to establish a list of drugs which are considered essential to meet the health needs of the country, the purchase of the required quantity of such drugs through a central agency and the implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

In countries having reached a sufficient level of socioeconomic development, it is essential that governments encourage local or regional pharmaceutical production whenever feasible and implement adequate legislation in order to ensure that manufacturing facilities and quality controls are at least equivalent to the WHO recommendations. WHO is collaborating with UNIDO in this respect.

From the public health point of view, it is undesirable that an excessive number of pharmaceutical products, particularly identical products, are marketed. Appropriate registration procedures may enable health authorities to select the best drugs introduced on the market and to ensure that adequate information is provided to the health professions on the uses and prices of drugs.

On the basis of the information contained in this report and of the discussions and decisions of the Executive Board, particularly resolution EB55.R21, the Organization’s activities on prophylactic and therapeutic substances will place particular emphasis on the following measures:

1. To assist countries in the further development and implementation of national policies and programmes in drug research, production, regulatory control, storage, distribution and the monitoring of drug utilization.

2. To assist countries in the procurement, at reasonable cost, of essential drugs of established quality for their national health care systems, particularly programmes for deprived populations, such as primary health care programmes, and in the establishment of local or regional production of such drugs wherever feasible.

3. To assist countries in the education and training of scientific and technical manpower for drug research, evaluation, control and distribution, and in the improvement of education of the health professions and the public in the proper use of drugs.

In addition to giving new emphasis to assistance to countries in this programme area, activities of a worldwide character will be further developed to raise the standard of drugs and to ensure the availability of safe and efficacious drugs. The main objectives are:

1. To establish and promote international standards for safe and effective prophylactic and therapeutic substances, together with guidelines for their evaluation, regulation and production control.

2. To develop and adapt the international exchange of information on drugs, including systems for monitoring of adverse reactions through coordination of national efforts, in order to ensure the safest possible use of drugs.

3. To promote international cooperation in the production and distribution of existing essential drugs, and in research on and development of new and more effective products in response to world health needs, and particularly for the control of diseases prevalent in the developing countries.

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Annex 14

UTILIZATION AND SUPPLY OF HUMAN BLOOD AND BLOOD PRODUCTS

Information Provided by the Director-General

It was brought to the attention of WHO by the League of Red Cross Societies and members of some WHO Expert Advisory Panels that commercial firms are obtaining blood or plasma from paid donors in developing countries in order to produce blood derivatives for sale in their own countries or for export.

Most of the plasma is obtained by plasmapheresis. In this procedure whole blood is withdrawn from the donor into anticoagulant and centrifuged, and the plasma is separated from the red cells. The red cells are then transfused back into the donor (single plasmapheresis). The procedure may, however, be repeated during the same session (so-called “double plasmapheresis”), when 500-600 ml of plasma are

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1 See resolution WHA28.72.
removed from the donor. In some centres single or double plasmapheresis may be repeated up to several times per week on the same donor.

It appears that this practice started about 10 years ago in Central and South America and has more recently spread to Asia and Africa. Some countries have already taken legislative measures to forbid or control the export of human blood and blood derivatives.

As a result of this information, WHO, in 1973, made inquiries through the regional offices and some members of its Expert Advisory Panels to find out the extent of this commerce and the possible dangers for the health of donors and recipients. Later the same year WHO and the League of Red Cross Societies held a preliminary joint consultation to discuss the problem. It was concluded that although the available evidence seemed to confirm an extensive trade in human blood and its derivatives in many countries, the evidence was as yet inadequate to be presented to the health authorities of Member States because it consisted mainly of views of individuals rather than of official confirmation from governments.

In order to acquire official and more detailed information on these commercial undertakings, in particular their extent and any legislation enacted in this field, the Organization in 1974 sent out a questionnaire to the health authorities of 17 selected countries of which 12 replied. These replies are summarized as follows:

<table>
<thead>
<tr>
<th>Number of replies</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Countries having received requests from firms to set up plasmapheresis centres</td>
<td>11</td>
</tr>
<tr>
<td>Existence of commercial plasmapheresis</td>
<td>5</td>
</tr>
<tr>
<td>Legislation regarding export of blood and blood derivatives</td>
<td>4</td>
</tr>
<tr>
<td>Importation of blood derivatives</td>
<td>8</td>
</tr>
</tbody>
</table>

Following this, a second joint consultation was held by WHO and the League of Red Cross Societies in December 1974 to consider the new information obtained and make further recommendations. The group carefully studied resolution XVIII adopted at the XXII International Conference of the Red Cross in Teheran, 1973, which

"...affirms that a service based on voluntary blood donation, motivated by humanitarian principles, is the safest and most effective way of supplying blood needs,

urges the Governments of all nations to adopt the highest standards in providing a safe blood service to their citizens, and to formulate those standards on the concept of non-remunerated blood donation, recommends to each National Society and its Government that they undertake a strong combined effort to attain the humanitarian objectives of a total national blood service based on the broad voluntary participation of the people”,

and fully endorsed the principle of voluntary donation of blood.

