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SOME ASPECTS OF THE PRODUCTION, DISTRIBUTION AND CLINICAL TESTING OF CONTRACEPTIVES IN DEVELOPING COUNTRIES

THE ROLE OF WHO [1]

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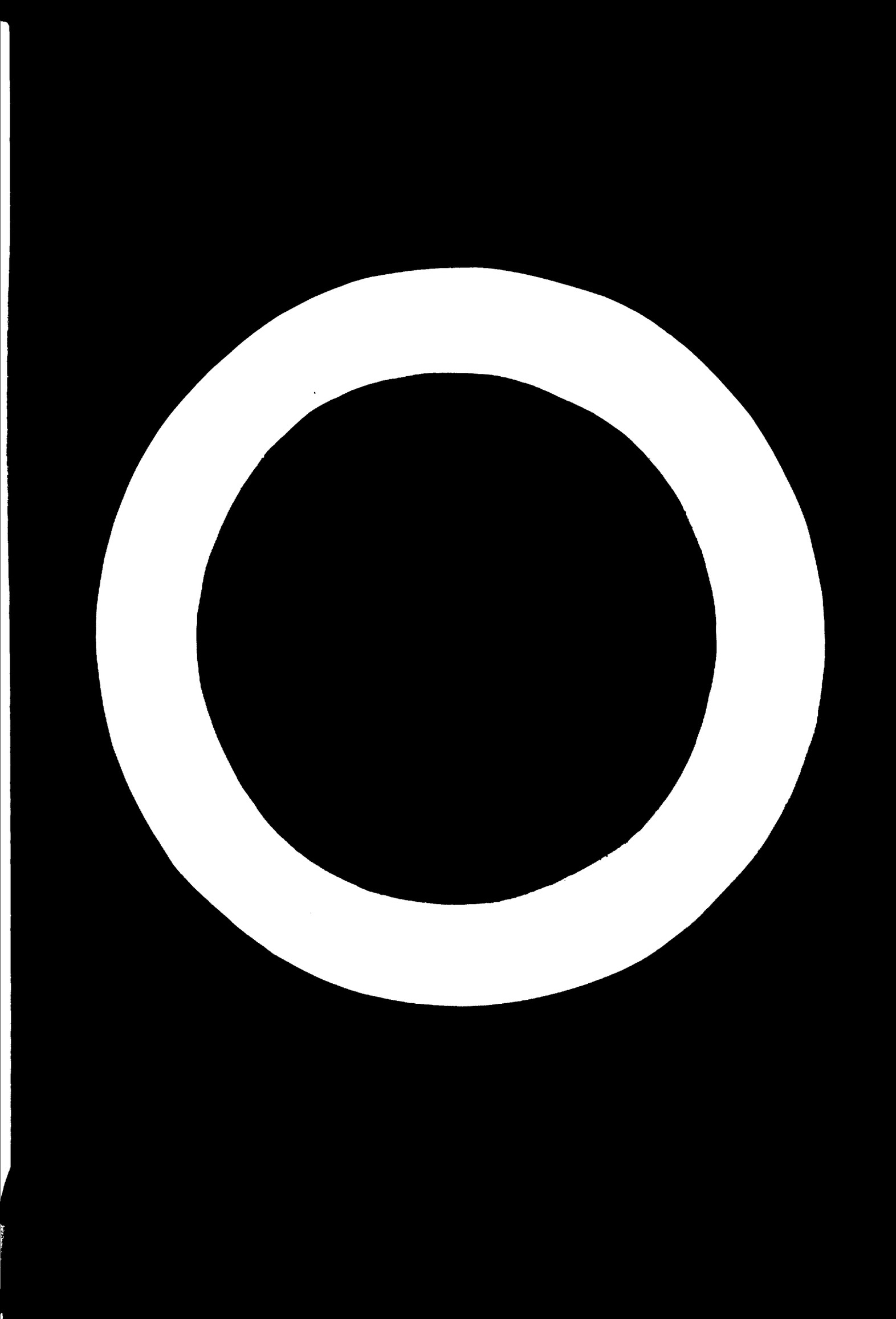
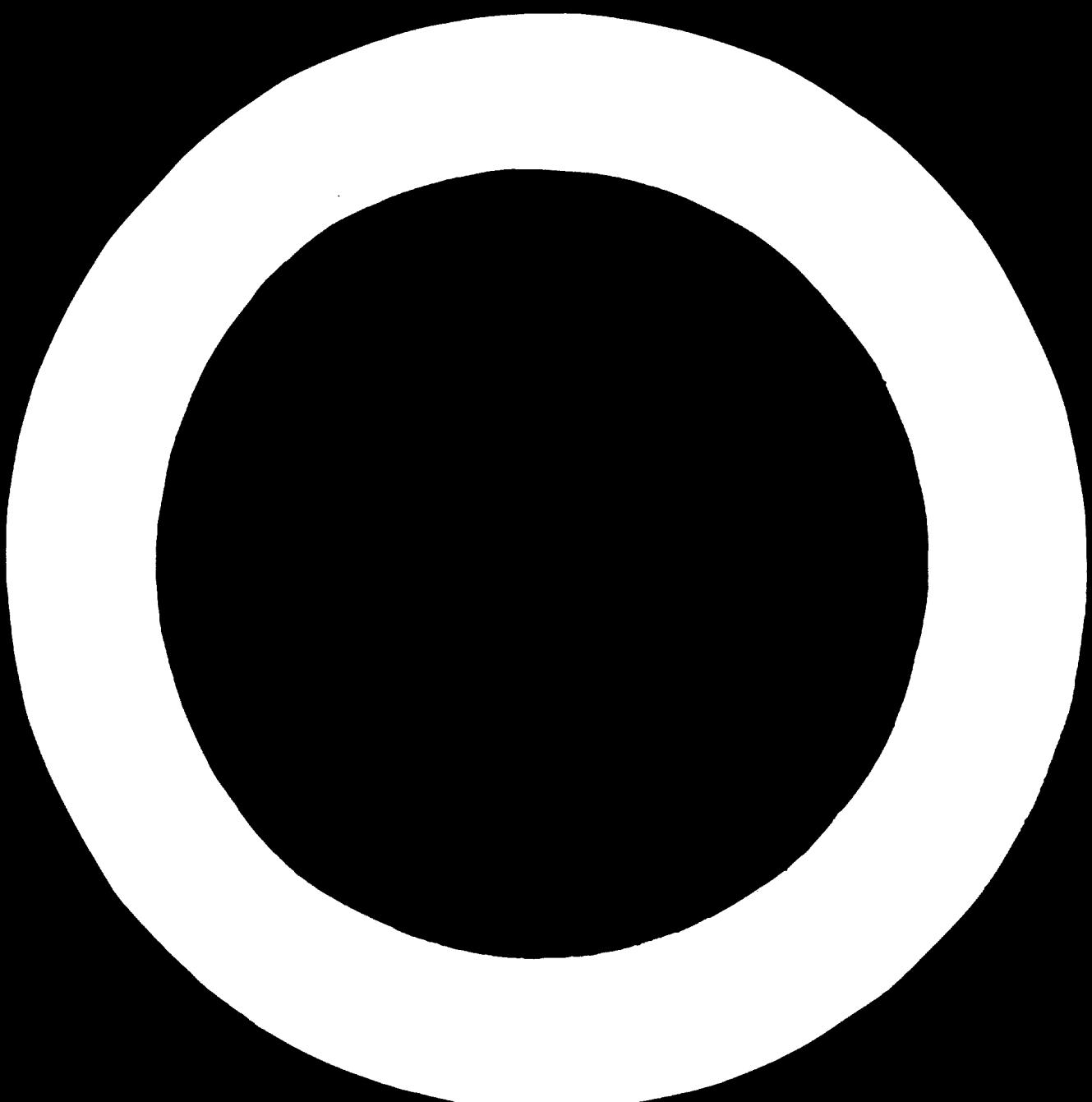
1/ The views and opinions expressed in this paper are those of the consultant and do not necessarily reflect the views of the Secretariat of UNIDO.





