AAMRNet

Australian Antimicrobial Resistance Network

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AAMRNet Position Statement

Pricing and reimbursement of novel antimicrobials in Australia

May 2022

Australian Government
Department of Industry, Science, Energy and Resources

Industry Growth Centres

CONTENTS

EXECUTIVE SUMMARY

This position statement supports the National Antimicrobial Resistance (AMR) Strategy – 2020 and Beyond and its focus to ensure the continued availability of effective antimicrobials for Australians. The Australian Antimicrobial Resistance Network – AAMRNet - and respective member organisations have developed this position statement to guide the way in which pricing and funding of novel antimicrobials in Australia is undertaken.

The intent and purpose of this position statement is to:

- Support the establishment of innovative ways to fund or stimulate research and development (R&D) and improve market access for antimicrobials that are urgently needed in both the public and private sectors in Australia
- Acknowledge that the discovery of new classes of antimicrobials is an essential public good for human health. Additionally, the discovery, development and commercialisation of new antimicrobials has the potential to reduce public and private expenditures related to patient complications resulting from AMR and associated hospitalisations
- Acknowledge the broader health benefits of antimicrobials, including as key enablers of the health system
- Ensure there are sufficient incentive options in Australia to reinvigorate the antimicrobial R&D pipeline
- Retain existing and attract new pharmaceutical company investment to commercialise new antimicrobials that treat drug-resistant infections
- Support a One Health approach to the development, use and manufacture of antimicrobials across health, economic, social, and environmental goals.

WHY CHANGE IS NEEDED

Stakeholder	Perspectives
Patients	▪ Australians are already dying from multi-drug resistant (MDR) infections. A recent report estimated that over 1600 deaths were attributable to AMR in Australia in 2019[1], and as more antimicrobial drugs stop working, more lives will be put in danger. Additionally, patients may incur long term suffering related to complications from hospitalisation for MDR infections. In the United States (US), the types of patient complications arising from a hospital stay are defined as hospital acquired conditions (HAC). Hospitals in the US are measured on performance of quality metrics, which include HACs ▪ Currently, patients in the US and European Union (EU) have access to a greater number of antimicrobial options for treating MDR infections than those in Australia ▪ MDR infections can affect anyone, anywhere, and due to the interdependence of our world today, no one is safe from infectious diseases unless everyone is safe

[1] The Lancet, 2022: Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis

Stakeholder	Perspectives
	▪ The COVID-19 pandemic has increased the vulnerability of older and immunocompromised populations to secondary infections, including MDR infections, due to complications of COVID-19 infection and emerging mutants/variants.
Clinicians	▪ Optimal patient treatment is significantly delayed when access is needed to an antimicrobial or other treatment that is unavailable in Australia, putting Australians at risk of poorer health outcomes ▪ Australia will continue to see a rise in drug-resistant infections, imported from overseas via international travel and due to the COVID-19 pandemic, during which high levels of antimicrobial use has been observed due to secondary infections which, in COVID-19 patients, are a strong predictor for death compared to those with influenza. This means clinicians will need better access to novel antimicrobials to treat patients ▪ Presence of resistant organisms impacts on the ability to deliver optimal care in various settings. Effective antimicrobials, for example, are necessary to prevent infections in surgery, and to deliver chemotherapy to cancer patients ▪ Antimicrobial stewardship (AMS), treating the right patient at the right time with an appropriate antimicrobial at the right dose, has been shown to improve patient outcomes ▪ Current payment models favour the use of antimicrobials with broad spectrum activity because of indication-based rather than activity-based approvals, in direct opposition to the known advantages of precision medicine and AMS. Stewardship principles advocate use of antimicrobial therapy with a narrow spectrum of activity where appropriate. While empiric antimicrobial therapy may be initiated with a broad spectrum of activity, stewardship encourages de-escalation to a narrower spectrum following microbiologic testing/isolation of the causative pathogen.
Industry	▪ Revenue generated by novel antimicrobials is insufficient to pay for R&D, manufacturing, commercialisation, distribution and other post approval costs ▪ Current Australian initiatives are heavily focused on “push” incentives, primarily in the form of grants and funding to support the surveillance and data collection of AMR and drug-resistant tuberculosis (DR-TB). While surveillance is important in understanding the incidence, prevalence, range across pathogens and geographical patterns related to AMR, these initiatives do not stimulate the market entry of novel antimicrobials ▪ If Australia contributed its “fair share” in global pull incentives (i.e., an annual subscription per novel drug equal to about $9M) Australian access to antimicrobials would be assured ▪ Incentivise companies to adopt world’s best practice standards on environmental impact of manufacturing antimicrobials.

