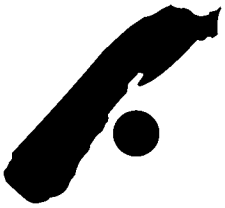

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A. Language

Article 12 (1) of the International Covenant on Economic, Social and Cultural Rights, states: "The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health." It is important to respect this language (**physical and mental health**) not only in the title, but also in the provisions of the Guidelines.

B. Observations and Comments

1. Generic Drugs and Health Security

- If a pharmaceutical company claims to have been a victim of patent abuse of their drugs, it is their responsibility to provide adequate proof.

- That a drug is generic should not lead to a lowering in its quality.

2. Fabrication, Promotion and Marketing of New Drugs

- A new drug is an innovative and accessible product that aims to provide a new, optimally improved therapy to reduce, cure, offer care for the symptoms, manifestations, and genes of the illness which it treats. The drug must do so while generating the least number of side effects possible.

- A new product can only be placed on the market if it has been subject to several clinical trails that demonstrate its effectiveness, its weaknesses, and its capacity to offer a new, improved therapy optimised to treat relevant illnesses.

- A new drug that, when compared to other drugs, appears to cause more undesirable side effects such as leading to dependence, or a worsening of symptoms, should be withdrawn from the market with all responsibilities and costs borne by its producer.

- The marketing policy to promote a new drug should provide true, precise, up-to-date information, geared towards addressing the concerns of, and providing support to doctors, paramedical personnel, the patients and their friends/families.

- All new drugs must be subject to a regular, periodic evaluation of their effectiveness and their secondary, undesirable side effects.

- A new drug can only be prescribed by a doctor when he has adequate information on the invention of the drug, how it has been improved, its capacity to cure, and all secondary, undesirable side effects it may produce. All patients have a right to attain this information.

- All new drugs should live up to the highest expectations in terms of treating those who suffer from the disease they are destined for.

3. **Tests/Clinical Trials of New Medicines**

- A clinical test of drugs carried out on an individual or on a population without their free and evident consent is a crime (against humanity, if the test is done on a population, e.g. in developing countries).

- Before a new drug is placed on the market, any doubts about its capabilities/function that may have risen during the research phase must be successfully cleared.

4. Effective Access to the Drug

To allow effective access to the drug, the following conditions should be borne in mind:

- The drug must be transported and packaged appropriately, based on the demographic conditions and climatic hazards in the zone where it is being sent.

- Adequate quantities of the drug should be available in the regions that suffer from the illness it treats.

- The medicine should be available not only to treat the disease it is destined for, but also to treat secondary infections and opportunistic illnesses that can be caused by the primary disease. (e.g. HIV and AIDS and their related opportunistic infections)

- The drug should be priced at a reasonable cost, sensitive to the purchasing power and living conditions of the population to whom the drug is being sold.

- The drug should be given out in doses adapted specifically to the anatomy, physiology, physical and mental conditions of the persons whom it is prescribed to.

- Controls and checks must be instituted to ensure the quality of the drug and to prevent fraudulent imitations.

- Adequate information on the drug must be available to all.

5. **Treatment through Prevention**

- Research geared towards inventing new drugs should also focus on preventing the concerned diseases.

- Pharmaceutical companies, in their research, should develop a policy that combines prevention and cure, with an aim to improve the quality of life of those affected by the diseases being researched.

6. The rights of Children and access to medicine

- For drugs adapted specially to suit the psychology and physiology of children, pediatric research is necessary. The research must respect ethical and economic rules and should conform to the norms related to the rights of the child.

- Experimentation and clinical trials of new medicines for children should strictly respect the rights of children and should be conducted within the boundaries of ethical economic and psychological practices.

7. The gain of profits and the Right to Health

- Intellectual property protection should not prejudice the implementation of States' international commitments related to the right to health.

- No one can use intellectual property as a justification to deny access to medication to an individual or a population.

- The making of profits by pharmaceutical industries should be compatible with physical and mental health imperatives of individuals and populations.

- Effective access to medication involves a dimension of human rights.