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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

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POSSIBILITIES AND IMPOSSIBILITIES OF PRODUCTION, MARKETING AND DISTRIBUTION OF ORAL CONTRACEPTIVES IN DEVELOPING COUNTRIES [1]

by

D.H.J. Hannema
Regional Manager for Africa,
Australasia, Japan and South East Asia
Organon International

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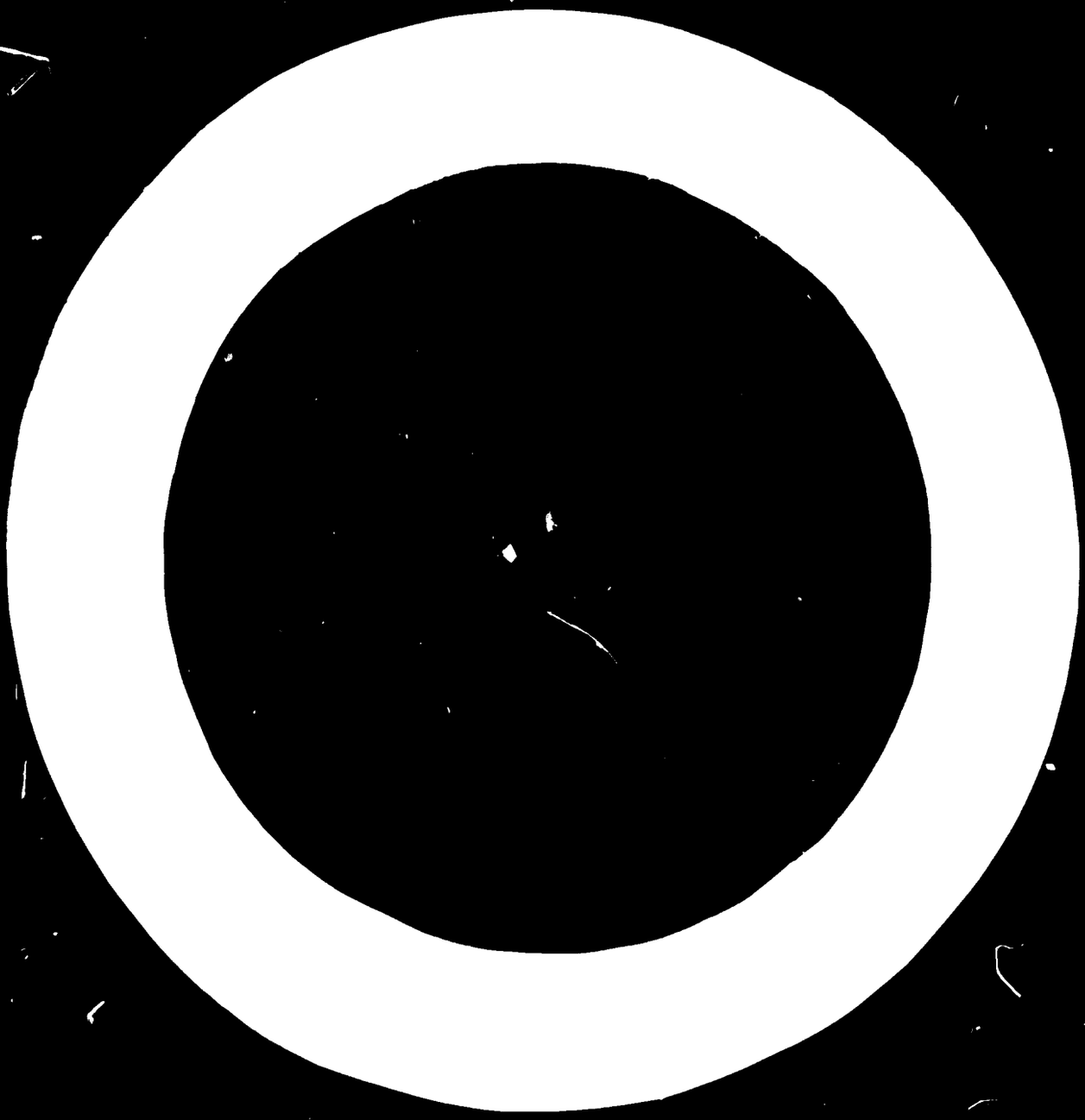

POSSIBILITIES AND IMPOSSIBILITIES OF PRODUCTION, MARKETING AND DISTRIBUTION OF ORAL CONTRACEPTIVES IN DEVELOPING COUNTRIES.

