

DRIVE-AB Work Package 2

Task 2 – High-Level Parameters

High-level parameters are meant to provide additional boundaries to the scope of WP2's responsibilities. These parameters have been derived from the feedback gathered from the January 2015 Uppsala meeting. All recommendations must be in accordance with these parameters (as well as other criteria defined within each task).

These parameters provide further detail to WP2's vision and key messages, which are:

Vision: Transforming the way policymakers stimulate innovation, responsible use and global access of novel antibiotics to meet public health needs

Key Messages:

1. The antibiotic business model is broken. The historic price/volume model is not a sustainable model for the future; it is ineffective in generating an attractive return on antibacterial R&D investment. In addition, a new model in which responsible use is encouraged rather than volume sales is urgently needed to minimize antibiotic resistance. Low returns but also scientific challenges are two reasons investments have increasingly been steered to other therapy areas leading to a dearth of new antibiotics to address the threat of resistance.
2. Many reward mechanisms to incentivize greater investment in antibiotic R&D have been suggested but few have been tested. DRIVE-AB will quantitatively model and test the most promising mechanisms against both attractiveness of return and public health benefit. This will include in-depth analysis of the entire economic model, covering the value chain from discovery through development and approval and onto treatment of patients. Responsible use interventions will be included in the simulations and evaluations.
3. Any new economic model must have built in provisions for equitable and appropriate patient access since today there is far more morbidity and mortality from a lack of access to appropriate antibiotics than from antibiotic resistance.

The high-level parameters are:

- DRIVE-AB's recommendations will focus only on antibiotics, not all antimicrobials.
- DRIVE-AB is only one component in a multi-faceted effort to combat antibiotic resistance. DRIVE-AB will issue recommendations on how to strengthen innovation of antibiotic and related technologies. We will not address non-investment related aspects of resistance such as increasing surveillance and infection control. Our recommendations will be limited to investment in antibiotics for human use only.
- All recommendations will reinforce responsible use of antibiotics.
- Our recommendations will seek change on a global scale, yet necessary scale and geographical scope for each recommendation will be analyzed and documented.
- Our recommendations will encourage reforms to explicitly help improve access to effective antibiotics globally. Such reforms will, however, rely on active participation of national governments, regions, multinational organizations and/or regulatory agencies in order to properly implement and ensure that the right patients receive the appropriate treatment at the right time, and at an appropriate price.

- Our recommendations aim to create sustainable solutions. Lack of sustainability will be treated as a major draw-back of any proposed mechanism.
- The incentives we recommend will be geared towards the creation of novel antibiotics intended for both hospital and community settings.
- Our recommendations will seek to stimulate increases in both public and private sector investments. Both sectors must increase investment levels in order to achieve sustainable solutions.
- We recognize that private sector actors are profit-making organizations. Any recommended solution meant to stimulate the actions of the private sector will need to include a fair profit. However, the focus of our recommended solutions will go beyond simply creating an attractive commercial case for private sector organizations. We recognize that defining “fair” is contentious.

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