Categories and Definitions

At launch, the aim of the presented information in the Dynamic Dashboard´s Incentive Gallery is on capturing, displaying and tracking currently implemented incentives, worldwide, with the potential to improve the functioning of markets – and the broader R&D ecosystem – responsible for the development and distribution of therapeutics for the treatment of priority, human, bacterial infections.

The exclusion criteria are to ensure – in the absence of output or impact data – the focus of our incentive capture remains on those activities with the potential to have more than a narrow, local or transient impact. We will work towards fostering a long-term, sustainable, R&D ecosystem.

The scope and definitions provided below represent this initial focus.

Categories have been developed, that represent targets for incentives or incentive strategies, along the value-chain from discovery to consumption.

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1. Incentives in Scope

Any currently implemented or trialled activity with the potential to improve the functioning (efficiency, productivity) of the R&D ecosystem responsible for the development and distribution of therapeutics for the treatment of priority, human, bacterial infections.

The activities could include but are not limited to:

- Direct financial support, through a dedicated or majority-focused financing tool/stream
- Dedicated initiatives, structures, organizations, networks or activities with an AMR product R&D relevant mandate (in part or full)
- Legislative or regulatory actions that have been ratified into law

2. Supporting definitions:

• **Push incentive** (covers categories 01-04):
Input-based; push mechanisms target current work and reduce a developers cost & risk of researching and developing new drugs either by lowering the costs, decreasing the barriers to participation or by sharing the costs/risks across multiple parties.

• **Pull incentive** (covers categories 05-09):
Output-based; rewarding the successful development of a drug by increasing or ensuring future revenue. Can be achieved through market-making (financial) tools or market-shaping (lego-regulatory policies) rewards.

• **R&D ecosystem**:
Public and private product developers including the R&D context or facilitatory environment in which they conduct their work. Includes actors, collaborations, infrastructures, lego-regulatory frameworks, institutions and competencies.

• **Priority infections**:
Human bacterial infections considered a current or emerging public health priority as defined by the WHO´s priority pathogen list.

3. Exclusion criteria

Information will not be collected for incentives on:

- Policy proposals, discussions, draft legislation or legislation in development/revision
- Single or *ad hoc* financial awards that do not present the possibility for a sustained impact
- Activities that are very-narrow in their focus such as those targeting a specific/single indication, syndrome, product or trial
- Non-dedicated or majority-earmarked activities (for investments these are captured by our investment gallery)
- One-off or time-limited interventions (less than 5 years)
- Tax-based incentives
- Interventions specifically targeting the tuberculosis (TB) market
- Interventions targeting non-human or non-therapeutic product markets
- Sub-national (state-level) interventions

4. Categories

Our launch categories have been created to represent targets, or strategies, for incentives along the value-chain. As much as possible, these try to be mutually exclusive and encompass all incentives that may conceivably be implemented now and in the future. As with all taxonomies categorization can sometimes be an artificial exercise that will fit some incentives better than others.

1. Supporting early-stage R&D
Includes support (financial or otherwise) for research, development and translation relating to discovery and preclinical research, and Phase I clinical trials.

2. Enhancing clinical trial conduct
Includes strategies to enhance clinical trial conduct and infrastructure to improve efficiency, reduce duplication and generate better data.

3. Supporting late-stage R&D
Includes support (financial or otherwise) for the conduct of Phase II and III registration trials through to product filing.

4. Streamlining regulatory requirements
Includes the clarification, optimisation and convergence of regulatory requirements across indications and regulators to decrease the time and expense for products to reach patients.

5. Earlier & broader uptake
Includes support for new data-generation and better use of all available data so patients may benefit from newer agents more rapidly. Also includes mechanisms to cushion smaller developers in the initial post-launch phase.

6. Improving continuity of supply
Includes system, regulatory and market-making measures with the objective of fostering a sustainable and predictable market for older efficacious antibiotics (particularly for those products where there are few or no alternatives).

7. Enhancing relative market attractiveness
Includes strategies to enhance the attractiveness of the market relative to other therapeutic areas, and within the antibiotic class, by implementing regulatory, system and financial levers nationally, trans-nationally or globally.

8. Expediting sustainable global patient access
Includes measures to improve the speed of access and affordability to patients globally while ensuring appropriate stewardship.

9. Priority signalling & orientation
Includes actions to signal and reinforce the global public good nature of antibiotics and public health need for an R&D ecosystem oriented towards the development, distribution and preservation of priority antibiotics, globally.