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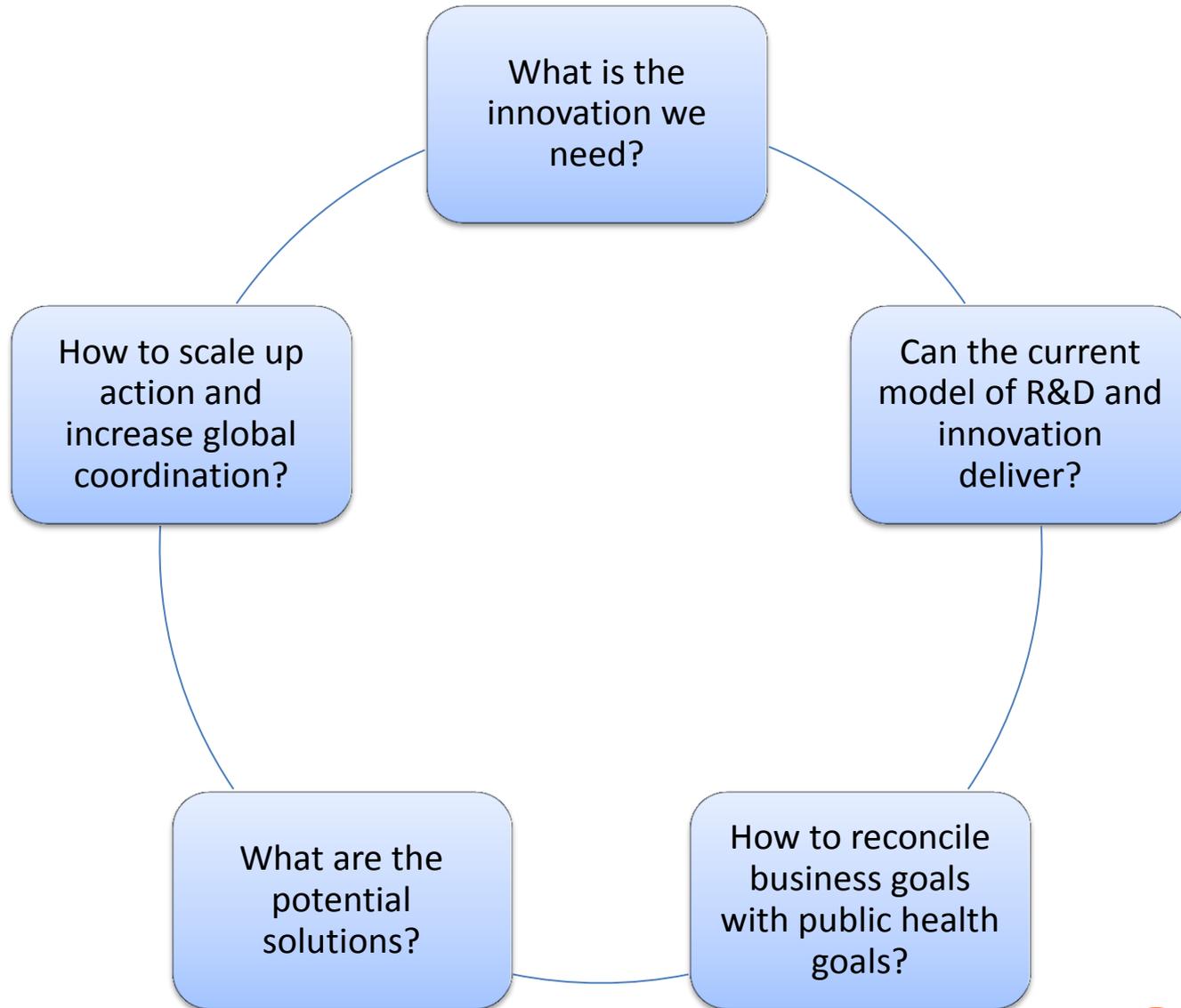
Promoting Innovation in New Antimicrobial Medicines, Vaccines, and Diagnostics

