HKAPI
香港科研製藥聯會

The Future of Antimicrobials – Industrial Perspective

Sabrina Chan

Senior Executive Director

The Hong Kong Association of the Pharmaceutical Industry

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The Hong Kong Association of the Pharmaceutical Industry (HKAPI) members

Mission: **To drive the expedient access to innovative healthcare solutions for the people of Hong Kong and Macau with high ethical standard**

The Role of the Industry

Research and science

Invest in R&D to meet public health needs with new innovative medicine, diagnostics and vaccines

Effective access of medicine, diagnostics and vaccine

Combating AMR by addressing the continuum of care

(from prevention, surveillance, screening, to treatment)"

Promoting **appropriate use**

Reduce environmental impact when produce medicine

The Davos Declaration (Jan 2016)

100+ signatories (including pharma companies)

1. Work to reduce the development of antimicrobial resistance	2. Invest in R&D that meets global public health needs with new innovative diagnostics and treatments	3. Improve access to high-quality antibiotics and ensuring that new ones are available to all
Support appropriate use and improved stewardship	Invest in innovative antibiotics, vaccines, alternative technologies, and diagnostics	Ensure affordable access to new and existing antibiotics
Encourage infection control	Support research in academia and Small and Medium Enterprises on new and re-purposed antibiotics	Support programs to improve global access
Support the one health approach and responsible use	Support open collaboration between industry and public researchers	
	Develop new valuation mechanisms and commercial models with payers and policy makers	

Source: IFPMA

The Roadmap (Sep 2016)

- Signed by 13 leading pharma companies at the UN General Assembly high-level meeting on AMR

COMMITMENT 1

Reduce the environmental impact from the production of antibiotics

COMMITMENT 2

Help ensure antibiotics are used only by patients who need them

COMMITMENT 3

Improve access to current and future antibiotics, vaccines, and diagnostics

COMMITMENT 4

Explore new opportunities for open collaborations between industry and the public sector to address challenges in R&D

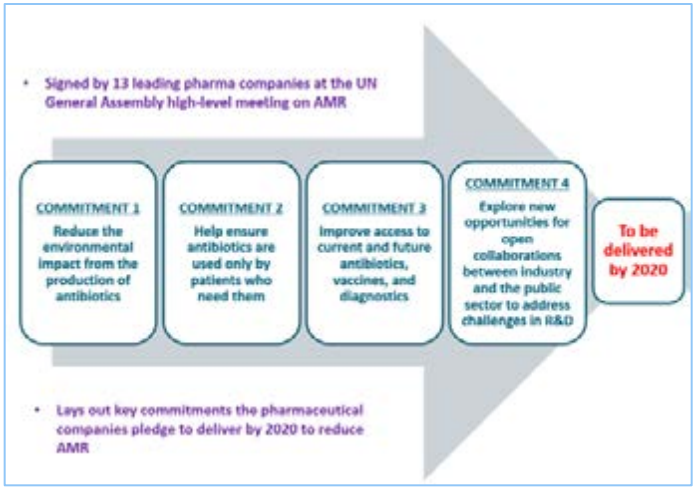
To be delivered by 2020

- Lays out key commitments the pharmaceutical companies pledge to deliver by 2020 to reduce AMR

The AMR Industry Alliance
(May 2017)