Stakeholder	Perspectives
Researchers	▪ The technology exists to develop novel and alternative antimicrobial treatments to address current and emerging MDR infections, however there is a lack of R&D investment, for both academic research and support of relevant companies ▪ If antimicrobial R&D is unprofitable, young scientists will choose other fields, crippling our research potential for a generation.
Australian Government/Hospitals Regional Public and Private Payers	▪ Costs incurred by national and regional Australian payers are exacerbated by patient complications and long-term sequelae due to poor antimicrobial management of MDR infections ▪ Examples of such costs include extended hospital stays, hospital readmissions, and additional diagnostic procedures and medications.

Position 1

An Australian antimicrobials funding model should be developed in collaboration with AAMRNet, considering relevant aspects of models being explored internationally, such as the United Kingdom's de-linked approach whereby reimbursement is not linked to the volume of antimicrobials sold, but rather to their broader societal value and guarantee of 'as needed' supply.

WHY A NEW FUNDING MODEL IS NEEDED

DRIVE-AB (Driving Re-InVEstment in R&D and responsible AntiBiotic use) was a public-private, collaborative multinational consortium funded by the European Innovative Medicines Initiative to recommend options to stimulate innovation and responsible use while ensuring global access to novel antibiotics to meet public health needs. Its final report highlighted that "new economic models that create incentives for the discovery of new antibiotics and delink the return on investment from volume of sales are long overdue" [2].

This issue has been prioritised by the G7, which, on 13 December 2021, released a statement on Actions to Support Antibiotic Development[3] to strengthen G7 preparedness against the "silent pandemic" of AMR. The statement commits all G7 members "to expedite their implementation of existing strategies … and to take additional specific and appropriate steps to address the antibiotic market failure and create the right economic conditions to preserve essential existing antibiotics and ensure their access, strengthen AMR antibiotic R&D, and bring new drugs to market where they meet identified public health needs". The statement outlines possible steps that "could include exploring a range of market incentive options, with a particular emphasis on supporting relevant pull incentives, implementing new pilot projects, contributing to new national governance structures to develop economic strategies to strengthen antibiotic development, and exploring legislative and regulatory measures".

[2] DRIVE-AB, Novel business models needed to revive reinvestment in antibiotics http://drive-ab.eu/wp-content/uploads/2015/07/Novel-business-models-needed-to-revive-reinvestment-in-antibiotics_Ursula_BiotechnologyJournal.pdf

[3] https://www.g7uk.org/wp-content/uploads/2021/12/AMR-G7-Finance-Ministers-statement-on-supporting-antibiotic-development-final-13-Dec-2021.pdf

A recent House of Representatives Standing Committee on Health, Aged Care and Sport report - *The New frontier – Delivering better health for all Australians* - recommends the Australian Government takes strong action on AMR.

Recommendation 27 includes:

- Develop additional reforms to data exclusivity timeframes to support research and development into new drugs and novel medical technologies in areas of unmet need
- Consider future funding initiatives for novel drug discovery and support research and development partnerships in Australia. This would assist new drugs and novel medical technologies in early stage and pre-commercial development
- In partnership with the states and territories, develop and implement a pilot scheme for value-based payments for new antimicrobial drugs.

Recommendation 29 is also worth noting:

- The independent Health Technology Assessment Review reassess relevant aspects of the Health Technology Assessment process to ensure there are future pathways for treatments and therapies that do not fit neatly into the current system such as rare cancers, antimicrobials, orphan drugs, and precision medicines.

