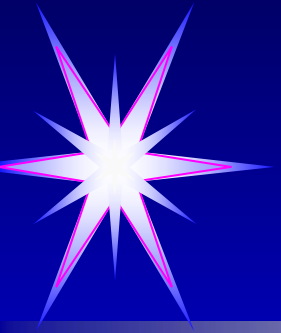


Drug Regulatory & Licensing System

Through

South – South – Collaboration



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(A) Legislation and Regulations Situation in Egypt :

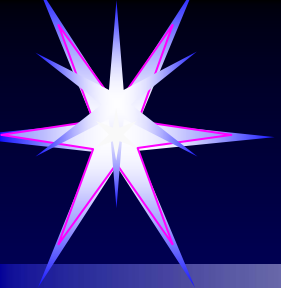
1) Pharmaceuticals

- Pills 1. Needs registration as a pharmaceutical product
- Injectables 2. Manufactured only in a licensed pharm manufactory (controlled G.M.P & standards)
- Implants

2) Medical Devices:

- IUDS Needs registrations as R.H commodities (a Division of Medical Devices)
- Condoms Does not need registration but quality testing before marketing

- ## **3) Kits**
- Does not need registration but quality testing (random) before marketing



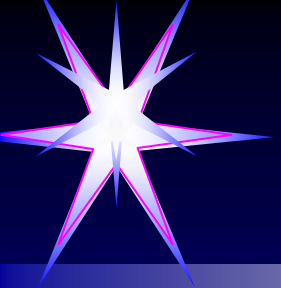
(B) Import Rules

Pills, Injectables, Implants, IUDS:

* Needs Previous import license.

Condoms, Kits

* Doesn't need import license, but health customs release is required.



(C) Distribution:

Pills, Injectables:

Distributed only through pharmacies & hospitals .

Implants:

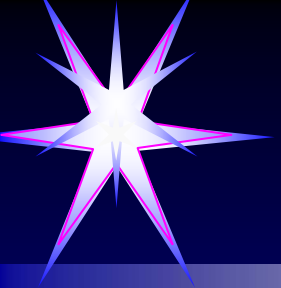
Distributed only through clinics.

IUDS:

Distributed only through pharmacies, hospitals & clinics.

Condoms:

Free distribution.



Objectives:

Regulations are directed to be the key role to play towards ensuring the availability, affordability and sustainability of essential R.H pharmaceuticals and commodities which are scientifically proven to be therapeutically effective, safe, high quality, easy to use and cost effective.

These pharmaceuticals & commodities have to be economically within the reach of existing budgets and satisfy the health care needs of the majority of people especially un-met demand group.

Continuous care that regulatory constrains not stand as a barrier for the availability of essential R.H pharmaceuticals and commodities.



Future Work Needed:

1. Review regulation polices and practices for R.H pharmaceuticals and commodities to ensure better prevalence of products that meet international standards and ensure greater opportunities of investment by private sector based on market- competition and avoiding complicated systems.
2. Identify which products would technically and financially feasible to local manufacture.
3. Setting appropriate product testing.
4. Advocating exemptions of all contraceptives from import duties and sale taxes.
5. Some efforts on “ Harmonization “ between market- structure and health needs.
6. Ensure good storage, transfer and distribution system practices.



Future Work needed in South – South Collaboration:

- Mechanism for devising and possibly uniform standards for G.M.P , G.S.P ,G.D.P.
- Quality assurance regulatory laws & Procedures using reasonable & measured indicators.
- South – South Collaboration on Research, Development, Technology Transfer, Production, R.H Pharmaceuticals & Commodities integration.
- Recognition of the difficulties in setting up independent separate regulatory bodies among S-S Countries and the need of Regional / Sub regional facility for drug approval for importation of needed products to facilitate broader and more rapid market access.
- Fast track review & registration of products suited to our markets.



South - South and International Agreements :

Short term action :

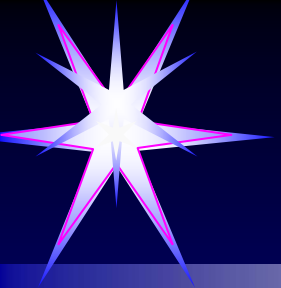
Advocate patent exemption on essential R. H pharmaceuticals & commodities for the developing countries.

Long term strategy :

- 1) Seek immediate amendments to TRIPS to be included in the general provisions & basic principles.
- 2) Adopt appropriate legislation in favor of fast track method & compulsory licensing to produce market import licensing & “ Bolar provisions “.
- 3) Promote the creation & permanent review & monitoring body with TRIPS council.

This body would provide developing countries with information about implementing TRIPS standards and can work with WHO to ensure that IPR standards –setting process does not undetermined standards setting in human rights, development of health (article in TRIPS).

- 4) Develop model laws for IPR protection for use by developing countries.



THANK YOU