Policy Brief #01: March 2021

GLOBAL AMR R&D HUB

National Policy Options for New AMR Health Technologies

Based on the study

Vogler, Sabine; Habimana, Katharina; Fischer, Stefan; Haasis, Manuel Alexander: Novel policy options for reimbursement, pricing and procurement of AMR health technologies. Austrian National Public Health Institute: Vienna, 2021. ppri.goeg.at

A steady & certain supply of new antibiotics & diagnostics (novel AMR health technologies: HT) is imperative given the inevitability that resistance will reduce antibiotic efficacy over time & that diagnostics are the key to optimising antibiotic use. This 'novel AMR HT' component in our response to the growing challenge of antimicrobial resistance (AMR) has long-been acknowledged. However, international alignment on how the public sector should 'pull' – or reward – successfully developed products remains a more elusive challenge.

The current patent-based system links the development of products to their commercialization in one chain. For AMR HT, not only do revenues from sales insufficiently stimulate innovative development but challenges in development also hinder health-systems ability to secure access & value them appropriately (below).

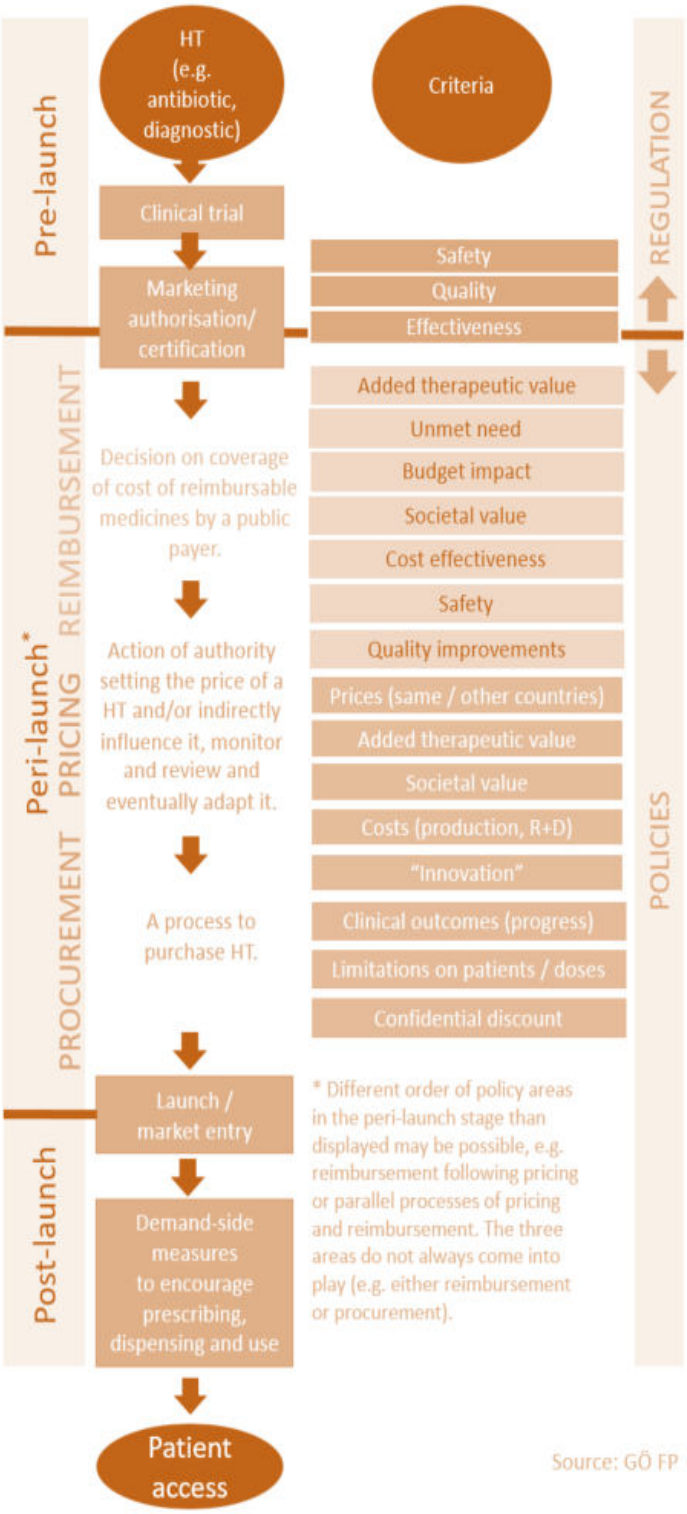
POLICY GOALS FOR AMR HT

- **Capturing Wider Value Attributes**
- **Aiding Clinical Differentiation**
- **Expediting System Uptake**
- **Improving Revenues**
- **Generating Further Data**
- **Reducing Fragmentation of Demand**
- **Lessening Payer & Developer Uncertainty**
- **Need to Ensure Access & Stewardship**

Following licensure, medicines & medical devices usually enter the market after the public authority has decided whether, & to what extent, the public payer will cover the costs (right).

