

Importance of Strong Drug Regulatory Systems

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3rd November 2015 at Hotel Taj Mansigh



- Why Medicines be regulated?
- Main reasons for regulating Medicines
- Principle of Medicines regulatory function
- Factors contributing to effective regulations
- Importance of Strong Medicines Regulatory system
- Conclusion

Why Medicines be regulated?



- Use of ineffective, poor quality, harmful medicines can result in
 - Therapeutic failure
 - Increase severity of disease
 - Resistance to medicines
 - Some times death
 - Undermines confidence in health system

Main reasons for regulating Medicines



- Patients/consumers not equipped to make independent assessments of Q,S and E
- Desperate patients may buy ineffective or even toxic medicines
- Misuse of medicines
- Freely accessible
- Self medication

Area of Regulatory Weakness	Potential systemic effect
Circulation of low-quality drugs and inconsistent enforcement of manufacturing standards	Lack of confidence in drug quality and preference for more expensive branded or imported drugs
Weak licensing process for businesses and products	Fewer products on the market, potential procurement delays in the launch of new drugs
Sale of prescription drugs over the counter	Risk of irrational use of a drug or use in cases where the drug is contraindicated, with negative impacts on individual's health; drug resistance
Inadequate information provided with drugs	Risk of irrational use of a drug or use in cases where the drug is contraindicated, with negative impacts on individual's health; drug resistance
Lack of oversight for clinical trials	Reduction of in-country clinical trials by drug companies and trial data that is unacceptable to regulatory authorities; harm to patients



Principle of Medicines regulatory function



- Licensing of manufacture, import, export, distribution, promotion and advertising of medicines
- Assessing of S, E and Q and issuing MA
- Inspection and surveillance of manufacturers, importers, sellers etc
- controlling and monitoring the quality
- Monitoring of adverse reactions
- Providing independent information on medicines to professionals and the public

Factors contributing to effective regulations



- Political will and commitment of regulation
- Strong public support
- Effective cooperation between the NRA and other Govt. agencies ie police, customs
- Sufficient qualified and experienced professionals
- Clear mission, adequate legislations, regulations
- Clearly defined roles and responsibilities
- Adequate staff, financial support
- Accountability and transparency

Importance of Strong Medicines Regulatory system



- Quality should be built in the product, not by merely testing the final product
- Ensure S, E and quality of medicines
- Protection of patient safety and wellbeing
- Make available medicines information to the public
- Involvement of public in the approval process
- Public awareness program
- Application of sound medical, scientific and technical knowledge and skills
- Operate with in the legal frame work
- Building of confidence
- Trust on quality of products
- Transparency and predictability

Conclusion



- Predictable and Transparent
- Application of sound medical, scientific and technical knowledge and skills
- Operate with in a legal framework
- Avoid Command-and-Control regulatory approach
- Cultural shift, as a facilitator
- Communication Skills
- Decision making
- Uniform Immmplementation