The broad headings, under which the various facets of WHO assistance to the production, distribution and testing of contraceptives in clinical countries falls, are as follows:

(a) Advisory services. This includes upon request assistance to governments regarding characteristics of fertility agents and on their health service implications, and advice regarding purchase of contraceptives, quality control and research developments taking place.

(b) Assistance to governments in purchasing or production of contraceptives. This could be when the government is purchasing contraceptives with its own funds or United Nations funds.

(c) Assistance to national family planning programmes with respect to the use and distribution of contraceptives.

(d) Organization of clinical trials and surveillance programmes with new contraceptive agents and also training personnel to carry out these trials. This includes a collaborative global network of clinical trial centres and establishment of a WHO Research Team in this field.

(e) Support of research in reproductive biomedicine aimed at production of new contraceptive agents. Besides the usual mechanism of grants, contracts and consultant assistance, an expanded programme of research in reproductive biomedicine is now beginning.

(f) Documentation on contraceptive agents. This includes references on on all contraceptives used, lists of contraceptives marketed in some countries, the pharmacological, toxicological and clinical trial work carried out by pharmaceutical houses with their products and the health and new drug regulations in different countries.

Production and distribution of contraceptives

WHO collects information about the experience of countries with contraceptives of various types. WHO provides this information in a number of ways. Firstly, it has a reference section in which there are up-to-date reports on contraceptive drugs and devices, including information about the pharmacology and toxicology of all contraceptive drugs on the market, and details of legislation in different countries concerned with these drugs; this information is made available on request. Secondly, it continuously reviews developments in the field

of fertility regulation, partly by convening meetings of experts, and partly by more informal consultations. The information that results is published in the technical reports of the World Health Organization, copies of which are widely distributed. Examples of the many technical reports that directly concern the subject of contraceptives are those on hormonal steroids in contraception, on the intrauterine device and on developments in fertility control. Another service which WHO renders is the immediate dissemination of reports of side-effects of contraceptives or of the withdrawal from use of a contraceptive in any country; one example of this is the report from the United Kingdom in 1970 that oral contraceptives containing high doses of estrogen were more likely to cause thromboembolism than those with lower doses. Such knowledge may enable a country to avoid investing in large quantities of a drug which has been recently shown to be unsatisfactory in use elsewhere.

When a contraceptive has been chosen for manufacture in a country, it is necessary to lay down standards by which its quality can be controlled. In some cases standards already exist, such as those contained in the monographs in the International Pharmacopeia and its supplements. But if no standards are available, WHO often provides them. This it does by obtaining and making known those standards which may already have been adopted by a country or an organization or by calling a meeting of experts to advise on what the standards should be. In addition, WHO organizes seminars and courses in methods of quality control.

WHO can often be of assistance in the distribution of contraceptives particularly through its newly instituted Maternity-Centred Programme, under which centres have already been set up or planned in Ceylon, Ecuador, Egypt, Indonesia, Iran, Iraq, Pakistan, the Philippines, Turkey and others. These centres should be excellent places from which to organize the distribution of contraceptives and instruction of their use.

Recent examples of WHO's activity in this field include assistance with the bulk purchase of steroids for oral contraceptive manufacture in Egypt; and the shipment of free gifts of oral contraceptives and intrauterine devices.

Clinical testing of contraceptives

This is naturally essential before a new contraceptive can be adopted for use on a large scale. But it is also highly desirable when a contraceptive which is already satisfactorily in use in one population, is proposed for use in another. The second population may react in an

entirely different and unexpected way; the contraceptive method may not work so well, it may not be acceptable, or it may produce different side-effects. A possible example of the last is the report that some oral contraceptives cause thromboembolism in Western peoples but do not do so in the East. Such differences cannot be predicted. They can be detected, if they exist, only by clinical testing, and WHO is therefore anxious to encourage this and to give it support. The organization has held successful inter-regional training courses in the methods of clinical trials of fertility regulating agents, in Delhi and Teheran. It sponsored last month in Oxford a Seminar on the surveillance of side-effects in the use of contraceptives, in which members of eighteen different countries took part. It also provides grants for the training of investigators in this field and for the training of clinical pharmacologists who are such important contributors to trials of this kind. WHO has supported trials of such contraceptive methods as long-acting injectable drugs, and several types of intrauterine devices.