In Australia, as in other countries, companies seeking to invest in the development of novel antimicrobials face multiple challenges:

- Uptake of novel antimicrobials is slow as they are typically held in reserve by healthcare practitioners until resistance to older treatments has emerged, and when they are used, it is only in acute situations and for short course dosing regimens. This immediately limits the use of a new product and the ability to recoup R&D and commercialisation costs. These barriers are not faced by therapeutics used as longer course treatment regimens for chronic conditions such as cancer or heart disease
- There is no nationally consistent reimbursement system for antimicrobials in Australia. There are multiple payers with regard to novel antimicrobials and the payer will depend not only on the Pharmaceutical Benefits Scheme (PBS) status of the drug, but also on individual patient circumstances. For example, state governments will bear the cost of treatment for public hospital inpatients. However, in private hospitals, the payer could be the patient, insurer, hospital or the Federal Government when the antimicrobial is listed on the PBS and prescribed in accordance with PBS restrictions
- Constrained hospital budgets can mean that the use of novel antimicrobials may be discouraged for financial reasons, even when they may be a more clinically appropriate treatment for a patient than a generic antimicrobial[4]
- There is a lack of rapid point-of-care diagnostics to identify which patients need immediate access to newer antimicrobials and which can be treated with generics
- Novel antimicrobials are generally undervalued by reimbursement systems relative to the benefits they bring to society as indispensable, life-saving drugs. This is because of the existence of low-cost, often generic comparators which are still effective for many infections and the inherently narrow focus of health technology assessment (HTA) on direct health costs and benefits. While it may be appropriate to maintain that narrow focus for many therapies, the societal benefits of having a supply of novel antimicrobials requires a broadening of the HTA perspective. Indirect costs, such as delays in surgical procedures for patients with AMR, need to be considered in estimating the value of new antimicrobials. Additionally, longer term direct health costs associated with development of complications of AMR, such as hospital readmissions and extended lengths of hospitalisation should be considered in HTA

[4] Bhatti, T et,al 2018, A Perspective on Incentives for Novel Inpatient Antibiotics: No One-Size-Fits-All, Journal of Law, Medicines and Ethics, p60

- Precision medicine is more important than ever in antimicrobial therapy, but regulatory and reimbursement challenges based on clinical indications exist. Developing a precise (narrow spectrum) therapy for a specific bacterial pathogen is economically unattractive under the current Australian reimbursement model. However, development of targeted precision-focused therapy is imperative to control the collateral selection pressure that is driving AMR development.

Position 2

AAMRNet is committed to working with government to help re-stimulate the market for these crucial medicines and is an appropriate partner due to the national and international expertise of its members and stakeholders. Novel reimbursement approaches are needed to support and ensure a continuing pipeline of novel therapies.

NEW FUNDING APPROACHES IN THE UK AND SWEDEN PROVIDE EXEMPLARS FOR AUSTRALIA TO CONSIDER

New antimicrobials are not being made available to Australian patients because of a lack of commercial incentive for international companies to market here. Of 19 new agents registered overseas since 2011, only three are commercially available in Australia (Appendix A), placing it fourteenth when compared to fifteen other high-income countries[5]. As a result, Australians have fewer treatment options than those in comparable overseas jurisdictions. A new approach to funding antimicrobials is required to address this market failure and ensure Australians have access to the most appropriate treatments.

The UK National Institute for Health and Care Excellence (NICE) recently launched a pilot program using a 'de-linked' model where companies are paid an annual subscription fee to supply as much or as little of an antimicrobial as required. This 'insurance' results in more predictable revenue for the manufacturer and predictable access to urgently needed medicines for the health system in the event of disease outbreaks. In other words, companies are paid for antimicrobials based on their expected value to the health system and population as a whole, as opposed to the actual volume used.