Davos Declaration

Industry Roadmap

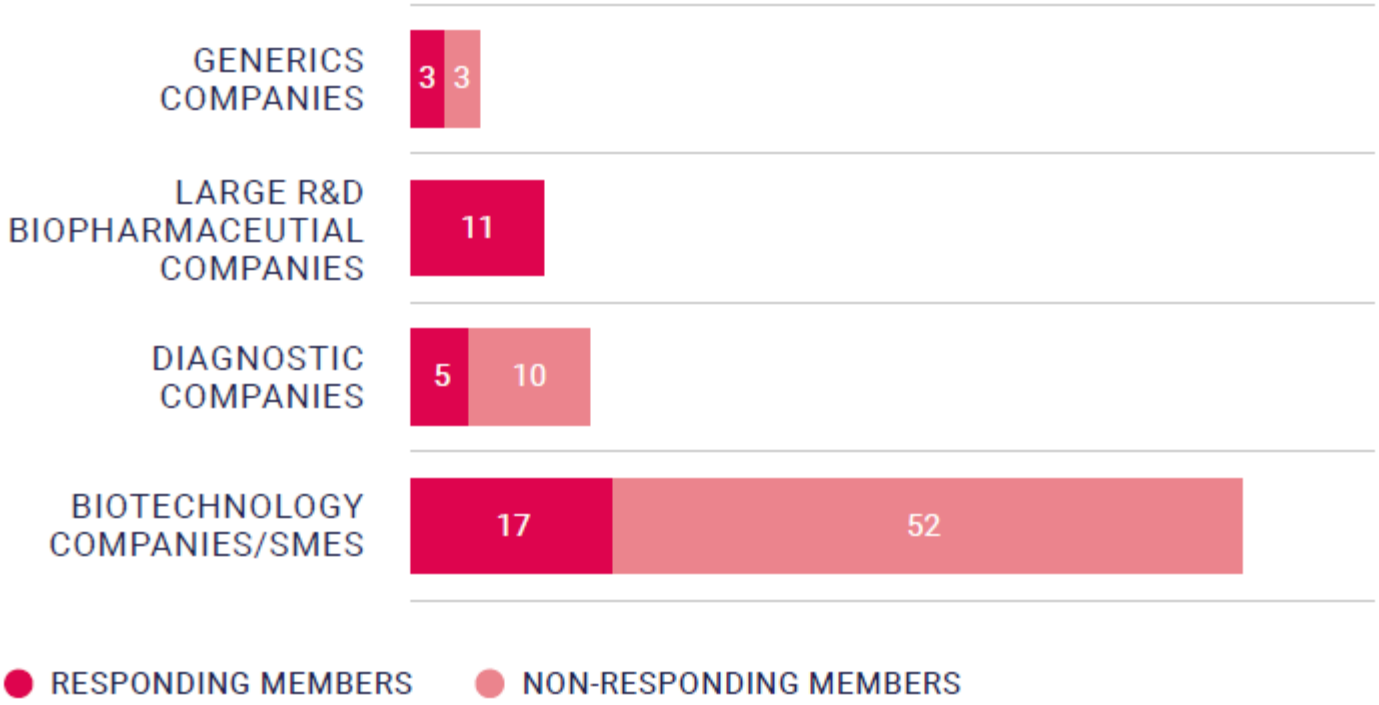


AMR Industry Alliance

- The largest private sector coalition to provide sustainable solutions to curb AMR with 100+ biotech, diagnostics, generics and research-based pharma companies joining forces to drive and measure the industry's progress in the fight against AMR;
- Hosted and supported by IFPMA;
- **To contribute & report on progress in four key areas: (1) Research & Science (2) Appropriate Use (3) Access (4) Manufacturing & Environment**
- The **first progress report** was launched **on 18 Jan 2018**.

AMR Industry Alliance
First Progress Report (Jan 2018)

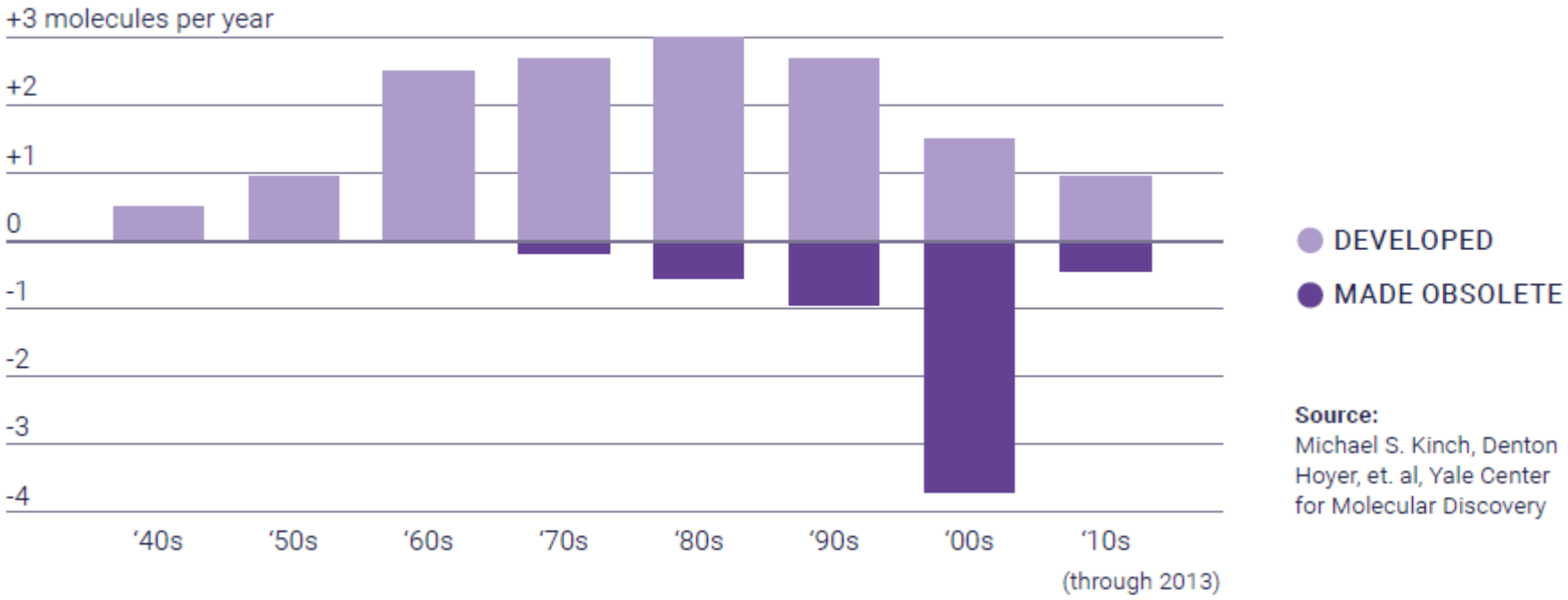
36% of Alliance member companies (36 of 101) responded to the survey on their AMR-relevant products.



BREAKDOWN OF ALLIANCE MEMBERS COMPANIES THAT RESPONDED TO THE AMR ALLIANCE INDUSTRY SURVEY BY SECTOR.

