A review of proposed models, their implementation and how they deliver on each of the pillars

David Findlay  DRIVE-AB Work Package 2 & GSK
‘Transforming the way policymakers stimulate innovation, responsible use and global access to novel antibiotics to meet public health needs’

DRIVE-AB’s principles

Innovation

Access

Sustainable use

Hoffman S, Outterson K, et al. JLME 2015
# DRIVE-AB’s shortlist of incentives

<table>
<thead>
<tr>
<th>Incentive</th>
<th>Type</th>
<th>Innovation stimulated</th>
<th>Required funding per annum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grants</td>
<td>Push</td>
<td>Early phase research</td>
<td>Additional $250 ++</td>
</tr>
<tr>
<td>Pipeline coordinator</td>
<td>Push</td>
<td>Key health threat pathogens through discovery and development</td>
<td></td>
</tr>
<tr>
<td>Market Entry Rewards</td>
<td>Pull</td>
<td>Most pressing public health threats</td>
<td>$1-1.25bn per AB</td>
</tr>
<tr>
<td>Continuity model</td>
<td>Pull</td>
<td>Ensures product availability post MER period</td>
<td>TBD on a case basis</td>
</tr>
</tbody>
</table>
Criteria for Market Entry Rewards

• **Targeted**....to key public health priorities.

• **Sustainable**...predictable, reliable and not subject to budget changes. A MER will not incentivise if it is likely to disappear 5 years into a 10 year development programme!

• **Transparent**....the criteria for delivering a MER should be clear and publicly available – Target Product Profiles, contract conditions, funding timelines...

• **Sufficient**...the MER must maintain existing investment and generate new public and private capital investment into AB R&D through increasing ROI to attractive levels
In a fully delinked MER, all developer revenues associated with the eligible antibiotic would be from the MER payments for the lifetime of the IP; the antibiotic would be supplied at cost price.
A partially delinked MER preserves some flexible market-based elements, which lowers the upfront financial commitment and allows developers to operate within their existing business model.
The MER would be offered as a set of “top-up” payments over five years that ensure the developer earns an agreed target revenue each year. If revenue from sales is greater than the MER in a given year, then there would be no MER payment and any excess revenue would be discounted from the following year’s MER payment.
Sustainable use: DRIVE-AB recommendation

- Sustainable use measures for developers should be contractually linked to both market entry rewards and long-term supply continuity awards.
- Countries should also commit to high-level sustainable use commitments and adherence to antibiotic-specific guidance documents developed by the World Health Organization or other relevant bodies.
- We recommend that a special working group (perhaps under the guidance of the EU commission, G20 or TATFAR) convene to develop standard sustainable use measures both for developers and governments.
MERs must be bound by sustainable use and equitable availability obligations on the developer.

- We define sustainable use as the implementation of policies targeting a range of actors to ensure the preservation of a specific, novel antibiotic.
- It is vital that any innovation incentive promotes sustainable use to ensure the longevity of the AB and continued benefit to patients.
- For sustainable use activities that are within the control of developers, DRIVE-AB recommends that these obligations are contractually agreed between the funder and developer, with annual reporting.
- MER conditions should not be so numerous or complex that they make the MER unattractive to developers or too difficult to effectively administer, both from an industry and a public payer perspective.
Options for developer sustainable use measures

**Pragmatic recommendation**
- Sales of active ingredient outside of human medicine prohibited*
- Product promotion limited to appropriate use only. All materials reviewed at least 90 days prior to use
- Review and apply antibiotic discharge framework across supply chain (including API).
- Sales and surveillance data disclosure
- Reduce/eliminate volume-based remuneration of sales staff
- Support on-going self regulatory initiatives via the Davos Declaration and AMR Industry Alliance

**Stringent recommendation**
- Sales of active ingredient outside of human medicine prohibited*
- No product promotion, similar to existing FDA off-label restrictions, with defined exceptions for the dissemination of use-related information – safe harbours.
- Review and apply antibiotic discharge framework across supply chain (including API)
- Sales and surveillance data disclosure
- Eliminate inducements related to volume sales
- Externally enforce developer controls

*unless product classified by the World Organization for Animal Health’s veterinary antimicrobial list as critically or highly important.
Options for country sustainable use measures

1. Actively implement its National Action Plan on AMR
2. Meet a minimum threshold for public financing in the health sector
3. For each MER-recipient antibiotic, the WHO develops AB specific policy guidance
4. Comply with the antibiotic-specific guidance document
5. Report adverse events and instances of resistance

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For each MER-recipient antibiotic, the WHO develops AB specific policy guidance. To ensure sustainable use, countries must:

- Actively implement their National Action Plan on AMR.
- Meet a minimum threshold for public financing in the health sector.
- Comply with the antibiotic-specific guidance document.
- Report adverse events and instances of resistance.
Building in equitable availability: DRIVE-AB Recommendation

• Equitable availability measures for developers should be contractually linked with both market entry rewards and long-term supply continuity awards.

• A special working group (perhaps under the guidance of the Global Antibiotic Resistance Partnership) should be convened to develop standard equitable availability measures.
Building in equitable availability

Companies must submit an access plan.

Countries or other healthcare providers not included in the access plan can submit a letter of interest.

The company (if requested) must commit to assist the World Health Organization to develop an antibiotic-specific policy guidance.

The company commits to monitoring activities.

Access
DRIVE-AB’s recommended models

- Basic Science
- Preclinical
- Phase I
- Phase II
- Phase III
- Market
- Generic market

- Grants
- Pipeline Coordinator
- MER
- Continuity
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