WIPO, WHO, WTO Joint Technical Symposium on Antimicrobial Resistance

25 October 2016

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Business perspective

- Priorities for R&D and innovation driven by commercialization potential
- Uncertainty of future returns of business R&D investment
- Complexity and cost of breakthrough innovation
- Marginal improvements over existing products can be profitable
- Increased R&D outsourcing, in-licensing and collaborations
- Reduced R&D efficiency compensated by increase in the financial value new blockbuster products launched



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Business perspective

- Pricing strategy designed to maximize profits
- Pricing freedom in key markets backed by patent and other market monopoly rights enables pricing strategy, key for blockbusters
- Sales volumes increase marginal revenues
- Marketing used to increase sales volumes
- Mergers, acquisitions and consolidation as growth strategy
- Access to finance is particularly critical for SMEs



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Public Health perspective

- Realization of the right to health remains distant goal
- Significant unmet health needs
- Rising costs of health care
- Products often unaffordable or inappropriate to meet needs
- Insufficient or misplaced business R&D investment. Few breakthroughs at high price
- Lack of information on private R&D costs and sharing of clinical trial data
- Government scarce resources require control of pricing and reimbursement
- Complexity of price negotiations due to asymmetrical information and bargaining power
- Insufficient to rely on firm voluntary licensing and differential pricing



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Public Health perspective

- Public and private resources and R&D capacities can be pooled to support needs-driven R&D – shared responsibility
- Need for fair social returns to public funds invested in R&D
- Regulation is necessary to ensure therapeutic value, quality and safety of products
- Patent and other exclusive rights may pose barriers to availability and affordability of products and delay entry of genetic competition
- Governments should make use of TRIPS flexibilities and facilitate generic entry to market for affordable access