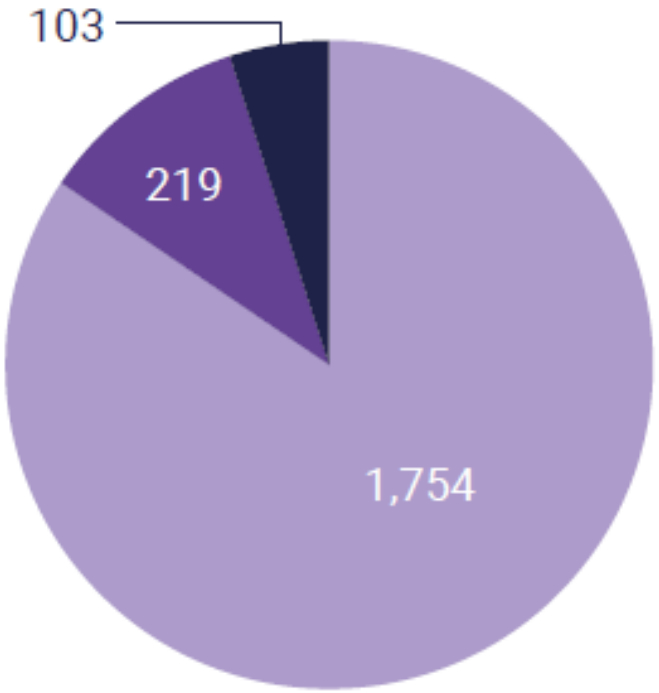
Progress: (1) Research & Science

Average new antibiotic molecules per year decreasing in the recent decades



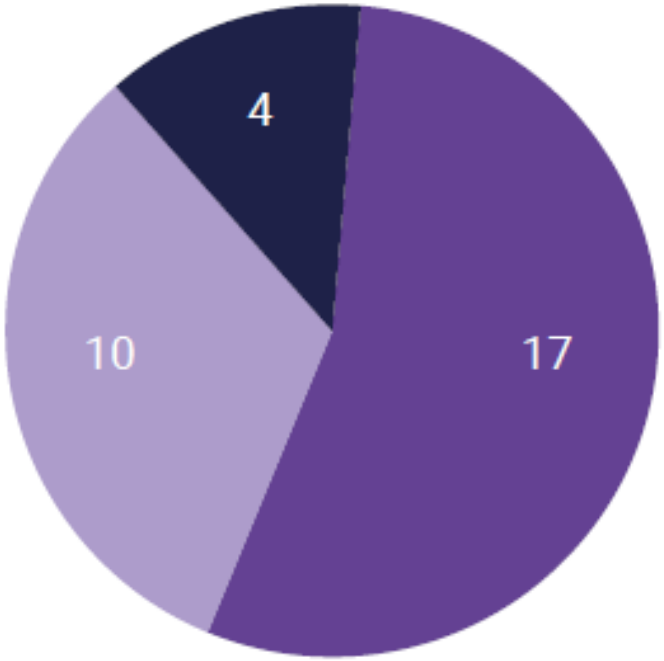
Source:
Michael S. Kinch, Denton Hoyer, et. al, Yale Center for Molecular Discovery

Progress: (1) Research & Science



In 2016, 22 Alliance companies invested at least USD 2 billion in R&D dedicated to AMR-related products.

Progress: (1) Research & Science



Of the 36 companies that responded to the AMR Industry Alliance survey, 31 are active in early-stage research and development to address AMR.

WWW.AMRINDUSTRYALLIANCE.ORG

Progress: (1) Research & Science

2 novel antibiotics brought to market since 2016.

COMPANY	ANTIBIOTIC	ACTIVITY AGAINST PRIORITY PATHOGENS	WHO PPL PRIORITY	CDC URGENT THREAT LIST
The Medicines Company	Vabomere™ (vaborbactam + meropenem)	Carbapenem-resistant *Enterobacteriaceae* (CRE)	Critical	Urgent
Melinta Therapeutics Inc.	Baxdela™ (delafloxacin)	Acute bacterial skin and skin structure infections	High and medium	Serious

Progress: (1) Research & Science

9 antibiotics in Phase II or later development reported by responding companies.

COMPANY	ANTIBIOTIC (DEVELOPMENT PHASE)	EXPECTED ACTIVITY AGAINST PRIORITY PATHOGENS	WHO PPL PRIORITY	CDC URGENT THREAT LIST
Achaogen	Plazomicin (PIII)	CRE	Critical	Urgent
Actelion	Cadazolid (PIII)	*Clostridium difficile*	*Not included in WHO PPL*	Urgent
Entasis Therapeutics	Zoliflodacin (PII)	*Neisseria gonorrhoeae*	High	Urgent
GSK	Gepotidacin (PII)	*Escherichia coli* and *N. gonorrhoeae*	Critical and high	Urgent
Merck & Co., Inc.	Imipenem/cilastatin + relebactam (PIII)	CRE and carbapenem-resistant *Acinetobacter baumannii* (CRAB)	Critical	Urgent and serious
Nabriva	Lefamulin (PIII)	Acute bacterial skin and skin-structure infections	High and medium	Serious
Pfizer, Allergan	Aztreonam + avibactam (PII)	CRE	Critical	Urgent
Shionogi	Cefiderocol (PIII)	CRE, CRAB, *carbapenem-resistant Pseudomonas aeruginosa* (CRPA)	Critical	Urgent and serious
Tetraphase Pharmaceuticals	Eravacycline (PIII)	CRE, CRAB, carbapenem-resistant *Pseudomonas aeruginosa* (CRPA)	Critical	Urgent and serious

Progress: (1) Research & Science

Highlight of vaccines in Phase I or later development reported by responding companies:

