

The Decline in Antibiotic Innovation: Causes and Possible Solutions

The Antibiotic Innovation Study

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What is the Antibiotic Innovation Study?

Survey of views of 24 experts to address and seek practical solutions to the problem of the declining rate of pharmaceutical innovation in the field of antibacterial medicines.

The Expert Interviewees:

- Scientists
- Doctors
- Pharmaceutical industry executives (big pharma, biotech and generics firms)
- PPP experts
- Institutional investors & pharma sector brokers
- Government regulators
- Purchasers and reimbursement authorities
- NGOs

Methodology

Individual interviews & face to face meetings with the experts

First draft of report – including summary findings and background information sent to participants for comment

Final version of the report presented to React today

Underlying hypothesis

That the government assumption that antibiotic innovation needs will be met by the market should be tested by interviewing the people who determine which medicines get developed and under what circumstances.

Headline Findings

- All interviewees see critical need for new antibiotics to respond to resistance
- That experts in drug development do not believe that the market alone will solve problem in time
- Majority in favour of PPP response

Current Situation: Need for Urgent Action

- Though new research is being done, it will not be sufficient to meet need
- Consequences = increasing numbers of sick and untreatable patients and deaths associated with lack of effective antibiotics – already visible
- Prognosis for five to ten years = grave
- Anti-infectives now face similar funding difficulties as neglected diseases

Range of Unmet Medical Need Requiring Solutions

- Treatments needed for new infections and emergent resistances in developed countries – particularly in field of Gram negatives
 - Medicines for community-acquired resistant infections needed in all markets
- New drugs needed for diseases that predominantly occur in developing countries, e.g. TB, Typhoid

Commercial reasons for lack of innovation

1. Antibiotics not as profitable as drugs to treat chronic diseases
2. Pharma industry consolidation: fewer people in fewer companies doing antibiotic research
3. Science is particularly difficult = financial risk
4. Highly genericised market – overall price is low
5. Push to reduce use to tackle resistance – reduces size of market
6. Risk-averse regulatory environment: onerous for antibiotics
7. Inevitability of resistance limits antibiotic lifespan – limits duration in market place

Report Findings

The Role of Government

1. Government needs to compensate for market failure
2. No consensus on nature of government intervention:
 - Option 1 – Work within existing market structures – invest more in early research, remove barriers to innovation, redefine and pay more for true innovation
 - Option 2 – Concerted action in form of more formal public-private agreement
 - Option 3 – Invest in new model that de-links innovation from end-profit for non commercial medicines

Report Findings: Scientific

- **Genomics** still offers immense potential
 - **Public library** of rejected chemical substances
 - **Diagnostics** offers huge potential: e.g. point of care test to check for bacterial v. viral infections, and improvements in pre-clinical tests for early identification of safety problems
 - **Vaccines** that specifically target antibiotic resistant bacteria

Report Findings: Regulatory

- Current assumptions about risk aversion need to be tested against patient views
 - Potential for increased efficiency in trial process, including improved predictive value of pre-clinical findings, improved pharmacokinetics to reduce PII & PIII trials
- Fast track and priority review already work for antibiotics, but could make difference to SMEs and developing countries
- Conditional registration could speed things up but post marketing surveillance problematic
 - Improved statistical probability possible
 - Price Incentives = double edged

Report Findings: Thinking Outside the Market

- Some needs will not be met by market
- Opportunity exists for government to remove sales volume as incentive and to act to ensure that knowledge base retained
- Existing PPP model not necessarily applicable to antibiotics:
 - resulting product likely to have commercial potential in some markets
 - PPPs have not solved problem of end-market
 - PPP would not necessarily be capable of meeting developing and developed countries simultaneously

Areas for further discussion

- What should government intervention consist of?
- Any public-private venture for antibiotics needs more specifics on scientific gap, medical need and size of market
- Views differ on roles of public and private partners – particularly in relation to push and pull incentives.
- The role of pricing as incentive is highly controversial
- Developing countries cannot rely on high price, low volume solutions

Overall Conclusion

Concerted Action is needed by scientists, doctors, pharmacists, governments, the pharmaceutical industry, regulators, purchasers, investors, patients, NGOs and insurance firms. Without it, we will be left,

“asking 21st century patients to accept 19th century medicine.”