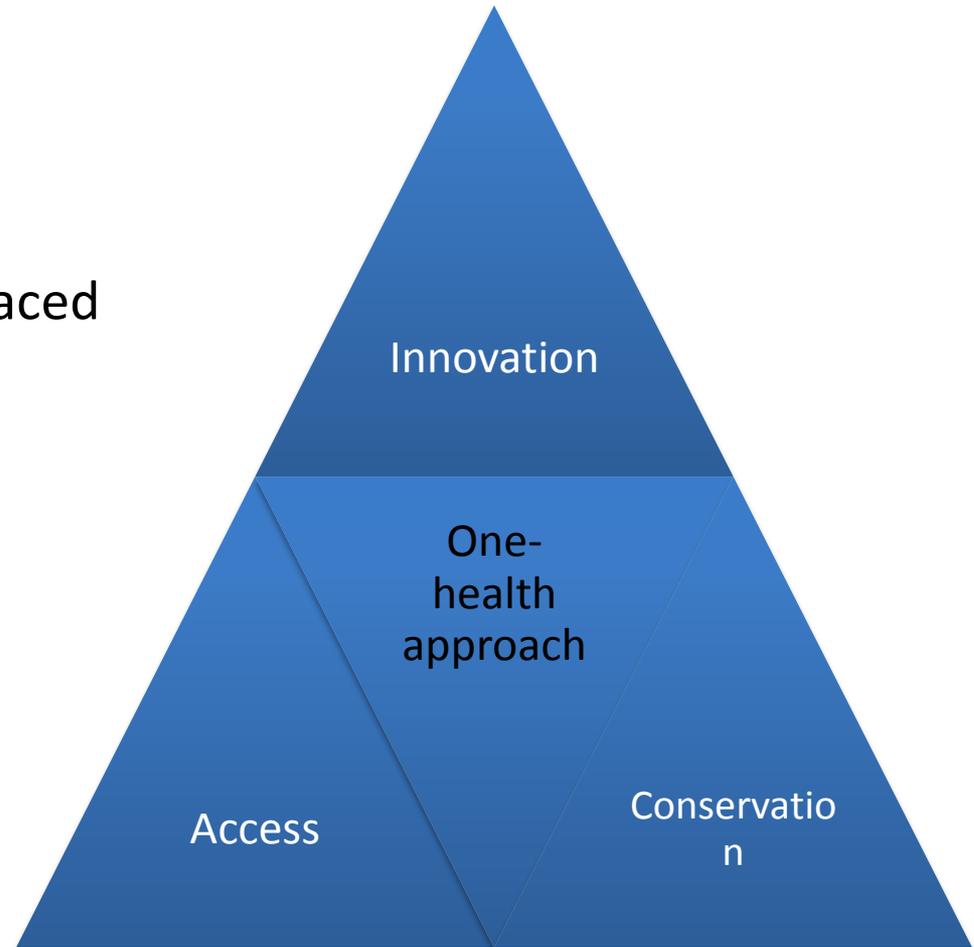


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Challenges in AMR

- Rise of resistance has outpaced innovation
- Lack of access
- Misuse and overuse



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An Enabling Innovation Ecosystem

1. Global perspective
2. Set priorities for R&D based on health needs
3. Delink pay of R&D from product high prices and sales volume - sustained financing and effective incentives
4. Appropriate intellectual property management
5. Transparency on true R&D costs, public funding received by all stakeholders, clinical trial data, patent information
6. More global collaboration and knowledge sharing



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Guiding Elements for Action

WHO

- Global Strategy and Action Plan on Public Health, Innovation and Intellectual Property, 2015-2022
- Global Action Plan on Antimicrobial Resistance, May 2015
- Follow up to the Report of the Consultative Expert Working Group: Financing and Development, May 2015

