Regulating transnationals companies, including pharmaceuticals, is fundamental to achieving public health objectives

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Purpose

- Within the context of
  - neoliberal globalisation
  - financialisation
  - tax evasion, tax competition
- Explore the role of transnational corporations (TNCs) in the modern global economy through a case study of big pharma
  - public policy objectives in relation to big pharma
  - role in wider political economy of globalisation
  - modalities for public goods regulation

Outline

- Medicines policy objectives
- Achievements and shortfalls
- Medicines prices
- Substandard and falsified medicines
- Regulation
- Rational use and ethical promotion
- The political economy of big pharma
- Modalities for the global regulation of big pharma

Medicines policy objectives: criteria for assessing the industry globally

- Medicines development (innovation, evaluation, prioritised)
- Medicines production and distribution (quality, safety and efficacy)
- Equitable access to necessary medicines (procurement, price, supply)
- Quality use of medicines (information, promotion, prescribing, utilisation)

Policy objectives	Achievements	Shortfalls
Development (innovation, evaluation, prioritised)	Antivirals, anticancer, biologicals, drug design, genomics	Antibiotics, neglected tropical diseases, Type II diseases epidemic risk diseases Shonky clinical trials
Production & distribution (quality, safety and efficacy)	High level marketing approval regulation (rich world) Effective regulation of substandard medicines (rich world)	Substandard and falsified medicines Weak post marketing surveillance Shonky promotion and off label use Regulatory capture (high standards for marketing approval; harness state power to police IP)
Affordable access (procurement, price, supply)	Universal health cover (for some) Generic manufacturing Use of TRIPS flexibilities	Impossible prices (due to extreme IP protection & monopoly pricing) Shortages due to failure to produce when profit too low
Quality use (information, promotion, prescribing, utilisation, review, feedback)	Evidence based clinical guidelines Public agencies for professional and consumer education	Widespread inappropriate use Aggressive irresponsible advertising and promotion

Medicine prices

- Cases
  - Treatment action campaign
  - Hepatitis C
- IP creep
  - Development of TRIPS
  - Doha Statement
  - TRIPS flexibilities
  - Take-overs of generic manufacturers
  - New regional trade agreements (TPP, TTIP, RCEP)
- WHO
  - Delinking R&D funding from profit from sales
  - R&D Treaty to fund drug development

Substandard and falsified medicines

- Conflation of generic with substandard medicines to harness regulatory structures for the policing of IP claims
  - 1992 definition of ‘counterfeit’
  - IMPACT 2006
  - High level IP laws and policing as solution to substandard medicines
    - EU seizures
    - Kenya ‘Anti-counterfeiting law’
  - ACTA – anti counterfeiting trade agreement
- WHO
  - SSFFCMP process: ‘substandard and fake’ distinguished from ‘counterfeit’
  - More rigorous approach to regulating for ‘substandard and fake’

Regulatory capture

- Capture of drug regulatory agencies for IP policing
  - IMPACT story
  - EU seizures
  - Kenya ‘anti-counterfeiting law’
- Capture of standard setting for marketing approval by industry and main host countries
  - International Conference on Harmonisation
- Debates over naming conventions for biologicals and biosimilars and standards for marketing approval with a view to obstructing the marketing of biosimilars
- Continued failure to implement mandatory registration of clinical trials

Rational use and ‘ethical’ promotion

- IP protected monopoly pricing funds aggressive marketing as well as R&D
- Aggressive marketing drives
  - over prescribing and inappropriate prescribing and
  - excessive burden on tax payers
- Trade agreements seek to limit nation-state regulation (including pushing DTC advertising)
- Promoting rational use
  - costs money; saves money
  - requires effective audit and regulatory capacity
- WHO resolutions but programs underfunded
  - Rational use
  - Ethical promotion

The political economy of big pharma

- Market concentration
- Research and development
  - cost of basic research
  - cost of clinical trials
  - role of extreme IP
- Aggressive marketing and promotions
- The alliance of big pharma (and wider networks of international capital) with rich country governments
  - role of IBM and Pfizer in the genesis of TRIPS (Paine and Santoro, 1992)
  - Super 301 and US PhRMA: coercion in the TRIPS ‘agreement’ (Drahos)
  - more extreme IP in regional FTAs (TPP, TTIP, RCEP, CETA)
  - IMPACT and ‘counterfeit’
- WHO
  - US pressure on WHO over communications regarding the use of TRIPS flexibilities
  - fierce debates over SSFFCMPs and delinking

Modalities for the global regulation of pharmaceuticals

- Delinking price setting (and revenues) from the funding of R&D (and marketing)
  - public funding of R&D
  - a global Treaty on R&D funding
- Clean up global policy making
  - wind back extreme IP agreements
- Effective regulation
  - production, marketing approval, retailing
  - promotion and prescribing
- Technology transfer and local national manufacturing
- Affordable access: reasonable prices and social sharing (through equitable taxation and subsidies) of the cost burden

Challenges for public health professionals

- Research and analysis:
  - engaging in comprehensive study of the political economy of big pharma
  - direct engagement in debates over regulatory strategies under globalisation
- Recognising the need to build collaboration (in teaching, research, and practice) between public health and
  - the political economy of transnational corporations, and
  - the empirics and politics of corporate regulation under globalisation
- Education of the public health profession (including students) and the community more widely
- Participation in community mobilisation and international advocacy around the policy objectives and strategies for corporate regulation under globalisation