New Economic Models Addressing Antibiotic Resistance

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Nasjonal strategi for forebygging av infeksjoner i helsetjenesten og antibiotikaresistens (2008–2012)

ANTIMICROBIAL RESISTANCE
Global Report on Surveillance

The evolving threat of antimicrobial resistance
Options for action

Chief Medical Officer Dame Sally Davies: Resistance to antibiotics risks health 'catastrophe' to rank with terrorism and climate change

The bacterial challenge: time to react
A call to narrow the gap between multidrug-resistant bacteria in the EU and the development of new antibacterial agents
Access

Innovation

Sustainable effectiveness

Conservation
Innovation and Access
Innovation and Access
The traditional pharmaceutical commercial model

David J. Payne et al. Phil. Trans. R. Soc. B
2015;370:20140086
Innovation and Access
Application of traditional commercial model to antibacterials

David J. Payne et al. Phil. Trans. R. Soc. B
2015;370:20140086
Commercial model does not incentivize future potential unmet needs

David J. Payne et al. Phil. Trans. R. Soc. B
2015;370:20140086
AB development - the status quo

• Lack of incentives for pharma cause companies to close down their AB R&D departments
• Reasons for the antibiotic market failure:
  – **Science**: AB R&D have become more complex and resource intensive
  – **Economics**: ABs have poor return on investments relative to other classes of drugs (e.g. drugs for chronic diseases)
  – **Regulations**: Pre/post market regulations deter AB development
• Only three of top 50 pharma companies develop ABs

R&D financing and incentive mechanisms

**Push mechanisms**
- Open knowledge innovation
- PDP financing
- Grants
- Subsidies
- Tax breaks

**Pull mechanisms**
- Advance Market Commitment (AMC)
- Milestone and end prizes
- Debt / loans
- Equity / bonds
- Government-backed volume guarantees
Innovation and Access – Market shaping – expand market
Innovation and Access – Delinkage – a separate innovation market
Principles of a de-linked model

- ‘lump sum’
- ‘series of payments’
- no marketing
- provide agreed no. doses/year or stockpile

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Recent proposals

- Könberg report (Nordic countries, 2014)
  - Nordic countries to take the lead in an international initiative
  - Total 5 year investments around 75 mSEK or 0.005 % of annual high income GDP

- O’Neill review (UK)
  - Global innovation fund
  - “Buy out model” = $ 2-3 billion vs. “Hybrid model” = $ 1-1.3 billion
  - Total investments of 0.003% of annual global GDP, i.e. around $25 billion over 10 years

- Leaders of global health funding and research organizations (PloS Med)
  - A global biomedical R&D mechanism for public health emergencies
  - $10 billion annually for infectious disease threats - AMR, emerging infections (incl Ebola), poverty related/neglected diseases
Historical Ebola outbreaks 1976-2014

- Died
- Survived
Fast track Vaccine development (Oct-Apr 2014/15)

- WHO Consultation on Ebola vaccines
- 1st WHO High-level meeting
- Guinea Country Working Group formed
- Approval RCN funding
- 2nd TC
- Protocol development started
- 1st TC
- Approval WT funding
- 2nd WHO High-level meeting
- AVAREF
- 3rd TC
- Ethical Approval Guinea
- Regulatory Approval Guinea
- Ethical Approvals WHO/MSF/Norway
- Choice of vaccine
- Meeting Guinea reg.
- 1st Visit Guinea
- 2nd Visit Guinea
- 3rd Visit Guinea
- 1st F2F meeting
- Approval CIHR funding
- 23.3 First ring vaccinated
- 7.3. Start of study
- Fast track Vaccine development (Oct-Apr 2014/15)
- Start Phase 1 trials
- Results Phase 1 trials
- Results Phase 1 trials
- Results Phase 1 trials
- Results Phase 1 trials
A global R&D fund and mechanism for innovations of public health importance

- Different, but similar challenges
  - Neglected diseases
  - Antibiotics (i.e. AMR)
  - Emerging infections, e.g. Ebola

- All need
  - More collaboration
  - Better coordination
  - Sustainable financing