A new development in this area has been the decision for WHO to establish a Research Team for the Clinical Evaluation of Fertility Regulating Agents at a medical school in the South-East Asian Region where WHO and national scientists will carry out work in this field. The team will have both laboratory and clinical facilities, and will consist of a pharmacologist, an obstetrician, an epidemiologist and an endocrinologist. Experts in other disciplines will be invited to participate in the activities of the team from time to time.

Recent technical reports concerned with clinical testing issued by WHO include those on the principles for the clinical evaluation of drugs and on clinical pharmacology - its scope, organization and training.

Research

In such a rapidly developing field as contraceptives, it is not enough to be content with present knowledge; one must search for more effective, safer, cheaper contraceptive methods, and for ways in which these methods can be made more convenient and acceptable to those who use them. For this reason, WHO lays particular emphasis on research in these fields, and this is reflected in the fact that its funds made available for research in human reproduction have increased from US$ 30,000 annually in 1963 to about US$ 4.5 million at the present time. Until very recently WHO has not itself undertaken research, but has encouraged and assisted that

undertaken by others in a number of ways. It supports, by fellowships and grants, scientists from developing countries who wish to study at established centres of research and arrange exchange visits between centres; it gives grants for the purchase of equipment and materials for use in research; it sends, at the request of member states, consultants who may spend up to 12 months in a country, establishing methods of or advising on plans for research on contraceptives - in 1971 consultants have visited Egypt, Iran, Pakistan and Turkey; it commissions, under contract, certain specific pieces of research; and it sponsors or assists meetings devoted to research topics - for example the meeting at Stockholm earlier this year, at which research on prostaglandins as a method of birth control was considered and discussed.

In these and many other ways, WHO has sought to give help and encouragement to research on contraceptives in many countries. Moreover, as an international organization, which is not confined by the boundaries between States, it has a special part to play. It is able to arrange for experts from all parts of the world to meet and discuss subjects of research into contraception, and to make available the results of their deliberations. An example of such a meeting is the one held at Geneva early this year - the control of male fertility - which made recommendations about the strategy which should be adopted for research in this field. It can also help to organize inter-regional collaborative enterprises as the Expanded Programme of Research, Development and Research Training.

This major programme is receiving financial support from a number of governments and a private foundation. It is the result of a year's study to determine how best to implement WHO's mandate to increase understanding of human reproductive processes including fertility control. Plans for the programme were drawn up following numerous consultations with leading scientists and with 69 research institutions in 23 countries. The programme will use a number of mechanisms to reach its objectives.

1. <u>WHO Research and Training Centres</u>

Several existing multidisciplinary research centres in different regions will be selected and provided with support to expand their programmes of research and research training in human reproduction. This will help to create a number of research groups with the necessary critical mass of scientific talent to achieve significant advances.

2. WHO Clinical Research Centres A worldwide network of clinical centres will be established as part of the programme. It will undertake collaborative clinical studies of new and existing fertility regulating agents. This network will be the first truly international mechanism for undertaking clinical trials simultaneously in a number of countries.

3. WHO Task Forces They will be organised to promote collaborative research directed towards specific objectives in the field of fertility regulation.