General - Oral Contraceptives and Organon

Organon has been producing and marketing oral contraceptives from the very beginning of the pill era - now about 10 years ago - with brands developed by their own research such as Lyndiol, Ovostat, Ovanon. Being one of the pharmaceutical manufacturers specialised in hormones, this was a natural development. Our world-wide marketing organisation - established in 90 countries including 19 manufacturing facilities - has given us a profound experience in the oral contraceptive field. As a result of this our products can be obtained not only in the developed countries, but also in virtually all developing countries, in spite of the often limited interest at present. But that is one of the points of the discussion over here.

1. Organon's experience with the oral contraceptive market in developing countries

1.1 - Africa

In our organisation we distinguish 3 marketing areas (geographically, ethnologically, etc.) :

North Africa, comprising of the Maghreb countries where one can say that there is a promising acceptance, use and distribution of oral contraceptives.

East Africa

Although there is an official government acceptance this has not yet led to general acceptance by the public, resulting in a limited use of oral contraceptives.

West Africa

This part of Africa is still in the very first beginning of the idea of contraception. E.g. in a country like

Nigeria with a population of 60 million there are perhaps not more than 3,000 women on the pill.

1.2 - Asia

Singapore/Hong Kong

Although smallest in size, these two, directly followed by Korea and Taiwan, are the most advanced in acceptance and use of contraceptives. In our opinion this is mainly the result of the unflailing efforts of the international organisations like IPPF, Population Council, Pathfinder Fund, etc.

Japan

Japan we can leave out due to the specific social structure.

Thailand/Philippines

Basic acceptance has resulted in a fair start of the use and distribution of oral contraceptives.

Indonesia

We started local production in Indonesia in 1964, now almost 7 years ago. The situation in this country will be highlighted later on.

Australia/New Zealand

These countries have the relatively highest use of oral contraceptives in the world.

1.3 General market potential

Before discussing population control and family planning with oral contraceptives, size and scope of the market

have to be established. The so-called maximum expected number of pill users in a total population is basic in establishing the potential size of a market.

Expected maximum number of pill users in a total population		
Population	100%	100 million
Total number of women	50%	50 million
Total number of fertile women	38%	19 million
Expected maximum number of pill users	1/3 *)	6,5 million

*) 2/3 will never use the pill because of: other contraceptive methods, wanting children, unmarried, religion, not acquainted with oral contraceptives yet, taboos, medical reasons.

Taking these figures the maximum number of packs that could be sold per month theoretically works out for :

<u>India</u>	population 500 million 32 million packs
<u>Indonesia</u>	population 120 million 7,8 million packs
<u>Hong Kong</u>	population 4 million 260,000 packs.

2. Evaluation of oral contraceptives versus other contraceptives

Oral Contraceptives

Advantages:
- virtually 100% effective
- medical technical infrastructure needed is small
- method of administration reasonably simple.

Less favourable factors:
- massive motivation education program necessary to secure regular taking of the pill by the user
- resistance both founded and unfounded from the medical profession in some countries
- side-effects: the low incidence of intrinsic side-effects must be evaluated against the large number of "side-effects" of a population explosion. To mention only here: infant and mother mortality, child mortality and higher incidence of tropical and/or other infectious diseases, one often sees in an overpopulation in developing countries.

IUD

- self-limiting as a result of (para)medical technical infrastructure needed
- high expulsion rate
- side-effects.

Sterilisation and abortion

- also here a rather extensive medical technical infrastructure is needed
- side-effects.

Injectables

In spite of the rather severe side-effects of bleeding more or less accepted in some developing countries due to its practical implications. However, also here a medical infra-structure is needed for the administration; not to mention the high drop-out rate. *

Condoms

In spite of its psychological disadvantages and a reliability of only 95%, this form of contraception is still widely used due to:

- being the longest known contraceptive
- established distribution
- availability
- no medical factors involved

In contrast to oral contraceptives the condom not always provides protection for the woman because the use is being decided upon by the man.

Miscellaneous

The other means of contraception mostly of mechanical or chemical character have an established but non expanding market share due to the rather complicated nature.