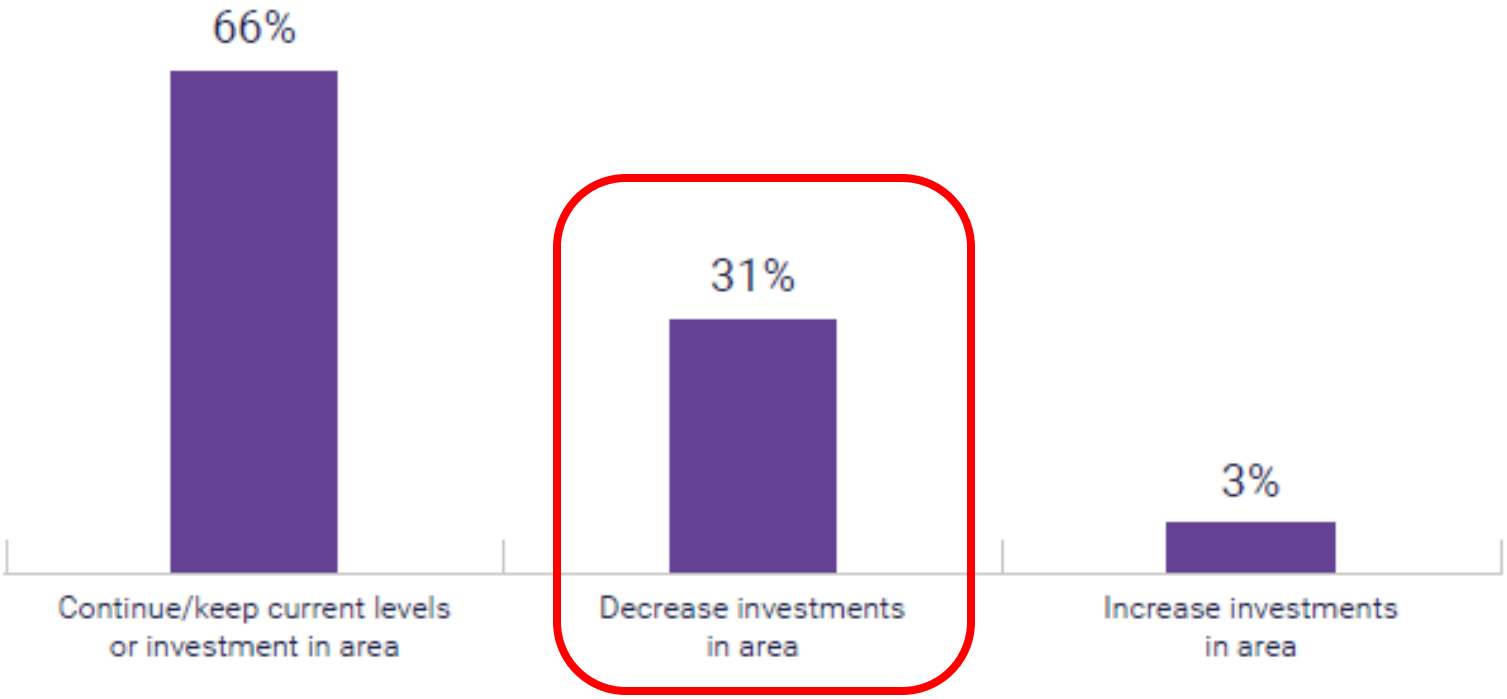
COMPANY	PHASE OF VACCINE CANDIDATE	EXPECTED PROTECTION AGAINST PRIORITY PATHOGENS	WHO PPL PRIORITY	CDC URGENT THREAT LIST
GSK	PII	Tuberculosis	Global priority	Serious threat
Merck & Co., Inc.	PII	*Streptococcus pneumoniae*	Medium	Serious
NovaDigm Therapeutics, Inc.	PI	*Staphylococcus aureas*	High	Serious
Pfizer	PI	*S. pneumoniae*	Medium	Serious
Pfizer	PII	*S. aureas*	High	Serious
Pfizer	PIII	*C. difficile*	*Not included in WHO PPL*	Urgent
Sanofi	PII	Tuberculosis	Global priority	Serious threat

Progress: (1) Research & Science

- **In summary, responding companies reported:**
  - **10 antibiotics with activity against WHO priority 1 or 2 pathogens/CDC Urgent or Serious threats**
  - **13 AMR-relevant vaccine candidates**
  - **18 AMR-relevant diagnostic products**

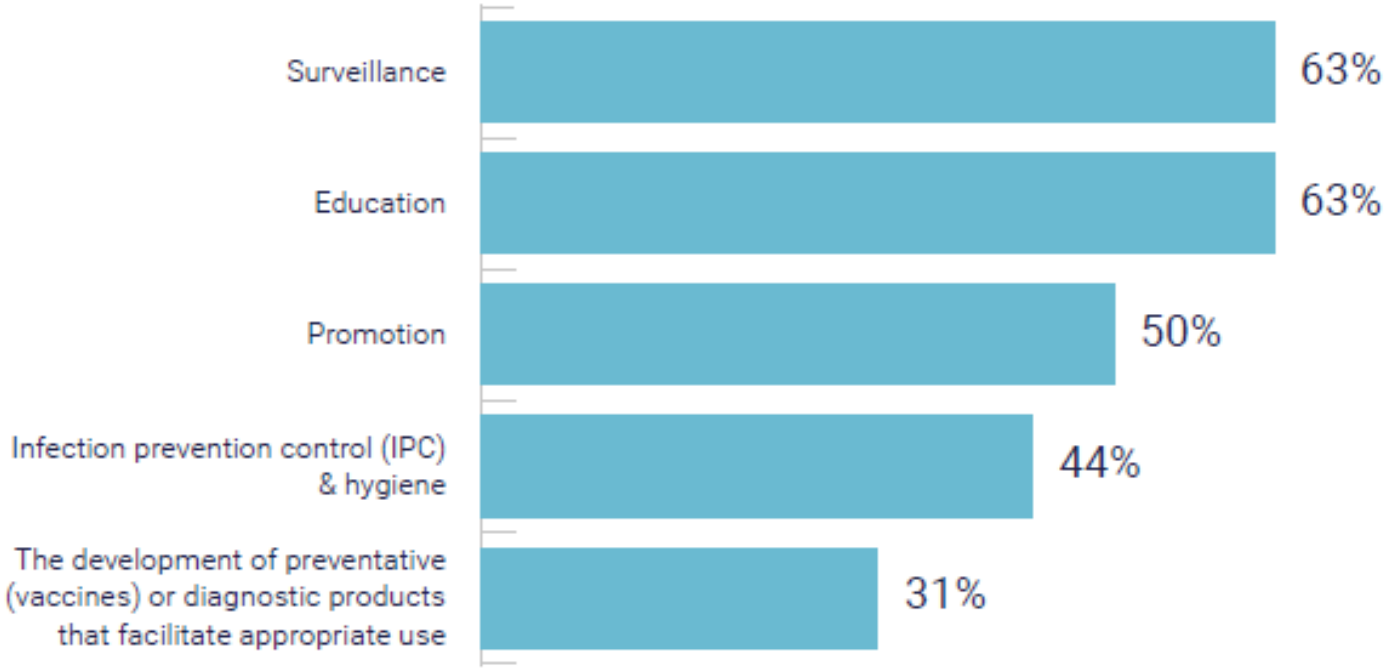
Progress: (1) Research & Science

How proportions of responding companies with AMR-relevant R&D will respond if valuation mechanisms and commercial models remain as they are (total: 29):



