Sustainable models to overcome the challenging economics of antimicrobial discovery and development

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Meeting the Challenge of AMR

Speed up antimicrobial discovery and development
- New research and targets
- Novel vaccines, antibiotics, and alternatives
- Diagnostics
- Novel economic models

Slow down the emergence of resistance
- Coordinated global effort
  - Infection prevention
  - Diagnosis and surveillance
  - Antimicrobial stewardship
  - Prevent transmission
- OneHealth + Ecological approach
Decreased Activity in Antibiotic R&D

Active Corporate Antimicrobial Programs

Adapted from: Kinch MS et al. Drug Discov Today 2014; 19(9):1283-7
Antibiotic development presents significant challenges

**SCIENTIFIC**
Bacteria are resilient and constantly evolving
Narrow “therapeutic window”

**DEVELOPMENT & REGULATORY**
Complex regulatory pathways
“Non-inferiority” clinical trials

**ECONOMIC**
Limited returns relative to other therapeutic areas
Challenging Economics of Current Model for Antibiotics

Current efforts generally focus on:
- “Push” incentives for early research through pre-clinical and early-stage grants and development partnerships
- Streamlining regulatory processes

“Pull” incentives to address limited return on investment are needed

Adapted from the Review on AMR
Multi-stakeholder efforts will be needed to deliver on the challenges outlined in the WHO Global Action Plan on AMR

- Improve awareness and understanding of AMR
- Strengthen surveillance and research
- Reduce the incidence of infections
- Optimize use of antimicrobial agents
- Ensure sustainable investment
The Private Sector Has an Important Role in Addressing AMR

Davos Declaration (January 2016) – over 100 companies and associations committed to:

- Increase investment in R&D
- Reduce resistance through appropriate stewardship
- Improve access to antibiotics and vaccines
- Called on governments to create a sustainable and predictable market

Roadmap on Progress on Combatting AMR (September 2016) – 13 leading companies committed to:

- Reduce the environmental impact from the production of antibiotics
- Help ensure antibiotics are only used by those who need them
- Improve access to antibiotics globally
- Explore new opportunities for collaborations between the industry and public sector
Incentives Are Needed to Promote Antibiotic R&D

*There is no “one size fits all” solution*

- Mix of “push” and “pull” incentives
- Market-based models that reward successful innovation
- Predictable and sustainable funding mechanisms
- Recognition of societal value of novel antibiotics
- Reduce Tension between cost and stewardship
Actions Needed to Incentivize Antibiotic R&D across the Product Life Cycle

Build on existing mechanisms
- Reimbursement Reform
- R&D Tax Credits

Explore novel incentive models
- Reward innovation earlier in product life cycle (competitive return on investment)
- Decrease proportion of manufacturer revenue from volume of sales

These models could include:
- Market entry rewards in key markets
- Transferable exclusivity
The Tension between Cost and Stewardship... A Real World Example

Leading Gram-Negative Molecule

What is the impact of generic entry

55,377
15th Year
Jun 2010
Generic Entry

Source: QuintilesIMS Midas/ France GERS
The Tension between Cost and Stewardship... A Real World Example

**Leading Gram-Negative Molecule**

- **Jun 2010**
  - 55,377
  - 15th Year

- **Generic Entry**

- **Jun 2016**
  - 123,921
  - 5 years Post-LOE

- **68,544 Growth**
  - 5 Years Post-LOE

**Why?**
- Reduction in Cost
- Removal of Hospital Restrictions

Source: QuintilesIMS Midas/ France GERS
Industry is Committed to Supporting Antimicrobial Stewardship and Enhanced Global Access

- Incentive models can be refined to reinforce antimicrobial stewardship and complement efforts to slow resistance.
- Programs to support appropriate use of and access to antibiotics should be developed and implemented in collaboration between industry, governments, and others.
- Industry committed to work with stakeholders to expand global access to antimicrobials based on success in HIV, vaccines, and reproductive health.
The Way Forward

Capitalize on the current momentum to deliver concrete action on AMR for patients worldwide

Collaborate with key stakeholders – governments, industry, civil society and others – to address this critical unmet need

Transform the societal perception of the value of antibiotics, addressing today’s reimbursement challenges and advancing novel incentive models