3. The attitude and objectives of population control of the three main groups involved

Two main considerations are gaining more and more acceptance in the field of population control:

a. A population growth of more than 2% per year in a developing country has proven to be a bar to an increase of the per

capita income of the population.

b. If world population control is to be acceptable, developed as well as developing countries must equally accept the objective of a stabilised population (i.e. a 2-child family and zero growth). *

Concerning the objectives of population control one can distinguish in general three groups. Although all three groups want oral contraceptives to be marketed and/or distributed on the largest possible scale, the backgrounds and motivations differ widely.

Governments

- political goals
- economical goals
- social goals.

Medical and paramedical groups

either or not in family planning structure; by virtue of their profession.

Pharmaceutical industry

Apart from the commercial interest we would also like to focus the attention to the social responsibility that has become an important part of the overall task of the modern pharmaceutical industry.

4. General factors in marketing and distribution of oral contraceptives

a. Prevailing cultural patterns and the resulting general opinion on procreation, ideal family size and structure, either or not influenced by religion.

b. Level of economical thinking in family matters by the man in the street. In this respect the role of the lay press and other means of mass communication are of major importance.

c. Existing governmental attitudes.

d. In some countries the medical profession has not yet accepted oral contraceptives unconditionally on founded or unfounded medical grounds in spite of the overwhelming advantages to be gained by the population as a whole.

e. Economic situation:

The influence of the standard of living on the development of the oral contraceptive market has been greatly over-estimated. Moreover, per capita income is not a yardstick as contraception is a family activity (only one person per family involved). Household income and expenditure are better criteria. We are now in the happy situation of operating at cost levels at which all countries with their differing standards of living can have an oral contraceptive market. It is almost solely the potential extent of the market which fixes price, and not fixed prices which determine the extent of the market. Of course, there are minimum levels of operation, but within the reach of every country.

f. At present the distribution of oral contraceptives is in most countries legally confined to medical prescription channels. In how far this is a self-limiting factor on account of the limited number of doctors in developing countries is something to be investigated. The consequences

of availability of oral contraceptives without prescription in some developing countries should be studied. Legal limitations on promotion and distribution play usually also a part here.

g. Physical distribution of oral contraceptives being dependent upon existing local infrastructure, accessiblity (trade channels, transport facilities, lack of communication due to isolated settlement).

We believe these to be the most essential factors although locally a lot of secondary factors may be involved.

5. Possibilities of local production in developing countries

An important result of mass production is of course the low unit cost. A local production may bring with it a number of difficulties such as :

a. duplication of all necessary secondary equipment and functions (quality control, competent staff, etc.)

b. In most cases a local production of only oral contraceptives, although understandable, is hardly ever possible economically. Combination with other pharmaceutical products is usually necessary. All this needs therefore planning and cooperation between government and industry in the interest of both so that the unit price remains workable.

6. The actual situation of oral contraceptives in various countries

From the efforts of the pharmaceutical industry on one side and the efforts of national and international institutions on the other, it has become clear which are the specific

difficulties of population control in the various countries. The question remains now whether the difficulties are "unsurmountable" or whether the approaches are "inadequate". We are of the opinion that they are not unsurmountable but that research on new and unorthodox methods should be considered. Generally speaking we have found that certain factors are of paramount importance in the development of oral contraceptive markets:

a. Motivation : a. government
b. society top level
c. public: political leaders
opinion leaders
medical profession
mass communication

b. Education: with the stress on the acceptance of new ideas.

c. Economical situation : a. standard of living
b. local and foreign funds

d. distribution : a. existing trade channels
b. F.P.A. centres
c. government institutions.

Not all of these factors have to be favourable, but if enough of them occur simultaneously, then promising results can be obtained. One should, however, be aware of attributing an absolute universal significance to an individual factor because various markets have different identities.

Australia

The success of oral contraceptives in Australia can be attributed to the fact that almost all abovementioned factors

were valid and acted simultaneously.

Indonesia

From the current plans it seems that some factors such as motivation, economical situation are there while a start with education and distribution has been made. With the dedication of all people involved Family Planning in Indonesia might become a success.

India

Objections from the medical profession founded and unfounded against oral contraceptives have until now prevented the government of going all out also in oral contraceptives and therefore the factors economical situation, distribution and education could not be fulfilled to a large extent.