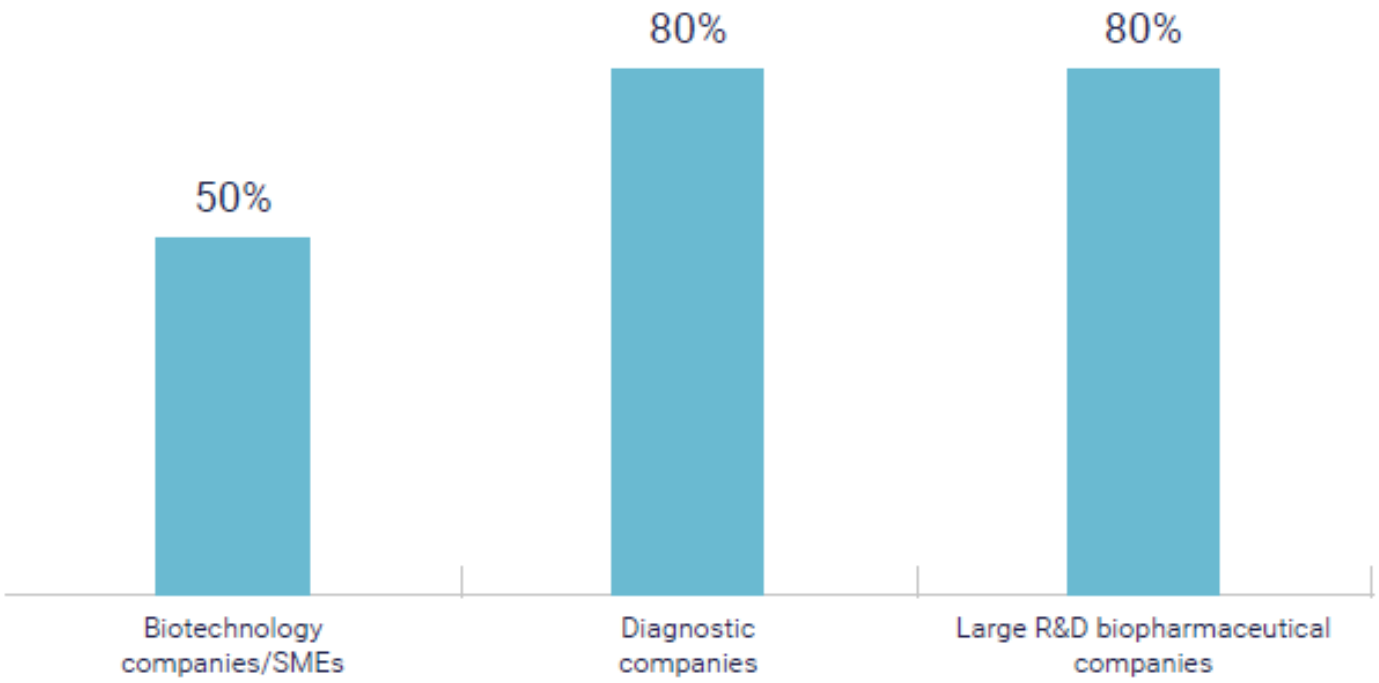
Progress: (2) Appropriate Use

The appropriate use strategies companies have in place or in development take a multifaceted approach and cover many aspects of appropriate use (total: 16):



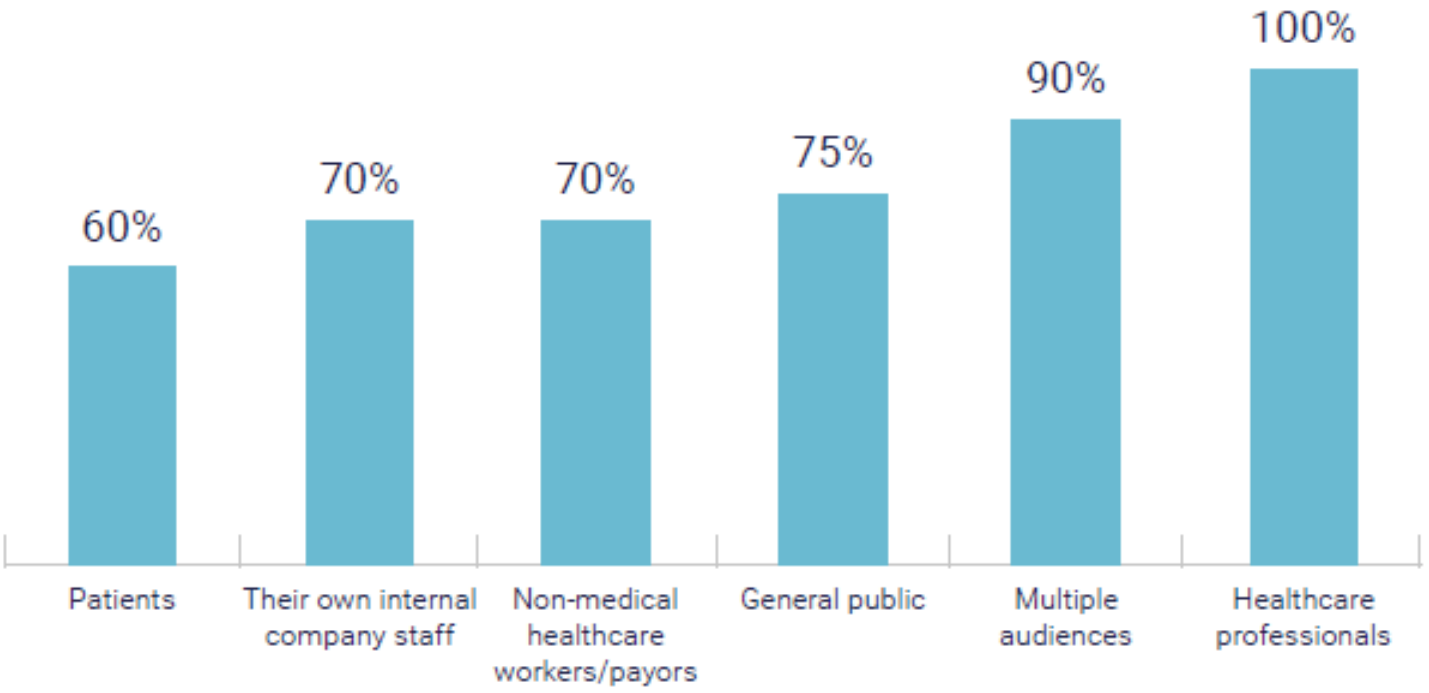
Progress: (2) Appropriate Use

Proportion of companies, by sector, currently collecting or supporting the collection of surveillance data (total: 35):