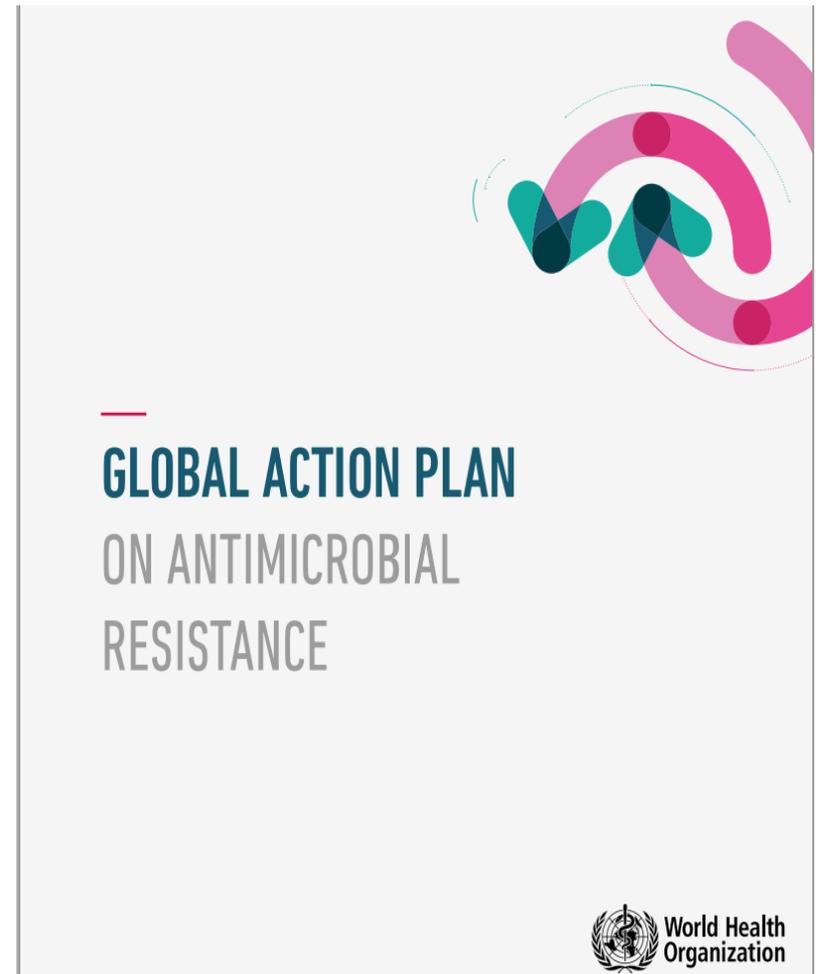
United Nations

- Human Rights Council Resolution on Access to Medicines, June 2016
- Political Declaration of the High-Level Meeting of the UNGA on Antimicrobial Resistance, September 2016
- SG High Level Panel on Access to Medicines, September 2016

Global Action Plan on AMR

2015

- Increase investment in new medicines, diagnostics tools, vaccines and other interventions
- The cost of investment in R&D may need to be delinked from price and volume of sales to facilitate equitable and affordable access to new medicines, diagnostic tools, vaccines and other results from R&D in all countries.



http://www.wpro.who.int/entity/drug_resistance/resources/global_action_plan_eng.pdf

Follow up to the Report of the CEWG: Financing and Coordination

WHA 69.23

- Health research and development should be needs-driven and evidence-based and be guided by the following core principles: affordability, effectiveness, efficiency and equity; and it should be considered a shared responsibility
- Promote policy coherence within WHO on its R&D related activities in terms of application of the core principles and the objective of de-linkage identified in resolution WHA66.22.
- The WHA in May 2017 will consider convening another open ended meeting of member states in order to assess progress and continue discussion on the remaining issues in relation to monitoring, coordination and financing for health R&D

UNHCR Resolution on Access to Medicines 32/L.23

- Recalls the GAP PHI and commends the efforts of the WHO to fill gaps in health R&D for the relevant needs of developing countries through the follow up to the report of the CEWG
- Reiterates that health R&D should be needs-driven, evidence-based, guided by the core principles of affordability, effectiveness, efficiency and equity, and considered a shared responsibility
- Calls upon States to continue to collaborate on models and approaches that support the delinkage of the costs of new R&D from the prices of medicines, vaccines and diagnostics for diseases that predominantly affect developing countries
- Panel discussion to exchange experiences and practices in first-half 2017 and report for discussion to the HRC 36th session

Political Declaration of the High-Level Meeting of the UNGA on AMR

21 September 2016

- All research and development efforts should be needs-driven, evidence-based and guided by the principles of affordability, effectiveness and efficiency and equity, and should be considered as a shared responsibility:
- We acknowledge the importance of delinking the cost of investment in research and development on AMR from the price and volume of sales so as to facilitate equitable and affordable access to new medicines, diagnostic tools, vaccines and other results to be gained through research and development,
- All relevant stakeholders, including Governments, industry, non-governmental organizations and academics, should continue to explore ways to support innovation models that address the unique set of challenges presented by antimicrobial resistance, including the importance of the appropriate and rational use of antimicrobial medicines, while promoting access to affordable medicines

Political Declaration of the High-Level Meeting of the UNGA on AMR - 2

21 September 2016

- Call upon the World Health Organization, together with FAO and OIE to finalize a global development and stewardship framework to support the development, control, distribution and appropriate use of new antimicrobial medicines, diagnostic tools, vaccines and other interventions, while preserving existing antimicrobial medicines, and to promote affordable access to existing and new antimicrobial medicines and diagnostic tools, taking into account the needs of all countries and in line with the global action plan on antimicrobial resistance.
- Request the Secretary-General to establish, in consultation with the World Health Organization, the Food and Agriculture Organization of the United Nations and the World Organization for Animal Health, an ad hoc inter-agency coordination group to provide practical guidance for approaches needed to ensure sustained effective global action to address antimicrobial resistance, including on options to improve coordination.

