

TABLE OF CONTENTS

1. Background

At the preparatory meetings, to select issues for discussion at the First Consultation on the Pharmaceutical Industry, several participants stressed the important role that medicinal plants and biologicals should play in developing countries, since these countries possess suitable raw material resources which are either underutilized or neglected (see progress report ID/WG.393-5, para 3).

At the Global Preparatory Meeting for Consultations on the Pharmaceutical Industry in April 1980, some participants felt that within biologicals, vaccines and sera should also be included in the list of issues for the First Consultation. Since the technology to produce classical vaccines was generally available, however, the meeting considered that focusing the discussions on all the three selected priority issues would be more practical to achieve results.

Two main documents have been prepared in this connection: namely a background paper on the aspects of transfer of technology for "The manufacture of vaccines in developing countries", and a reference study on "Prospects for production of vaccines and other immunizing agents in developing countries".

Since vaccines are a part of the larger field of biologicals, their production technology and infrastructure may be applied to other biological products. Annexure A presents a classification of the biological products.

To complement the range of biological products of wider use in preventive medicine, the following products have been identified in addition to vaccines:

a) the production of animal sera, in particular antivenom sera;
b) the human specific immunoglobulins;
c) the production of diagnostics, in particular through bio-technology methods.

2. The Documents

A. Transfer of technology for the manufacture of vaccines in developing countries

The disease pattern of developing countries differs considerably from that of developed countries. In particular, in the least developed countries, infectious diseases are among the leading causes of death and disability, each affecting over 5 million children annually. To expand health coverage to the majority of the population, drug-based curative medicine is insufficient and expensive, but necessary. Hence, efforts should be concentrated on strengthening preventive medicine for prevention is a more economical approach to control infectious diseases than curative measures, and it is the only way to prevent disability.

Within the preventice medicine, vaccines represent the active immunization products. In general there are two main groups of vaccines, namely the classical and the improved or modern vaccines, which have been developed in two different ways. The technology of classical vaccines was developed in the past 60 years, more in an empiric way then by systematic research and development work. The technology of improved, modern, and sophisticated vaccines is being developed through a systematic research and development approach. Annexure B gives a list of the most important classical and improved and/or recently developed modern vaccines.

Since the incidence of the most dangerous communicable diseases of children is very low in developed countries, there is a tendency towards decreasing interest in production of classical vaccines in those countries. If a significant decrease in classical vaccine output occurred in developed countries, many developing countries would be rendered defenceless against these communicable diseases, for they lack domestic production facilities for those vaccines.

Technology to produce classical vaccines is becoming readily available and only a modest investment is required to set up plants for local production in developing countries. To assimilate this technology, however, a long manufacturing experience is needed for numerous difficulties arise due to the often ill-defined empiric manufacturing process, which is the case, for example, in the production of pertussis vaccine. Although a number of developing countries in Asia and Latin America produce some classical vaccines, Africa, where diseases preventable by vaccination are the most prevalent, has only one producer.

Technology to manufacture improved and recently developed sophisticated vaccines of high purity is difficult to acquire for developing countries. These technologies are usually covered under patents; often there are one or few licensors and these are expensive.

To assimilate the technology to produce any modern vaccines a higher level of technical infrastructure is required. Hence, the more advanced developing countries seem to be in a better position to undertake this production and help ensure the adequate availability of these products in all developing countries.

B. Prospects for production of vaccines and other immunizing agents in developing countries

This reference study presents an overall view of the area of immunizing agents and stresses the need for a new approach to the problems of production of immunizing agents in developing countries.

3. The Issue

The documents stress the need to produce both classical and modern vaccines in developing countries, considering that the decreasing interest of developed countries to produce the former could render developing countries defenceless against the prevailing major communicable diseases, while no capabilities have been built up for the latter at all.

The biologicals, and in particular vaccines, are essential components of preventive medicine against communicable diseases. Since UNIDO has a specific role to give assistance in the development of industrial production of biologicals, participants at the Second Consultation are invited:

i) to review and recommend a list of biological products for production in developing countries;

ii) to advise UNIDO on steps to be taken for an effective transfer of technology to manufacture classical vaccines;

iii) to advise UNIDO on a stage by stage approach to obtain technology to manufacture modern vaccines in developing countries;

iv) to advise UNIDO on steps to be taken concerning the domestic production of biologicals other than vaccines.

ANNEXURE A

CLASSIFICATION OF BIOLOGICALS

1. Vaccines (for active immunization)

1.1 Vaccines for universal immunization

- BCG vaccine
- diphtheria - pertussis - tetanus vaccine
- diphtheria - tetanus vaccine
- measles vaccine
- poliomyelitis vaccine
- tetanus vaccine

1.2 Vaccines for specific groups of individuals

- hepatitis B vaccine
- influenza vaccine
- meningococcal vaccine
- pneumococcal vaccine
- rabies vaccine
- typhoid vaccine
- yellow fever faccine

2. Sera and immunoglobulins (for passive immunization)

- anti-D immunoglobulin (human)
- antirabies hyperimmune serum
- antivenom sera
- diphtheria antitoxin
- immunoglobulin (human, normal)
- tetanus antitoxin

3. Blood products

3.1 Human plasma fractions

- albumin
- coagulation factors: VIII concentrate
  IX complex concentrates
- immunoglobulins: normal
  specific

3.2 Blood cell concentrates

- red cell concentrate
- platelet concentrate
- leukocyte concentrate

4. Allergens

4.1 Diagnostic allergens

pollen allergens
microbial allergens: viral
bacterial: tuberculin
fungal
venoms
mite allergens

4.2 Desensitizing vaccines

mixed pollen vaccines
mite vaccine

5. Diagnostics

5.1 Diagnostics for blood grouping

blood grouping sera ABO
anti-D typing serum

5.2 Diagnostics for bacterial agglutination

agglutinable suspensions
agglutinating sera

5.3 Immunochemical diagnostics

precipitating sera and immunoglobulins
fluorescein-labelled reagents
enzyme-labelled reagents
radioisotope-labelled reagents

5.4 Lues diagnostics

Cardiolipin antigen
Haemolysin
Complement

Note: Different groups of biologicals are sometimes overlapping due to a comprehensiveness in the groupings. For example, immunoglobulins appear in group 2 and group 3.1.

ANNEXURE B

LIST OF THE MOST IMPORTANT CLASSICAL AND IMPROVED OR RECENTLY DEVELOPED VACCINES

CLASSICAL VACCINES

1. BCG vaccine against tuberculosis
2. DPT vaccine against diphtheria, whooping cough and tetanus
3. Tetanus toxoid
4. Diphtheria-Tetanus toxoid
5. Typhoid vaccine
6. Cholera vaccine
7. Oral and inactivated poliomyelitis vaccine
8. Live measles vaccine
9. Yellow fever vaccine
   etc.

IMPROVED, RECENTLY DEVELOPED AND FUTURE VACCINES

1. Rabies vaccine produced in cell cultures
2. Improved poliomyelitis vaccine for parenteral use
3. Hepatitis B vaccine
4. Meningococcal vaccine
5. Pneumococcal polysaccharide vaccine
6. Oral live galactose - epimerase - less typhoid vaccine
   etc.