In Sweden, a new reimbursement model is being piloted which aims to ensure the availability of new antimicrobials of special medical value with market protections in force. Sweden, like Australia, is a small market and has a low, but growing level of resistant infections. Also like Australia, it struggles to attract pharmaceutical companies to make their products available in the country. Under the pilot, pharmaceutical companies will, in exchange for a guaranteed supply volume of the originator antimicrobial, receive a minimum guaranteed annual revenue from the Public Health Agency of Sweden (PHAS), based on the cost of an estimated security stock amount. Regional health departments continue to buy and pay as usual for the products, and if the actual revenue from those sales is lower than the guaranteed income for a given year, the difference will be paid from the national level. If, on the other hand, revenue from the sales exceeds the guaranteed level for a given year, to ensure the attractiveness of the PHAS model, a bonus equal to the price of buying 10 per cent of the security stock amount will be paid[6].

In the US, the Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act also proposes a model that would provide market incentives for life-saving antimicrobial therapies. Under this Act, the US government would provide a subscription payment similar to the UK model, but larger (proportionate to the relative size of the US economy) and based on clear Target Product Profile characteristics rather than the HTA used by NICE. Developers would be paid annual, contractually agreed

[5] Outterson K, Orubu ESF, Rex J, Ardal c, Zaman M. Patient access in fourteen high-income countries to new antibacterials approved by the FDA, EMA, PMDA, or Health Canada, 2010-2020. Clin Infect Dis. 2021 Jul 12

[6] Gotham D et al. Reimbursement models to tackle market failures for antimicrobials: Approaches taken in France, Germany, Sweden, the United Kingdom and the United States https://www.sciencedirect.com/science/article/pii/S0168851020302980#bib0140

amounts for a duration ranging up to the antimicrobial's patent life. The government would offer an upfront payment for access to the eligible antimicrobial and would consider the clinical need and novelty of the therapy. Under this proposal, patients in the US insured by national payer plans (Medicare or Medicaid) would have access to PASTEUR Act antimicrobials at no additional cost to the government. The Act would also provide education on stewardship to facilitate appropriate use of new antimicrobials. A decision on the Act is expected before the end of 2022.

Also in the US, the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) Act has been proposed. In the DISARM model, antimicrobials that meet criteria as a qualified infectious disease product (QIDP) would be reimbursed to hospitals separately from the general diagnosis related grouping in-patient reimbursement system. Hospitals participating in the DISARM Act model would be required to adopt stewardship programs and would be eligible to receive full reimbursement for use of novel antimicrobials designated as a QIDP.

Another approach that has been proposed is to introduce a market entry reward based on susceptibility, with a staged bonus for antimicrobial developers when resistance to their drug remains low over time[7].

Some of these countries are also exploring the feasibility of using environmental criteria in decision making on antimicrobial procurement. This is designed to encourage manufacturers to ensure their products meet international standards that limit or eliminate antimicrobial pollution into the environment from the manufacture of antimicrobials themselves. Through this process, companies can be encouraged to achieve world's best practice standards and to adopt innovative strategies to minimise environmental pollution and help combat AMR. The recently released 2021-2022 priorities for the WHO/FAO/OIE Global Leaders Group on AMR, where Australia is represented by the Minister for the Environment, has explicit commitments and key performance indicators (KPI) to reduce and eliminate antimicrobials in manufacturing discharge.

Elements of all these approaches could be considered for possible incorporation into an Australian pilot.

A PRAGMATIC VALUATION APPROACH

Countries around the world are looking at how to tackle the challenge of bringing novel antimicrobials to market. The UK has already spent several years developing a workable model to determine the expected value[8] which takes into account their full value to society, including spectrum value, transmission value, enablement value, diversity value and insurance value (STEDI – Appendix B). This work is ongoing, as they acknowledge the need for balance between the difficulty of the task, the complexity of the modelling required and the use of expert opinion. Australia, through AAMRNet, could consider these developments and how they might be pragmatically adapted for use within its own HTA processes.

Position 3

Establish a pilot Australian fund to provide access to new antimicrobials and support their appropriate use, allowing clinicians to prescribe the right drug to the right patient at the right time. The fund would encourage investment in AMR R&D and demonstrate Australia's leadership in the face of a growing global health crisis. KPI metrics, such as impact of the pilot on healthcare and hospitalisation costs, and number of antimicrobial resistant infections in the respective region, would be developed to measure outcomes.