The consultants drew attention to the following points:

1. Most of the plasma is obtained by plasmapheresis from members of the community in return for remuneration and is used to prepare derivatives such as albumin, immunoglobulin and concentrated coagulation factors as well as in vitro diagnostic reagents and quality control sera.

2. Commercial plasmapheresis in developing countries seems to carry high risks for undernourished plasma donors and may result in a deficiency of proteins or other essential plasma components and lead to the impairment of the body’s natural defence mechanisms; it is also accompanied by an inevitable small loss of red cells and, when repeated frequently, might provoke iron deficiency and anaemia. Compensation by a post-donation meal rich in proteins, iron and vitamins is, in the opinion of the consultants as well as members of the WHO Expert Advisory Panel on Nutrition, not sufficient to compensate for the loss of plasma in the undernourished.

3. The sale of blood might become the principal source of income for certain people, particularly those dependent on alcohol and drugs, who are attracted by the remuneration.

4. For the recipients of at least some of the plasma derivatives, e.g., coagulation factors, it has been established that there is a higher risk of transmission of diseases, particularly hepatitis, when the plasma has been obtained from paid rather than from voluntary donors.

5. The existence of commercial centres for bleeding paid donors could interfere with all efforts of a country to establish and operate an efficient national blood transfusion service based on voluntary donations. Not only may the total number of voluntary donors become insufficient, but also certain valuable donors with rare blood groups and antibodies of diagnostic importance are attracted by offers of payment by commercial centres and therefore are not available to national blood transfusion services.
6. It is not easy to obtain detailed information on these commercial operations. However, from the answers provided by health authorities and from information available to the consultants and to National Red Cross Societies it appears that the practice of commercial plasmapheresis is widespread.

The reason for the commercial firms seeking plasma abroad is financial. Thus one litre of plasma may be obtained for US $2.00 to 4.00 in some developing countries while it would cost US $20.00 to 40.00 or more in some of the developed countries.

7. The poorer people, who can, for health reasons, least afford to part with their blood, are encouraged to give blood for the benefit of the wealthier populations. Where this is associated with remuneration for blood donation, pressures are created on human beings to accept practices which in themselves could be dangerous to health. The lack of knowledge of the donors regarding the health risks involved in repeated plasmapheresis creates doubts as to whether their informed consent has actually been obtained.

8. Less developed countries provide blood to those that are wealthier to facilitate production of blood derivatives, which are mainly used in developed nations because of their high cost and the more advanced facilities for medical treatment.¹

9. In many countries legislation governing the operation of blood transfusion services and related aspects, including plasmapheresis, is inadequate or is wholly lacking.

10. Because of the health hazards and ethical problems involved in the trade of blood components mainly obtained by plasmapheresis on a commercial basis, it was felt that these facts should be brought to the immediate attention of the World Health Assembly.

Annex 15

PROMOTION OF NATIONAL HEALTH SERVICES
RELATING TO PRIMARY HEALTH CARE

REPORT BY THE DIRECTOR-GENERAL

[A28/9—18 April 1975]

CONTENTS

I. Introduction .......................... 112
II. Statement of the problem .......... 113
III. Primary health care approach .... 114
IV. Required national action ........... 116
V. WHO’s programme in primary health care 117

I. Introduction

The Twenty-seventh World Health Assembly, in resolution WHA27.44, called on the World Health Organization to concentrate its efforts in order to assist governments to direct their health service programmes towards their major health objectives, with priority being given to the rapid and effective development of the health delivery system for underserved populations. This same resolution requested the Director-General to report upon the steps which could be undertaken by WHO to further the implementation of this and the related resolutions WHA23.61, WHA25.17, WHA26.35 and WHA26.43. Because of its relevance, resolution WHA20.53 has also been taken into account.

In response to these resolutions the Director-General prepared a report to the fifty-fifth session of the Executive Board entitled "Promotion of national health services". A full debate on this report led to the adoption of resolution EB55.R16, which requested the Director-General to prepare a further report on this subject for presentation to the Twenty-eighth World Health Assembly. This further report reflects (a) presentations to and discussions by the Executive Board; (b) consultations with Member States (regional offices were visited in

¹ The inequalities inherent in this situation must result in that unequal development in the promotion of health which is rejected by the preamble to the WHO Constitution and indeed by the first Article of the Universal Declaration of Human Rights, which states that "All human beings are born free and equal in rights...".

² See resolution WHA28.88.