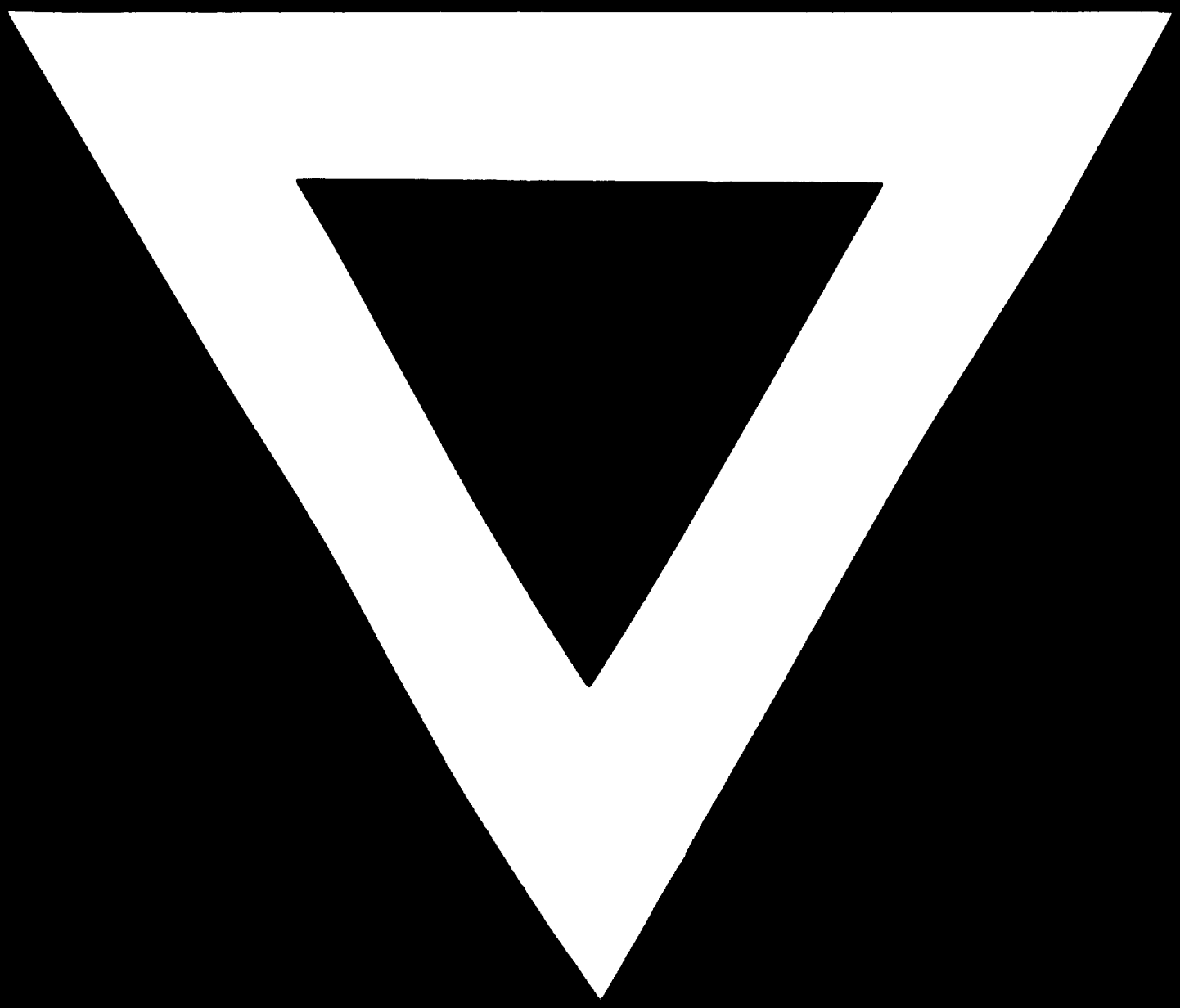
4. WHO International Documentation Centre The WHO documentation centre will compile and maintain a complete file of all published material on the biomedical aspects of reproduction.

5. A number of other WHO activities will also be expanded, including grants to scientists and institutions for support of research in priority areas, and the provision of essential supplies and equipment to collaborating institutions.

An international group of outstanding scientists is being established to advise WHO on research priorities and the allocation of resources.

The WHO programme is to harness the talents of scientists in many countries in an international effort to develop new approaches to the regulation of human fertility.

In summary, the WHO programme with respect to contraceptives is many-faceted and with the recent initiation of two large-scale programmes - the Maternity-Centred Family Planning Programmes and the Expanded Programme for Research, Development and Research Training - WHO should be a major contributor in the field of contraceptive development, clinical testing and field use.



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