

Politics of Global Regulation of Medicine and other Health Products

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TWN

Regulation...?

- What?
- Why?
- How?
- Who?
- Transnational Regulatory Networks agenda of regulatory harmonisation

Mandate

- to propose conventions, agreements and regulations, and make recommendations with respect to international health matters and to perform such duties as may be assigned thereby to the Organization and are consistent with its objective; (WHO Constitution Art.2.k)

...Art 21

- Standards with respect to the safety, purity and potency of biological, pharmaceutical and similar products moving in international commerce
- Advertising and labeling of biological , pharmaceutical and similar products moving in international commerce

Art.2

- (l) To standardize diagnostic procedures as necessary
- (m) To develop, establish and promote international standards to food, biological, pharmaceutical and similar products

Implementation of Art.2(l) and (m)

- WHO Expert Committee on specifications on Pharmaceutical Preparations
 - WHO Expert Committee on Biologics
 - WHO Expert Committee on Selection of Essential Medicines
 - Various Strategic Advisory Group of Experts
- Conduct is regulated through WHO Guideline Handbook

Expert Committee on Pharmaceutical Substance

Questions

- Accountability
- Participation
- Transparency
- Conflict of Interest
- Level of Regulation

Accountability

- To WHO constitution and public health
- Member States

Participation

- As on November 2017 there are 554 Experts in 43 Experts Advisory Panels

USA 72

UK 57

India 31

Australia 30

Canada 24

COI

- What is COI?
- Declaration of interest and Guideline for the assessment of declaration
- 57 out of 176 Guidelines (36%) reported contributors with COI
- Wrong approach
- Lack of oversight
- Lack of transparency

Regulation v Regulatory Capture

- Why ? (purpose)
- What level? (appropriateness)
- For whom?

ICH

- Established in 1993
- A transnational regulatory network with the private sector participation for the harmonization
- Steering committee consisting of 10 members with 6 members having voting rights
- Secretariat at the IFPMA
- WHO is an observer

...ICH

- “Smaller pharmaceutical companies, generic companies and many larger companies responsible for essential drug production in developing countries may be effectively squeezed out of drug manufacturing if ICH guidelines start to be interpreted as the only global standard”. (Report of the WHO Expert Consultation on ICH 2001)

ICH Reform

- Participation or Cooption

Other international instruments

- International Conference of Drug Regulatory Authorities (ICDRA)
- Pharmaceutical inspection convention
- International Coalition of Medicine Regulatory Authorities (ICMRA)

IMDRF

- International Medical Devices Regulators Forum (IMDRF)
- Transformed into a intergovernmental body from a PPP known as Global Harmonization Task Force(GHTF)
- Cooption or cooperation

Bio-therapeutic

- Bio Similar
- Burden of similarity

Counterfeit Medicines

- What is a counterfeit medicine?
- Does counterfeit medicine kills patents?
- Who behind the counterfeit agenda?
- Current state of play

WHO drops the Term Counterfeit

- In 2016 MSM on SSFFC decided to drop the term and adopted new term Falsified

Tasks Ahead

- Understand the politics and demystify the quality issue (Add some quality to quality debate)
- Look at the accountability and transparency of regulatory authorities
 - Conflict of interest
 - Appropriateness of regulation/regulatory capture
 - Links with Transnational Regulatory Networks