Nov 21, 2023
Amit Khurana, Director, Sustainable Food Systems programme, CSE
Assessment of antibiotic pipeline, July 2023

Deliberations with experts, July-Oct 2023

Initial report, Nov 2023
Key facts we know so far… (1/2)

- **Global antibiotic pipeline: weak (and fragile, dry, anemic!)**
  - Only 77 candidates in clinical stages; 45 traditional small molecules
  - Clinical pipeline **stagnant** against priority pathogens (33 in 2017; 28 in 2021)
  - Near-term scenario is bleak: in phase 3, only **nine** traditional small molecules; none for TB
  - Long term scenario also not promising: Less than 15% (31/217) in preclinical are in advanced stages (CTA/IND-enabling studies)
  - Thin compared to >10,000 in clinical development for cancer and >1,800 for neuropsychiatric conditions

- **Big pharmaceutical companies not focusing on antibiotic R&D**
  - **13/1007**: antibacterial candidates in clinical pipeline (of select 15 high-earning companies)
  - Only **four** involved in antibiotic R&D; **8/13** are in GSK pipeline; many have exited (some were pioneers in antibiotic R&D)
  - Collective 2022 revenue: USD 711 billion; Collective R&D expenditure: **USD 124 billion** (~17.5% of revenue)
Key facts we know so far...

- Instead, big companies are focusing on profitable areas
  - Out of 1007, 411 (cancer), 150 (immunology, allergy, inflammation or respiratory diseases), 91 (areas related to neurosciences), 84 (cardiology, metabolism or renal disease areas)
  - Most blockbuster drugs (> USD 1 billion yearly revenue) are in these areas
  - Suggests that shift in focus not just about failure of market for antibiotics

- Micro, small and medium-scale companies filling the gap but are facing challenges
  - 84% of preclinical candidates and many in clinical stages are being developed by them
  - Challenges include bankruptcy, diminished values, exits
Suggested way ahead: broad areas

• **Greater public financing and reforms** (such as related to markets, reimbursements, regulatory approvals, cost of new antibiotics, clinical trials)

• **Governments need to come together for a coordinated response** (prioritizing antibiotics and developers, testing and piloting incentives and removing access barriers)

• **Need to strike the right balance in public-private partnership** for antibiotic development.

• Time to discuss if antibiotics/any other aspect of AMR response can be considered as a **global public good**
Deliberation 1 with global experts | July 2023

THE CRISIS IN ANTIBIOTIC RESEARCH AND DEVELOPMENT

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At a time when existing antibiotics are becoming ineffective, pharma companies are not investing in R&D for new antibiotics. Is the world staring at a serious health emergency in the near future?

Date: FRIDAY, 28 JULY 2023
Time: 5:00 TO 6:30 PM (IST)
Platform: ZOOM
Key takeaways

- The crisis of AMR is **not limited to the crisis of antibiotic R&D**. It is in fact a **triple crisis** (antibiotics becoming ineffective, antibiotic development crisis, the issue of access)
- Society and healthcare systems place a **low value** on antibiotics (despite high AMR risk; signal to developers that antibiotic R&D investment is not a priority)
- Pipeline **fragmented** and lacks **predictability** (in addition to being weak)
- **Coordination** and **collaboration** key (in addition to funding)
- Current scale of investments is insufficient; need for **sustainable and predictable financing** (which is also **robust and resilient**; not impacted by external global negative events)
- **Push incentives are working** but they cannot serve the entire purpose alone
- **Need to build on** the experience of countries currently implementing **pull incentives**
- **Targets for new antibiotics** should be developed and abundantly informed by public health needs. Suggestions: Priority Indications List; better understanding of gaps and the desired ‘good pipeline’
- **Access** and **predictability in demand** are linked
- **Sustainable and equitable access** to antibiotics should be an integral part of all measures
- The **Global Leaders Group** on AMR has an important role to play; also in view of UNGA 2024
Deliberation 2 with Indian antibiotic developers | Aug 2023

**THE ANTIBIOTIC WEBINARS: 2**

**SMALL AND MEDIUM SCALE ANTIBIOTIC DEVELOPERS**
Challenges they face and the way forward

At a time when existing antibiotics are becoming ineffective, major pharma companies have vacated the new antibiotic R&D space. Small and medium antibiotic developers have taken up the responsibility instead.

**Date:** THURSDAY, AUGUST 24, 2023

**Time:** 4:15-5:45 PM (IST)

**Platform:** ZOOM

**SUNITA NARAIN**
Director General, CSE and Member, Global Leaders Group on AMR

**VASAN SAMBANDAMURTHY**
Senior Vice President, Global Operations, Bugworks Research India Pvt. Ltd.

**SACHIN BHAGWAT**
Senior Vice President, Drug Discovery, Wockhardt Research Centre

**T. S. BALGANESH**
President, GangaGen Biotechnologies Pvt. Ltd.

**JITENDRA KUMAR**
Managing Director, Biotechnology Industry Research Assistance Council (BIRAC)
Importance of non-financial measures highlighted

• Need to harmonise global regulatory aspects during clinical development and in approval stages for antibiotics
  • In areas such as scientific and technical requirements, study design/sampling, cohort recruitment
  • Benefits include favourable marketing conditions for early access, reducing duplication of clinical testing
• Adoption of accelerated approval pathways for antibiotics can spur innovation (such as in some countries)
• Strike a right balance while supporting antibiotic development project (between a viable and well differentiated product for a short-term and innovative drug for long-term)
• Nurturing and conserving the discovery talent for sustainable long-term innovation of antibiotics is a must
• Clinical trials for innovative drugs need to be supported (such as through access to networks, patients)
• Collaborations in antibiotic development are to be explored and leveraged (b/w academic institutes and pharmaceutical companies; b/w big companies and small developers)

Additionally, big funding depends on the scale of resistance problem at the local level
Deliberation 3 with global experts | Oct 2023

RECOGNISING ANTIBIOTICS AS A ‘GLOBAL PUBLIC GOOD’: CHALLENGES AND POSSIBILITIES

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The Pandemic Fund Secretariat, Washington DC, USA
About global public goods

- The concept of global public goods is not new, but presently there is a **renewed interest in this concept**
- The conventional definition of global public goods (based on non-rivalry, non-excludability) is **narrow** and has its **own challenges**
- There are discussions on **other concepts to approach public goods**: e.g., **common goods for health** (as per WHO; require both public financing and public action), **global functions** (supplying global public goods, managing cross border externalities like AMR response, and exercising leadership to address trans-national challenges)
- **Antibiotics do not fit the conventional definition** of global public goods. But there could be different dimensions or characteristics which could fit. (e.g., AMR containment, antibiotic effectiveness, knowledge regarding antibiotic development)

Additionally,

- **Global collaborative action** and global governance is crucial
- Need a **holistic approach to AMR containment**; too much focus on antimicrobial development would not be very useful as new antibiotics will also become ineffective soon
About funding,

- Existing financing models like the push and pull incentives have limitations when looked at from a ‘global public good’ perspective
  - For example, subscription models in 1-2 countries may not be effective unless supported by other countries. Antibiotics will remain a **regional or a national public good otherwise**
  - **Milestone prizes** will work in right conditions - **intellectual property rights shared** for greater access, affordability is ensured, supply is enough etc.
  - If companies and public sector are willing to share or license their compounds to push funders to take forward its development, the **territory provided** in case license is available
  - **Compulsory financing** at country level could also be explored, though there has not been much political appetite for it (e.g., innovative financing mechanisms such as global taxes, along the lines of the airline tax)
Thank you!
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