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[7] Morel, C.M., Lindahl, O., Harbarth, S. et al. Industry incentives and antibiotic resistance: an introduction to the antibiotic susceptibility bonus. J Antibiot 73, 421–428 (2020). https://doi.org/10.1038/s41429-020-0300-y

[8] Rothery, C., Woods, B., Schmitt, L., Claxton, K., Palmer, S., Schulper, M., 2018, Framework for Value Assessment of New Antimicrobials. Implications of alternative funding arrangements for NICE Appraisal. EEPRU, Policy Research Unit in Economic Evaluation of Health &Care Interventions http://www.eepru.org.uk/wp-content/uploads/2017/11/eepru-report-amr-oct-2018-059.pdf

PROPOSED PRINCIPLES FOR AN AUSTRALIAN PILOT

The following principles could be considered for inclusion in an Australian pilot. They combine aspects from overseas exemplars.

1. The pilot could use the de-linked model whereby an annual subscription fee is paid regardless of the amount of antimicrobial used
2. The pilot could incorporate regulatory and reimbursement incentives for qualified infectious disease products, such as market entry rewards and additional market exclusivity
3. The pilot should be jointly supported by the Australian and state and territory governments. Joint funding models already exist (such as the National Blood Authority). The framework of the National Health Reform Agreement may also provide a basis for such funding
4. The pilot could be reserved for up to five drugs, at least two of which are therapies anticipated to be approved in the next five years; for example, new antimicrobial therapies with activity against organisms where resistance has a high impact in the hospital setting. Carbapenem-resistant Pseudomonas aeruginosa is a priority one pathogen according to the WHO[9] and is a major emerging AMR threat in Australia[10]. Novel antibiotics to treat this pathogen are available but they are expensive compared to cheaper generic options so can be under-used, even when they are the most clinically appropriate choice. In the US, the Food and Drug Administration (FDA) has granted IV cefepime-taniborbactam (under development by VenatoRx and with activity against Carbapenem-resistant Pseudomonas aeruginosa) QIDP
5. The pilot should ensure equity of access to the chosen drugs across metropolitan, regional, rural and remote Australia, in all states and territories
6. The pilot should support the AMS principle of using the right drug for the right patient, for the right organisms, at the right dose and formulation, at the right time, so that usage is always based on clinical need and appropriate use rather than the cost. This is consistent with infectious disease AMS which results in positive impact on patient outcomes
7. The pilot should recognise the broader social value of making novel antimicrobials available, including the STEDI values, while at the same time preserving their use according to AMS principles
8. The pilot should act as a signal to industry that the government is willing to create a stable market for novel antimicrobials
9. Metrics should be developed and aligned across all stakeholders to measure the outcomes of the pilot, such as hospitalisation/ healthcare costs in the respective region. The outcomes will help to refine, if needed, the design of the pilot moving forward.
10. The pilot should support international efforts through bodies like the G7, G20 and Global Leaders Group on AMR to assist in establishing environmental standards for the manufacture of antimicrobials through incentives and standards in the purchasing and reimbursement of antimicrobials by the Australian and state and territory governments.

The short-term benefit of such a pilot is that up to five novel antimicrobials could be available for clinicians to prescribe under clear AMS principles with no budget constraints.

The long-term benefit of such a pilot is that it would send a strong signal to the market that there is a reliable return for investing in antimicrobial R&D and would serve as an example for other countries to take action. Metrics should be established to measure outcomes resulting from the pilot.

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[9] https://www.who.int/medicines/publications/global-priority-list-antibiotic-resistant-bacteria/en/

[10] Williamson, Deborah. A., Howden, Benjamin P., Paterson, David L., 2019, The risk of resistance: what are the major antimicrobial resistance threats facing Australia? Medical Journal of Australia

ABOUT AAMRNET

The Australian Antimicrobial Resistance Network – AAMRNet – was established in 2020 by MTPConnect. It is an Australian-first network bringing together industry, clinicians and researchers to address the impact of antimicrobial resistance (AMR) on human health.

