

Combating Counterfeit Drugs: A Concept for an International Framework Convention and Other Strategies

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Policy

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1. The nature and scope of the problem.
2. International and National Efforts.
3. Why is an international framework convention necessary?
4. The purpose of the concept paper.
5. An outline of possible key elements.

Preamble, Objective(s), Principles and Definitions

1. Formulate coordinated approach to prevent and combat counterfeit drugs
2. Create a basic duty
3. Promote basic cooperation
4. Possible words to define: counterfeit drug, drug, medicine, pharmaceutical product, devices, traditional medicines

General Obligations

National measures to implement the objectives of a convention and to assure the quality of the drug supply

1. Establish national laws strengthening drug regulatory authority
2. Establish national law for registration and inspection of locally manufactured and imported medicines
3. Adopt international minimum standards for drug regulation

Quality of the Drug Supply

1. Chain of custody and tracking methodology
2. Licensing and documentation
3. Use of technology
4. WHO Certificate Scheme on the Quality of Pharmaceutical Products Moving in International Commerce
5. Quality Control Laboratories
6. Harmonize/streamline the registration of imported drugs

Education, Training and Public Awareness Campaigns

1. The Public
2. Professionals
3. Law Enforcement

Offenses and Sanctions

1. Establish substantive crimes under domestic law
2. Sanctions to include imprisonment, fines, confiscation, destruction of counterfeit drugs, materials or equipment used in the manufacture thereof

Other Issues

- A. Exchange of Information and Provision of Technical Support
- B. International Cooperation between the parties
- C. Research and Development and Scientific Cooperation
- D. International Trade Dimensions

Operation of the Framework and Creation of Institutions

- A. Secretariat and Conference of the Parties
- B. Other Institutions/subsidiary bodies
- C. Financial Mechanism

Typical Clauses

1. Implementation Procedures
2. Law Making Process and Final Clauses

Question ?

Is an international framework convention desirable to address the international dimensions of the problem of counterfeit drugs and to further normative guidelines on national standards?