AMR HT markets are beset with multiple problems & health systems are heterogeneous – both of these preclude simple, singular, solutions.

Despite the acknowledged need for new AMR HT for public health, individual AMR HT cannot, or are unable to, demonstrate a high additional therapeutic benefit – a key criterion considered in pricing & reimbursement decisions.



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The Austrian National Public Health Institute (GÖ FP) explored specific policies that are able to stimulate the development of novel AMR HT within the domains of reimbursement, pricing & procurement from 10 countries in a study commissioned by the Global AMR R&D Hub.

While 'standard' policy options across the 3 domains are not sufficiently designed to address the characteristics & challenges of AMR HT, specific policies were identified in the fields of AMR HT as well as orphan medicines, generics & oncology medicines which share some similar characteristics.

The study identified 16 specific policies across the domains for pricing, reimbursement & procurement. They can be categorized into exemptions (from cost-containment), modifications (of existing methods & policies) & additions (additional funding), for further rewarding innovation in AMR HT. Examples of each are displayed in the table.

Public authorities have existing, promising specific policy options that can further reward the development & market entry of new AMR HT.

The study identified considerably fewer examples of specific policy options for middle-income countries compared to high-income countries & for medical devices, including diagnostics, compared to medicines. This is attributable to the fact that overall, in middle-income countries & for diagnostics the extent of regulation & policy implementation (reimbursement, pricing & procurement) is lower.

Policy type	Reimbursement	Pricing	Procurement
Exemptions	**Inclusion in reimbursement despite limited evidence** (e.g. exemption of antibiotics from HTA / DEU; exemptions of orphan medicines from value assessment – AUS, KOR, TUR) **Waiving reimbursement restrictions** (e.g. exemptions of laboratory diagnostics for antibiotics from justification for prescribing – DEU) **Omitting reimbursement reviews**	**Free pricing** (e.g. for non-reimbursable medical devices – FRA, KOR & ESP; for all medicines in the first year after launch – DEU) **Omitting price reviews**	**Exemptions / reductions from mandatory discounts** of suppliers to public payers (in 4 of the 6 study countries that have an industry claw-back mechanism)
Modifications	**Faster access into reimbursement** (early access scheme – 7 study countries)	**Price negotiations** (for medicines in 10 study countries & for medical devices in study countries **Diverging from pricing policies** (in cases of value-based pricing approaches)	**Delinkage models** (e.g. for hepatitis C medications – AUS
Additions	**Higher reimbursement (rates)** (e.g. for medicines of added therapeutic value – France) **Add-on funding** (e.g. 'innovation funds' for innovative medicines – Italy, 'DRG carve-out' funding for hospital medicines – France, Germany	**Higher prices for defined HT** (e.g. for nationally produced medicines – South Africa, for biologicals – South Korea)	**Managed-entry agreements** (for medicines in 8 of 10 study countries) **Value-based procurement** (at least 4 study countries) **Pooled procurement** (PAHO Revolving Fund & PAHO Strategic Fund – Brazil, Gulf Cooperation Council pooled procurement for essential medicines & medical devices – Saudi Arabia)

Examples identified in the 10 study countries: Australia, Brazil, France, Germany, Italy, South Africa, Saudi Arabia, South Korea, Spain & Turkey; details & further examples in study countries & beyond in the study.

The lower level of policy implementation for medical devices, including diagnostics, is visible through the lower number of countries with medical devices price regulation compared to medicines (4 versus 8) & the considerably smaller number of devices included in reimbursement lists.

POLICY POTENTIAL FOR DIAGNOSTICS

Reimbursement for medical devices

Most study countries (7 out of 10) engage in HTA for medical devices. Findings need to be better integrated in the reimbursement policy framework.

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All identified policy options have strengths, limitations & come at a cost. A few specific policies qualified particularly to address the challenges for both diagnostics & antibiotics.

Adapted health technology assessment (HTA) frameworks could include criteria that capture more appropriately the societal value of AMR HT (e.g. spectrum, transmission, enablement, diversity & insurance), help discriminate the clinical value & to address their special characteristics. They can build on previous & ongoing work of targeted value assessment frameworks for other health technologies (e.g. for orphan medicines). This approach is encouraged over HTA exemptions (i.e. waiving AMR HT from cost-effectiveness analysis), since the latter entails missing the opportunity to collect data.

NOVEL POLICY OPTION IN HTA

Adapted value assessment frameworks

If policy-makers accept the development & application of such tailored HTA methodology & appraise their outcomes, then AMR HT can qualify for inclusion into reimbursement or inform value-based procurement despite absence of evidence for added therapeutic benefit.

Over the last decade, several governments have concluded so-called managed-entry agreements (MEA) with suppliers of high-priced HT which would not be affordable otherwise. Such MEA are tools to 'manage the uncertainty' since they are frequently concluded for medicines with limited evidence & may allow data generation over time as part of performance-based MEA (i.e. linking payments to defined outcomes).