Other High Level Commitments

G-7 Declaration of Health Ministers 2015

Need for greater interaction and synergies of research initiatives. Need for global access to – and availability, affordability and rational use of safe, effective, quality assured antimicrobials. Support a global antibiotic development partnership for product development new antibiotics, vaccines, alternative therapies and rapid care diagnostics. Explore innovative economic incentives, such as a global antibiotic research fund and a market entry reward mechanism for new antibiotics.

G20 Leaders' Communique Hangzhou Summit - 4-5 September 2016

We affirm the need to [...] unlock research and development into new and existing antimicrobials from a G20 value-added perspective, and call on the WHO, FAO, OIE and OECD to collectively report back in 2017 on options to address this including the economic aspects. In this context, we will promote prudent use of antibiotics and take into consideration huge challenges of affordability and access of antimicrobials and their impact on public health.

8th BRICS Summit – Goa Declaration 16 October 2016

We emphasize the importance of cooperation among BRICS countries in promoting research and development of medicines and diagnostic tools to end epidemics and to facilitate access to safe, effective, quality and affordable essential medicines.

G-77 Declaration on the HLP on AMR – 21 September 2016

We must support, as a matter of urgency, research and development of antimicrobials, especially new antibiotics, vaccines, diagnostic tools and innovation, including in traditional and herbal medicine. This must be done while ensuring that R&D efforts are needs-driven, evidence-based, and a shared responsibility. These efforts must be guided by the core principles of affordability, effectiveness, efficiency, and equity through delinking research and development costs from prices and sales volume. The Group of 77 and China is pleased to see this delinkage principle underlined in the Political Declaration.

UN SG High Level Panel on Access to Medicines

Findings / Recommendations :

- Market-based models of AMR are unsustainable
- Funding for R&D to address AMR and related challenges must be operationalized through delinkage models
- Governments should increase their investment in health technology innovation to address unmet needs
- Stakeholders should test and implement new and additional models for financing and rewarding public health R&D

<http://www.unsgaccessmeds.org/final-report/>

UN SG High Level Panel on Access to Medicines

- The UN SG should initiative a process for governments to negotiate global agreements on the coordination, financing and development of health technologies.
- Start negotiations for a binding R&D Convention that delinks the costs of R&D from end prices to promote access to good health for all.
- The Convention should focus on public health needs, including but not limited to, innovation for neglected tropical diseases and AMR and must complement existing mechanisms.
- Negotiate a Code of Principles for biomedical R&D. These principles would apply to public R&D funds and should be adopted by private and philanthropic funders, PDPs, universities, the biomedical industry and other stakeholders. Governments should report annually on their progress as a preparatory step to negotiating a Convention in the UNGA.