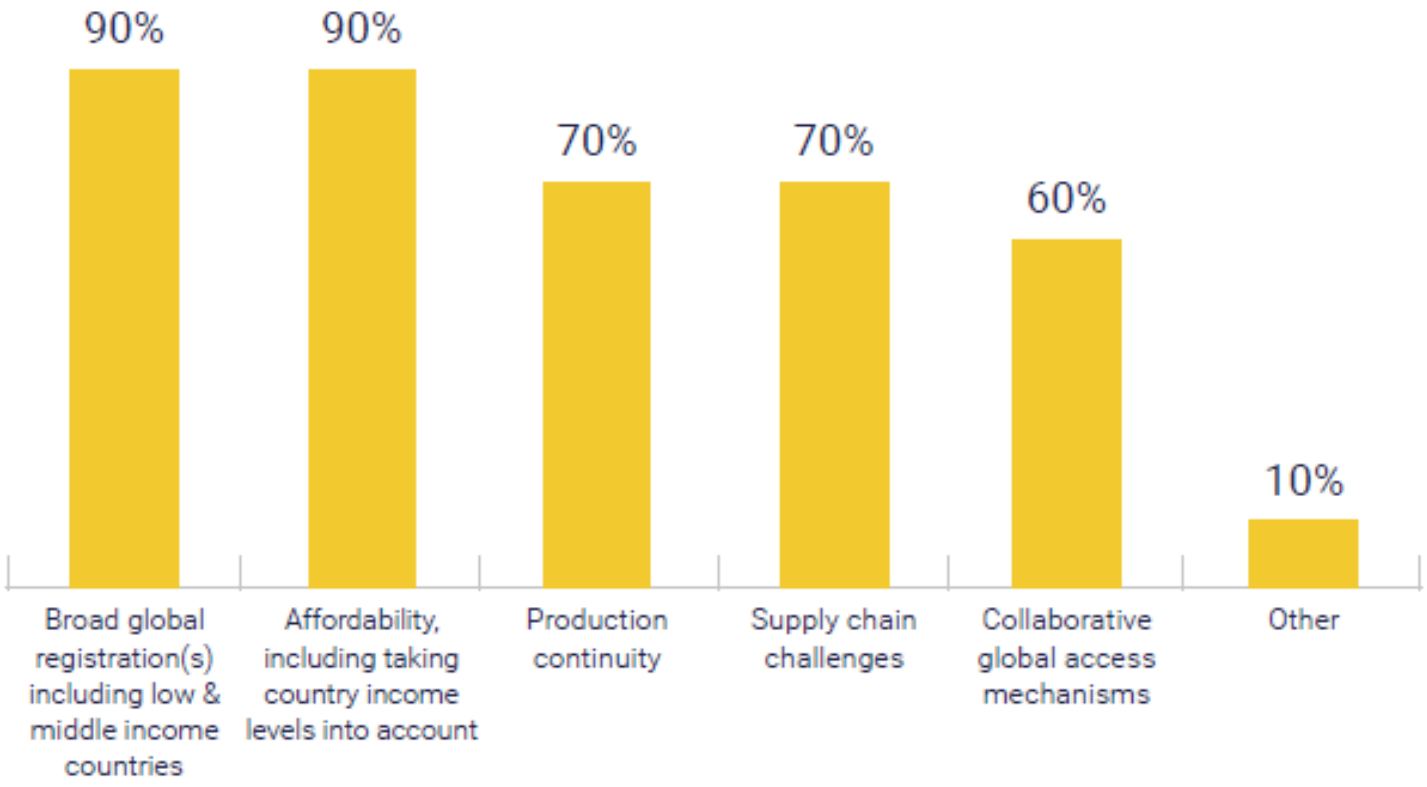
Progress: (2) Appropriate Use

Proportion of responding companies engaging in education with external stakeholders (total: 20):



Progress: Access

Proportion of responding companies' access plans, strategies or policies for patented antibiotics featuring these aspects (total: 10):