AAMRNet is operated by MTPConnect with cross-sector stakeholder investment and support.

Industry contributions provided by:

- Pfizer ANZ
- CSIRO
- MSD Australia
- GSK Australia
- Botanix Pharmaceuticals
- Recce Pharmaceuticals
- SpeeDx
- Medicines Australia
- Biointelect
- Monash Centre to Impact AMR

Partner organisations:

- AusBiotech Ltd
- BiomeBank
- Community for Open Antimicrobial Drug Discovery (CO-ADD)
- DMTC Limited
- Epichem Pty Ltd
- Formulytica Pty Ltd
- GARDP – Switzerland
- Incubator for Antibacterial Therapies in Europe (INCATE)
- LBT Innovations
- Menzies School of Health Research
- Microbio
- Monash Biomedicine Discovery Institute
- RESULTS International Australia
- Roche Diagnostics Australia

With its broad representation, networks, and expertise of its key stakeholders, AAMRNet is uniquely placed to drive some of the priority actions for combatting AMR which are identified in Australia's *National Antimicrobial Resistance Strategy – 2020 & Beyond.*

APPENDIX A – ACCESS TO NOVEL ANTIMICROBIALS IN AUSTRALIA

Only three of the nineteen antimicrobials considered to be novel and registered in Europe and/or the US in the last decade have been registered in Australia.

	Antibacterial[1,2]	Gram-negative AMR activity (Enzyme)[2,6,7,8]	Registered in USA[1]	Registered in Europe - Europe[1,10]	Registered in Australia[3]
1	Fidaxomicin		2011	2011	Yes - 2013
2	**Bedaquiline**		**2012**	**2014**	**No**
3	Dalbavancin		2014	2015	No
4	Oritavancin		2014	2015	No
5	Tedizolid phosphate		2014	2015	No
6	Finafloxacin		2014	N.R.	No
7	Delaminid		N.R.	2014	No
8	**Ceftolozane/tazobactam**	**Yes (ESBLs; *P. aeruginosa*)**	**2014**	**2015**	**Yes - 2015**
9	**Ceftazidime/avibactam**	**Yes (ESBLs, KPC; OXA-48; *P. aeruginosa*)**	**2015**	**2016**	**Yes - 2019**
10	Delafloxacin		2017	2019	No
11	**Meropenem/vaborbactam**	**Yes (ESBLs; KPC)**	**2017**	**2018**	**No**
12	**Plazomicin**	**Yes (ESBLs; KPC; MBL – variable; OXA-48; *P. aeruginosa* – variable)**	**2018**	**N.R. – Authorised 2018, withdrawn 2020**	**No**
13	**Eravacycline**	**Yes (ESBLs; KPC; MBL; OXA-48; *S. maltophilia)***	**2018**	**2018**	**No**
14	Omadacycline		2018	N.R. – withdrawn 2020	No
15	Sarecycline		2018	N.R.	No
16	**Pretomanid**		**2019**	**2020**	**No**
17	Lefamulin		2019	2019	No
18	**Cefiderocol**	**Yes (ESBLs; KPC; MBL - variable; OXA-48; *P. aeruginosa; A. baumannii; S. maltophilia*)**	**2019**	**2020**	**No**
19	**Imipenem/relebactam**	**Yes (ESBLs; KPC; *P. aeruginosa*)**	**2019**	**2020**	**No**

Note: agents with activity against priority pathogens are shown in **bold**; includes 'Urgent' and 'Serious' threats in the USA and "Critical' and 'High' based on WHO ratings for R&D.

