Strengthening Contraceptive Drug Regulatory and Licensing System through South-South Collaboration

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Challenges

- The lack of health fund and vast investment on cost-inefficient production caused inadequate utilization of resources.
- Scarcity of unified and standardized regulations and norms delayed the application of new production and techniques.
- WTO's TRIPS and other patent-protecting agreements brought constraints and limited the public health capacity in developing country.

- Incomplete marketing system weakened the accessibility, affordability and availability of essential health commodities.
- Unsatisfied people's needs urged us to solve these problems collaboratively.

Current status in China

- Research & Development
  - 27 researching institutes and collaborating center of WHO(located in Beijing, Shanghai, Tianjin, etc.)
  - 42 pharmaceutical factories or enterprises.
  - Products covered: Female, Male and Emergency contraceptives, IUD, Condom, Implant, over 50 types

- Produced both patent drugs and off-patent drugs
- Procedures of new drugs' development followed by international standards of GLP, GCP and GMP
- Manufacture and products were surveiled by Quality Control and Quality Assurance System

Drug Regulatory System in China

- National Drug Administration Law
- National Administrative Penalty Law
- National Advertisement Law
- National Anti-improper Competition Law

Pricing

The prices of Chinese products are reasonable and competitive

– the self-sufficiency of raw materials,

– self-owned patents

– relatively lower labor costs

Marketing system

- Charge-free delivery system
  - mainly target the rural or low-income people
  - through Contraceptive Supply Center or Family Planning Service Station
  - state-ordered products (low price but good quality)
- With charge delivery system
  - mainly target the urban or high-income people
  - through hospitals and drug stores
  - need-oriented products (including imported products)

Tax Polices in FP Commodities

- Zero tariff on both equipment and raw material importing
- Zero value added tax
- 50% discount of income tax

Criteria of Import Drugs

- Safety
- Efficacy
- Controllable Quality
- Clinical requirements

South-South Collaboration

- Sharing the experiences of essential commodity/drug policies to ensure the health care needs of people
- Promoting the transfer of intellectual property among the developing countries
- Sharing the human, technical, financial and industrial resources among Partners countries

- Enhancing the capacities for R&D, manufacturing and marketing to accelerate the utilization of essential health commodity
- Strengthening the training program specifically on the drug regulatory system, quality control and assurance system, as well as the protection of intellectual property

Thanks!