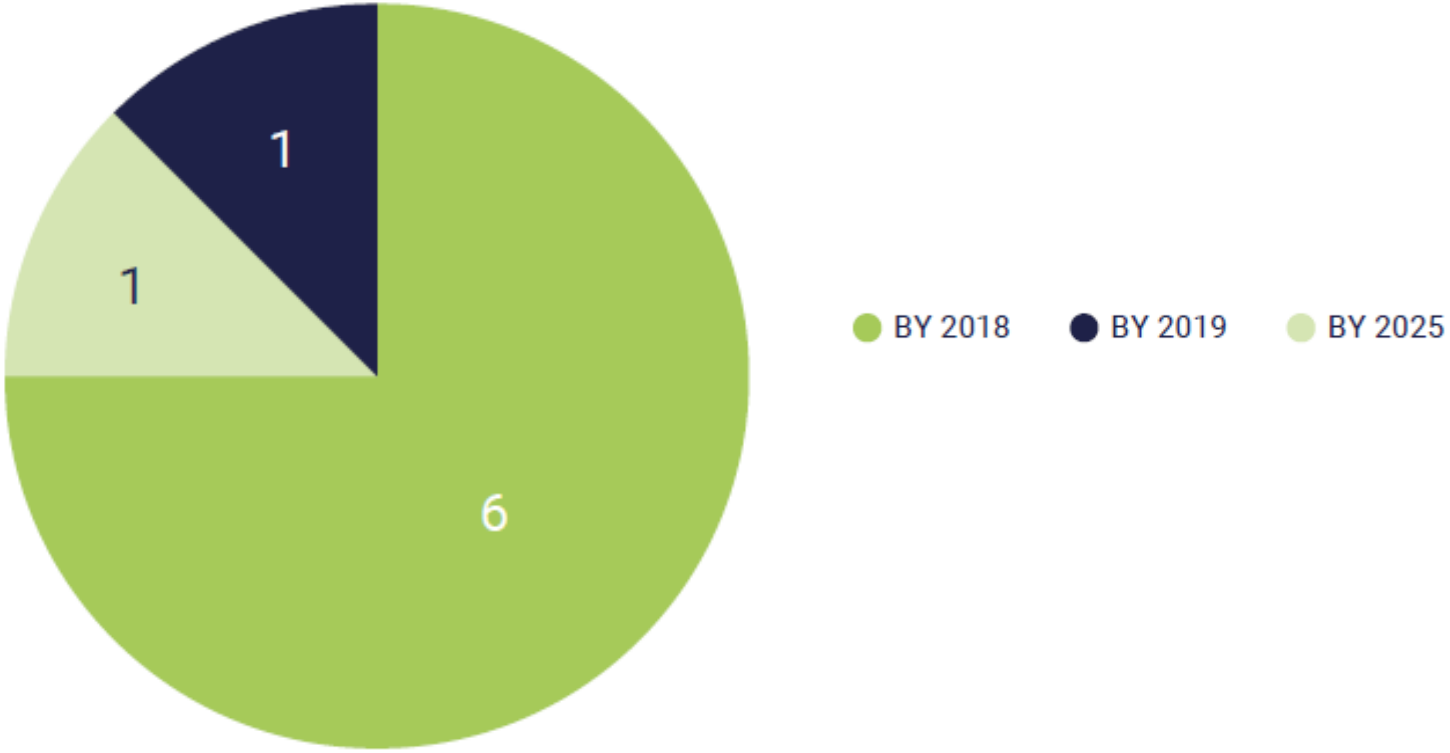


Progress: (4) Manufacturing & Environment

Proportion of responding companies (total: 8) implementing specific activities relating to reducing the environmental impact from production of antibiotics:

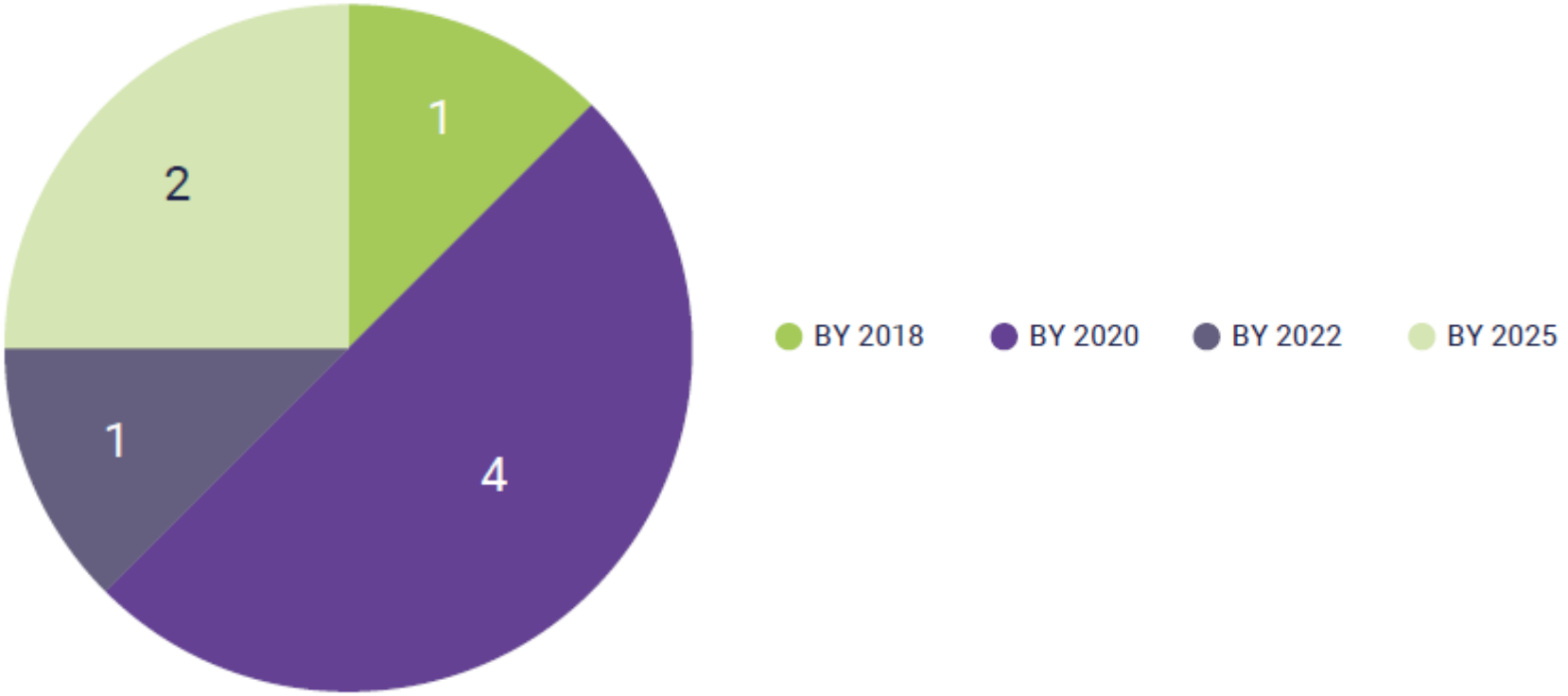
Progress: (4) Manufacturing & Environment

Proportion of responding companies (total: 8) that plan to implement good practice methods to reduce the environmental impact of manufacturing discharge by 2018, 2019 and 2025:



Progress: (4) Manufacturing & Environment

Proportion of responding companies (total: 8) that anticipate committing to discharge concentration targets 2018, 2019, 2022 and 2025:



Latest update on (4) Manufacturing & Environment

- In September 2018, the Alliance generic and research-based pharma companies took a further step by publishing **the first list of discharge targets** to guide environmental risk assessments for the manufacture of antibiotics.