(1) Butler MS, Paterson DL. Antibiotics in the clinical pipeline in October 2019. J Antibiot (Tokyo). 2020 Jun;73(6):329-364. doi: 10.1038/s41429-020-0291-8. Epub 2020 Mar 10. PMID: 32152527; PMCID: PMC7223789. Paterson DL, Isler B, Stewart A. New treatment options for multiresistant gram negatives. Curr Opin Infect Dis. 2020 Apr;33(2):214-223
(2) TGA, https://www.tga.gov.au/australian-register-therapeutic-goods
(3) Hillock NT, Karnon J, Turnidge J, Merlin TL. Estimating the utilisation of unregistered antimicrobials in Australia. Infect Dis Health. 2020 Mar;25(2):82-91. doi: 10.1016/j.idh.2019.12.001. Epub 2020 Jan 3. PMID: 31911133. Note limitation was that data from the SAS (May 2012-April 2017) was only retrieved for unregistered drugs identified in the eTG; other sources were South Australian Hospital Pharmacy Data (July 2015-June 2017) and NAUSP (Jan 2013 – Dec 2018).
(4) Donovan P. Access to unregistered drugs in Australia. Aust Prescr. 2017 Oct;40(5):194-196. doi: 10.18773/austprescr.2017.062. Epub 2017 Aug 15. PMID: 29109604; PMCID: PMC5662438
(5) Doi, Y. Treatment Options for Carbapenem-resistant Gram-negative Bacterial Infections 2019:69 CID
(6) 2019 AR Treats Report https://www.cdc.gov/drugresistance/biggest-threats.html
(7) https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf
(8) https://www.who.int/medicines/publications/WHO-PPL-Short_Summary_25Feb-ET_NM_WHO.pdf
(9) McKenna, M. The antibiotic paradox: why companies can't afford to create life-saving drugs. 19 August 2020. Nature
(10) Rex https://amr.solutions/2020/09/07/new-antibiotics-are-not-being-registered-or-sold-in-europe-in-a-timely-manner/

Fidaxomicin: https://www.ema.europa.eu/en/medicines/human/EPAR/dificlir
Bedaquiline: https://www.ema.europa.eu/en/medicines/human/EPAR/sirturo
Dalbavancin: https://www.ema.europa.eu/en/medicines/human/EPAR/xydalba

Oritavancin: https://www.ema.europa.eu/en/medicines/human/EPAR/orbactiv
Tedizolid phosphate: https://www.ema.europa.eu/en/medicines/human/EPAR/sivextro
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Ceftazidime/avibactam: https://www.ema.europa.eu/en/medicines/human/EPAR/zavicefta
Delafloxacin: https://www.ema.europa.eu/en/medicines/human/EPAR/quofenix
Meropenem/vaborbactam: https://www.ema.europa.eu/en/medicines/human/EPAR/vaborem
Plazomicin: https://www.ema.europa.eu/en/medicines/human/withdrawn-applications/zemdri
Eravacycline: https://www.ema.europa.eu/en/medicines/human/EPAR/xerava
Omadacycline: https://www.ema.europa.eu/en/medicines/human/withdrawn-applications/nuzyra
Pretomanid: https://www.ema.europa.eu/en/medicines/human/EPAR/pretomanid-fgk
Cefiderocol: https://www.ema.europa.eu/en/medicines/human/EPAR/fetcroja
Imipenem/relebactam: https://www.ema.europa.eu/en/medicines/human/EPAR/recarbrio

APPENDIX B – THE STEDI VALUES OF ANTIBIOTICS

Value	Description of benefit
Spectrum	Replacing broad spectrum agents with narrow spectrum agents and thereby reducing collateral damage to the microbiome
Transmission	Avoiding pathogen spread to the wider population by effectively treating patients
Enablement	Availability of effective treatment enables other types of medical interventions (e.g., surgery, oncology)
Diversity	Having a range of treatment options reduces selection pressure
Insurance	Having an agent available in case of a sudden or significant increase in the prevalence of pathogens resistant to existing agents

Outterson and Rex, Translational Research 2020
The STEDI concept was adapted from Rothery et al. Framework for Value Assessment of New Antimicrobials[11]

Source: Rex – NASEM Committee on AMR, 5 Jan 2021[12]

[11] Rothery et al. Framework for Value Assessment of New Antimicrobials.
http://www.eepru.org.uk/wp-content/uploads/2017/11/eepru-report-amr-oct-2018-059.pdf, 2018

[12] https://amr.solutions/wp-content/uploads/2021/01/2021-01-05_JH_Rex_-NAS_AMR_Committee_(vfinal).pdf

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