Experience gained from MEA could flow into novel procurement contracts. A major disadvantage of MEA – its common design based on confidential data, including discounts – could be addressed in novel procurement contract options committed to transparency. Contracts could be designed to link payments to defined outcomes, &/or to delink it from sales volume.

NOVEL POLICY OPTION IN PROCUREMENT

Procurement contract options

Procurement contracts can be designed in a way as to include AMR relevant conditions (e.g. good stewardship, environmental considerations). For antibiotics, contracts may be based on a 'delinkage model' which secures the supplier fixed payments independent from the sales volume. Contract options may build on knowledge gained on MEA concluded for medicines with high price tags & limited evidence.

Additionally, countries may gain from collaboration in procurement, as this allows increasing the purchasing volume & strengthening bargaining power which is particularly beneficial when many countries are struggling to secure access to newer AMR HT. There are both successful examples & existing mechanisms of joint procurement for HT that could be further explored & utilized.

Increasing public funding for certain HT without any conditions attached is a less promising policy option. Experience from dedicated budgets (e.g. innovation funds) in some countries has shown unintended effects of ever-growing budgets without improvement in access to cost-effective HT.

'DRG carve-outs' are a potentially promising option. Under this policy, AMR HT used in hospitals are individually reimbursed on top of DRG funding which is a bundled payment scheme. This incentivizes hospitals to procure novel antibiotics even if they are more expensive. However, this would need to be implemented based on clear & transparent rules (e.g. regarding criteria & processes for the selection into special funding schemes).

NOVEL POLICY OPTION IN REIMBURSEMENT

DRG carve-outs

Under certain conditions, individual reimbursement of AMR HT used in hospitals on top of DRG funding could be used to encourage procurement of novel & more expensive HT. This would benefit products targeting some of the most acute unmet clinical AMR needs.

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The study did not identify any example of specific policy options that addressed the 'pair' of an antibiotic & companion diagnostic tests. Possible reasons might include the general lack of specific policy options for diagnostics, different suppliers offering the antibiotics & the diagnostics as well as the fragmentation in health care systems. From other, albeit not acute areas, however, (e.g. oncology medicines), policies addressing both oncology medicines & the companion diagnostics as part of a personalized medicine approach are known.

NOVEL APPROACH TOWARDS DIAGNOSTICS

Funding for 'pairs'

One approach towards innovation in diagnostics could be novel funding mechanisms that jointly address the antibiotic & the diagnostic tests as its 'companion'.

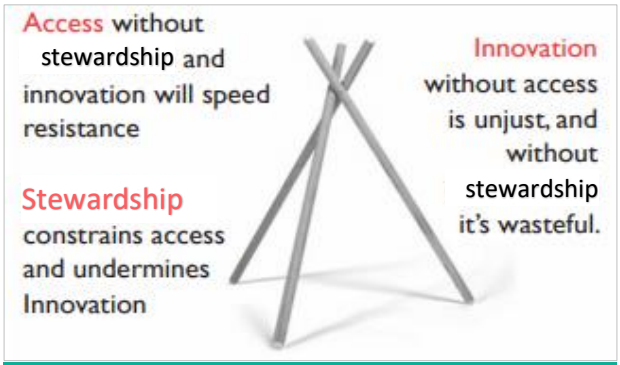
When implementing policy options, several things have to be well noted when it comes to transferability, context & cooperation.

While benefiting from experiences gained from existing policies, some caution with regard to **transferability** is advised:

- **No 'copy & paste':** Any policy implementation must take into account the specificities of the national policy framework (country context). Benefits come from strategic benchlearning among countries as a basis for national policy-making.
- **Combinations:** Overall, policy-makers should not focus on a single policy but work on implementing a well-aligned combination of policy options in the areas of reimbursement, pricing & procurement.
- **Financial implications:** Policy-makers should be aware of their 'cost' of the implementation of specific policy options & also with respect to the companies' 'cost' to navigate the 'adapted procedure' vs. the likely 'benefits (revenues)'.
- **Evaluation & monitoring:** Even if a policy is successful in achieving intended objectives, its effectiveness may decrease after some time ('fading out'). For AMR HT with limited evidence, evaluations are particularly important since data collection in 'real life' offers further insights.

The **context** with regard to the country, where a specific policy should be implemented as well as the context of the focus of a policy option should be taken into account during implementation:

- Different policies will suit different contexts depending on many factors such as the presence/absence of universal health coverage, resistance rates, maturation of the health system etc.
- While this study focused on the innovation component, health systems will always be bound by the need to balance policy objectives around the three-pillars of AMR.



The three pillars of AMR HT policy consideration. Adapted from: Hoffman, Outterson (2015)

Both national experience & purchasing power can be leveraged through **cooperation**:

- **Mitigating challenges:** Some of the noted disadvantages of some of the tools could be mitigated through cross-country collaboration. Alignment can reduce administrative barriers & costs for both makers & purchasers/users
- **Broad principles:** Should countries be willing to align on broad evidence-backed principles around implementation, this could strengthen the coherence of the collective response to this global public good challenge.

With many thanks to all participating countries.

The study is available for download from:

https://globalamrhub.org/category/news/