7. Development of future approaches in the oral contraceptive field in various countries

The relative failure of population control with contraceptives in a number of countries has been due, in our opinion, to inadequate methods in achieving the optimum in motivation, education, economics and distribution. This applies not only to existing contraceptives, but will also apply to new contraceptive means, no matter how sophisticated or simple they may be.

On guidance of the abovementioned major factors we will try to indicate some possibilities for the future.

a. Motivation

Indirect support by the international agencies and the industry for motivational activities in a country towards

the three groups involved (government, social top level, general public).

b. Education

Here we think of providing promotional know-how in different fields, namely:

- general posters (public - indoors, outdoors)
- clinic posters (hospitals, surgeries, FPA centres, dispensaries)
- mass communication media: press, radio, t.v., cinema
- special material or instruction programmes for the less-educated adults or the school-youth.

In this respect education in developing countries should be switched as much as possible to the schools in view of the fact that in developing countries sometimes 40-50% of the population may be at school age.

c. Economical situation

Apart from free-aid in early stages, local governments should be made aware that they can assist considerably in population control programmes by exemption or lowering of import duties on raw materials, or if there is no local production, on ready products, samples etc.

We may mention custom duties for oral contraceptives in :

Thailand	raw materials	40%
	finished packs	22%
Indonesia	raw materials	5%
	finished packs	free
Philippines	raw materials	23%
	finished packs	44,5%
Nigeria	finished packs	10%

Korea	raw materials	6%
	finished packs	6%

Tailoring duties on contraceptives to the general standard of living would be a major step forward in many countries.

d. Distribution

Realising that distribution in most countries is bound legally to medical prescription channels including pharmacies, one wonders whether in developing countries distribution outside the medical profession (only as far as distribution is concerned) would not reach a larger part of the population, as practised sometimes in other fields of medicine. Obviously this would require training of paramedical personnel. At the same time the burden on the medical profession in developing countries, being already very heavy due to relative small numbers, could be eased.

Generally speaking, closer cooperation between international agencies and the industry will be essential. No doubt there is an influence from the purchasing policy of international agencies on the marketing possibilities of pharmaceutical companies. In this respect we would like to stress the need for cooperation between agencies active in certain countries and those pharmaceutical companies having an existing market share in those countries. E.g. the appearance of certain oral contraceptive brands in the family planning market available to the public will have a substantial effect on the sales pattern in the whole country including the oral contraceptives outside the family planning. Hereby the growth possibilities

of other brands already existing in that market may be more or less limited, thereby not extending the intended increase of the total use of oral contraceptives.

Larger extensions of population control programmes in certain countries require cooperation between agencies and manufacturers in order to plan properly production and distribution.

SUMMARY

The pharmaceutical industry and the medical profession stood at the cradle of the pill. Without the efforts of the industry Dr. Pincus would not have been able to develop oral contraception. Only the further development of the pill by the industry made contraception and thereby population control and family planning possible on a world-wide scale.

It looks as if in the past the contributions of the pharmaceutical industry to the population control in developing countries were for a variety of reasons not synchronised with the activities of the international agencies and authorities. We should like to point out, however, that the industry has been building up a considerable know-how of production, marketing and distribution of contraceptives in developing countries.

In spite of many factors, which until now have prevented a closer cooperation between both parties, we believe that the time has come for a combined effort in the developing countries, in order to find new ways and means for expansion of contraceptives. A cooperation between agencies, governments and the industry would be of mutual interest to all parties, namely in providing public and civic sectors with the know-how and insights of the industry, at the same time providing the industry with the administrative and economical possibilities of agencies and governments.

Together they might succeed much quicker and more effective in finding new facts and new methods in population control and family planning, thereby contributing to an accelerated development of the third world.

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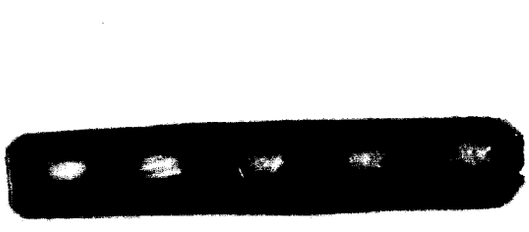

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countries is something to be investigated. The consequences