Building Innovative Capacity in Developing Countries

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Building Capacity

- Scientific infrastructure
- Product development
- Product manufacture
- Product distribution
- Product delivery
- IP management
- Regulation
- Economic evaluation
- Natural medicines
Scientific infrastructure

- Secondary education
- University education
  - Biomedical sciences
  - Clinical sciences
- Research training
  - Basic sciences
  - Clinical research
- Research management
Scientific passion

For:

- their science
- neglected diseases
- “making a difference”
Regulation

1. Drug regulation

2. Bioethics
Drug regulation (1)

- Scientific assessment and judgement
- Social values and judgements
Drug regulation (2)

Scientific assessment:

1. Evaluation of the evidence
   - Quality (in relation to efficacy and safety)
   - Efficacy (in relation to claimed indications)
   - Safety (in relation to efficacy)

2. Judgments about the evidence-base
   - Adequacy?
   - Weight?
   - Generalisability?
Drug regulation (3)

Social value judgements:

- risk-versus-benefit
Drug regulation (4)

Ensure public confidence:

- Probity
- Capture
- Arms length political control
- Patient/consumer/public involvement
Respect for bioethics

Fundamental principles:

- respect for autonomy
- nonmaleficence
- beneficence
- justice

Are these appropriate in other settings?
Bioethical regulation

Avoid replicating:

- UK - over-burdensome
- EU - Clinical Trials Directive
- US - IRBs
Economic evaluation

The missing words:

“Opportunity costs”