De-linkage

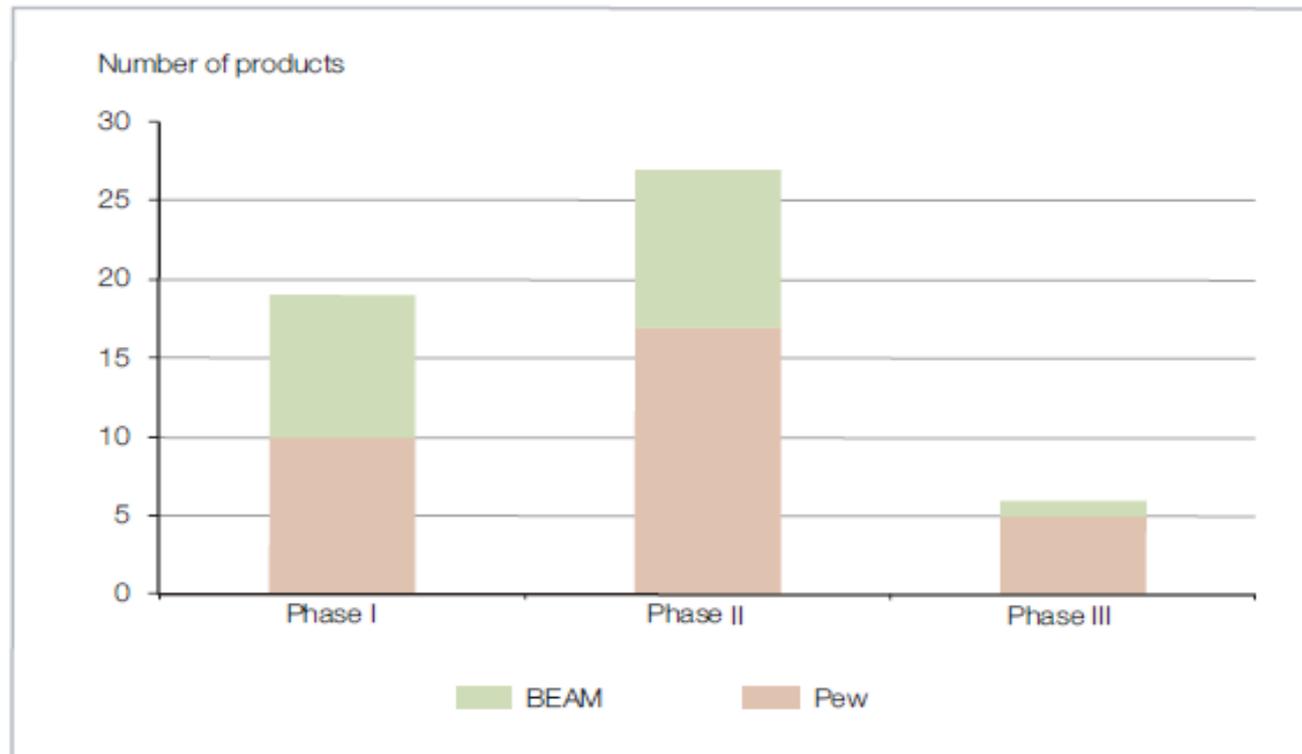
- Break link between funding / rewarding R&D, high prices and sales
- Create incentives to enable stakeholder participation
- Promote collaboration and knowledge sharing
- Do not allow patent and other market monopoly rights over products

LSE - WHO Review of European and International Initiatives to support innovation in antibiotics

- Antibiotic conservation and patient access objectives are poorly integrated into the existing innovation schemes.
- Many initiatives have not explicitly linked their incentives to high-priority medical needs in infectious disease.
- Unequal distribution of incentives across the antibiotic value chain favours basic research and drug discovery.
- Current incentives underserve SMEs

How aligned is the current pipeline with global priority needs?

Figure 14 Partial picture of the current development pipeline of antibiotics and related products



Note: Compiled from data provided by the Pew Charitable Trusts and the BEAM Alliance.^{15,17}