Antibiotic Development Presents Significant Challenges

SCIENTIFIC

Bacteria are resilient and constantly evolving

Narrow “therapeutic window”

DEVELOPMENT & REGULATORY

Complex regulatory pathways

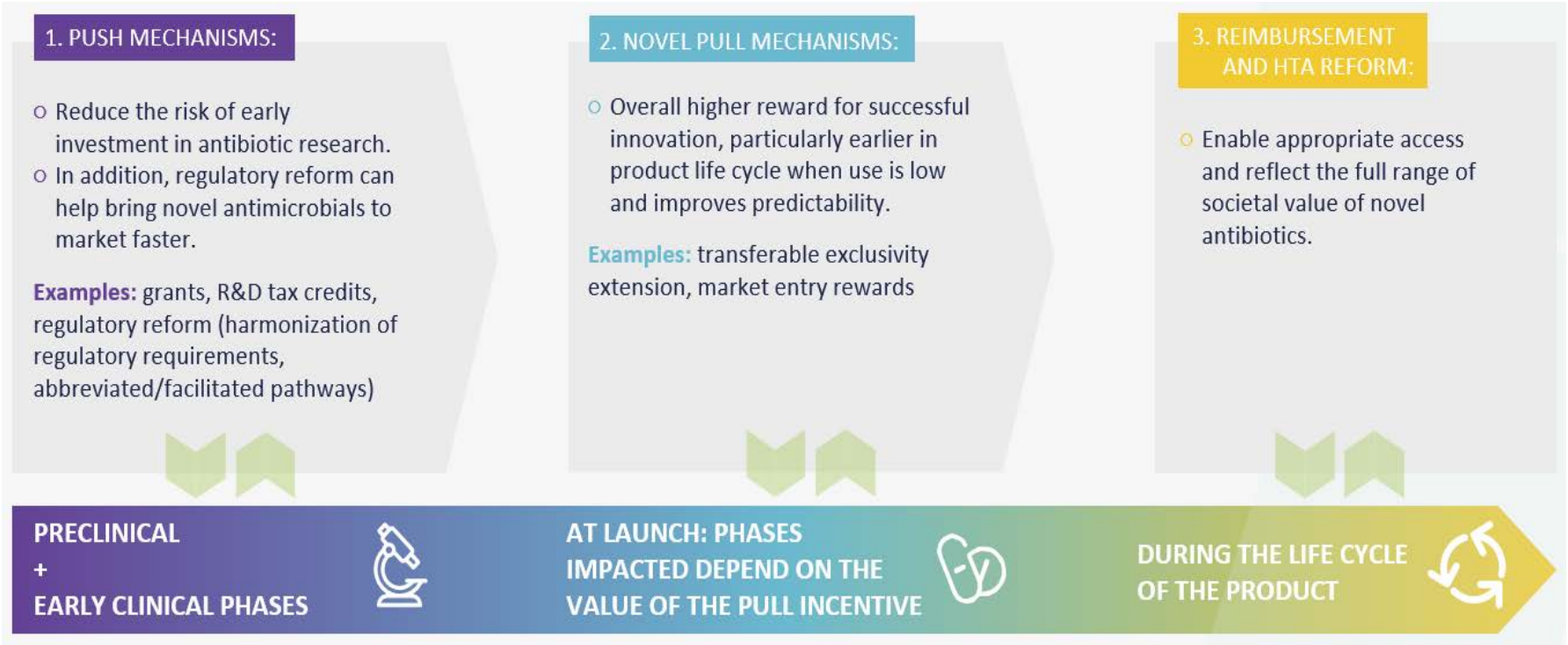
“Non-inferiority” clinical trials

ECONOMIC

Limited returns relative to other therapeutic areas

Source: IFPMA

A suite of incentives is urgently needed to support sustainable investment in R&D



Source: IFPMA

Case Study – SIRTURO® (bedaquiline)

- To address the threat posed by drug-resistant tuberculosis, SIRTURO of Johnson & Johnson (through its Janssen Pharma Companies) received accelerated approval by the US FDA at the end of 2012 for the treatment of multi-drug resistant TB. Conditional approval in the EU came in 2014.
- R&D spanned nearly two decades and involved 15 clinical trials, SIRTURO® represented the first new mechanism of action for TB treatment in more than 40 years
- Lesson learnt:
  - Regulatory mechanisms like the accelerated approval process
  - Collaboration: regulators and key stakeholders in high incidence countries created new paradigms to allow the country's participation in studies with an investigational TB agent
  - Required partnership, from development all the way through launch and roll-out, SIRTURO was aided by a range of partners across sectors, including USAID, the STOP TB partnership, the Bill & amp, Melinda Gates Foundation, Pharmstandard, the International Union Against Tuberculosis and Lung Disease, the TB Alliance and more

Call to Action

Within the last two years, several large pharmaceutical and many biotechnology companies have exited this space due to the scientific, regulatory, and economic challenges.

Current economic incentives focus on push and regulatory; pull incentives have been discussed but never implemented.

Governments need to implement new and alternative market structures that provide more dependable and sustainable market models for antibacterials. Given the fragility of the market, there is an immediate need to act.

Source: IFPMA

Alliance's next steps

- **Actively support member companies in filling in the gaps ahead of the next update, including:**
  - greater outreach to non-responding companies
  - greater efforts to share best practices and supporting materials

- **Work with stakeholders to better understand what steps industry needs to take to impact the most critical areas**

- **Next progress report will be published in 2020 (every 2 years)**

Local Support from industry

Prevention	•Encourage widespread implementation of vaccination programmes •**medical diagnostics**
Promote appropriate use	• **Provide funding for doctors and patient in education and training**
Encourage R&D	• **Providing funding for local universities in relevant clinical research projects**
Effective access	• **Accelerated pathways for regulatory approval for** new antibiotics, vaccines and diagnostics to the market

THANK YOU

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