Figure 12 Distribution of incentives used by antibiotic R&D initiatives

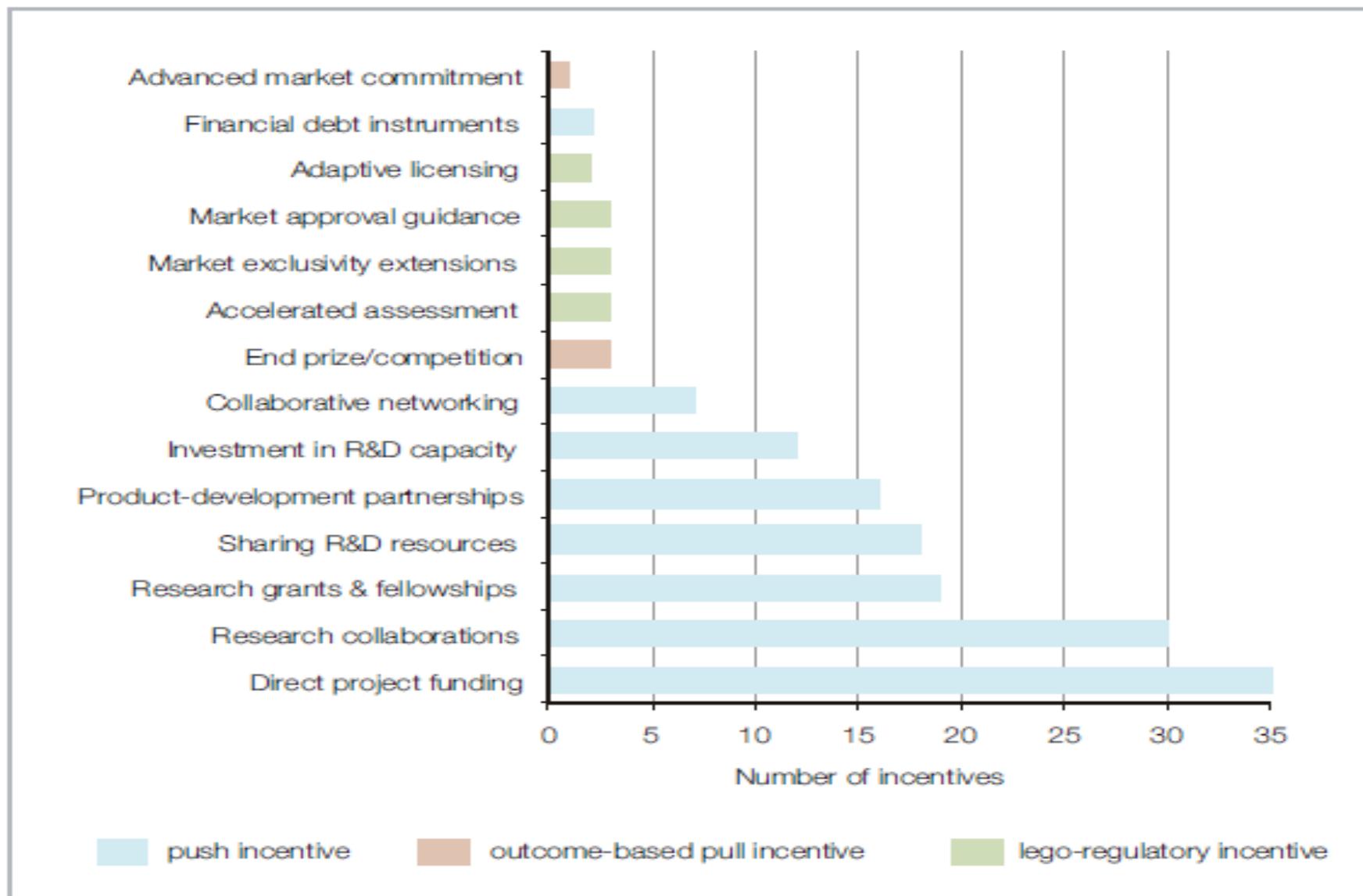
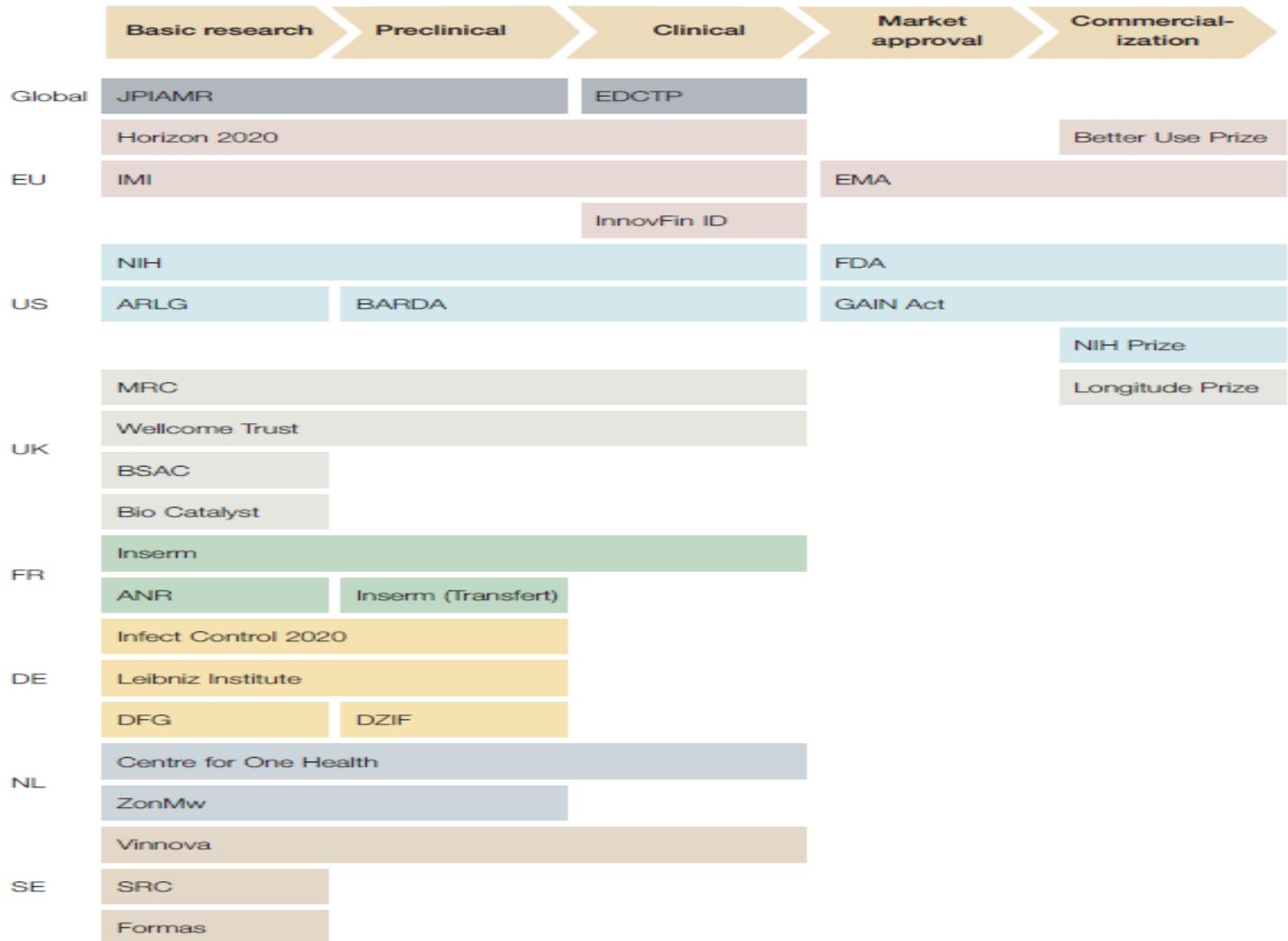


Figure 15 Distribution of international, EU and selected European national antibiotic R&D initiatives across the antibiotic value chain



Conclusions

- There is recognition of the failures of current biomedical innovation system and that promoting R&D and innovation to address health needs is a global challenge
- Agreed approach: delinkage of R&D costs from high prices
- Additional challenge in AMR: conservation – also delink R&D from sales volumes
- Variety of initiatives, increasing public R&D investment, diversity of pull-push mechanisms and partnerships. Need to integrate needs-based priority setting, affordability and conservation goals.

Conclusions

- One model of needs-driven biomedical innovation, based on agreed principles, supported by various initiatives and incentive mechanism
- Need to establish global framework to set R&D priorities, promote coordination among initiatives, guide R&D initiatives to implement agreed principles –affordability-, mobilize and pool resources to ensure sustainability, harness and build R&D capacities, promote transparency and inclusiveness
- Pay attention to the design of delinkage mechanisms
 - Priority setting
 - Eligibility criteria
 - Transparency, monitoring
 - Intellectual property management to ensure it is not barrier to affordability and collaboration

Thank you!

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