Target product profiles for new antibacterial agents

For therapy of:

- *severe infections caused by multidrug-resistant Gram-negative bacteria;*
- *antibiotic-resistant Gram-positive infections in immunosuppressed and critically ill patients; and*
- *community-acquired and healthcare-associated bacterial meningitis.*

World Health Organization

Target product profile for therapy of severe infections caused by multidrug-resistant Gram-negative bacteria

Focus: novel antibiotics for bloodstream infections and hospital-acquired or ventilator-associated bacterial pneumonia caused by third-generation cephalosporin- and carbapenem-resistant Enterobacterales, and carbapenem-resistant Acinetobacter baumannii and Pseudomonas aeruginosa

Multidrug-resistant (MDR) Gram-negative bacterial infections are a leading contributor to the global burden of antimicrobial resistance (AMR), with carbapenem-resistant strains causing an estimated 89,200 deaths between 1990 and 2021 *(1)*. WHO bacterial priority pathogens including third-generation cephalosporin-resistant and carbapenem-resistant Enterobacterales (3GCRE, CRE), carbapenem-resistant *Acinetobacter baumannii* (CRAB) and carbapenem-resistant *Pseudomonas aeruginosa* (CRPA), are associated with high mortality in severe and bloodstream infections (BSIs) *(2)*. Drug resistance in these organisms emerges through a combination of factors such as production of β-lactamases, efflux and porin alterations *(3–5)*. Current treatments largely rely on β-lactam (BL) and β-lactam/β-lactamase inhibitor (BL/BLI) combinations; however, their clinical utility is undermined by resistance, high treatment costs, and limited global availability *(6–8)*. The antibiotic research and development (R&D) pipeline remains inadequate, with only four innovative agents targeting priority Gram-negative bacteria, mostly BL/BLI combinations and therefore potentially susceptible to cross-resistance *(9).*

This Target Product Profile (TPP) aims to guide the development of novel antibiotics with activity against MDR Gram-negative pathogens, including 3GCRE, CRE, CRAB, and CRPA, featuring novel mechanisms of action, optimal pharmacokinetic profiles, and both intravenous and oral formulations, while ensuring equitable global access, affordability, and stewardship for severe infections including BSIs and hospital-acquired or ventilator-associated bacterial pneumonia (HABP/VABP). The present TPP does not focus on paediatric patients to avoid overlap with the *WHO TPP for therapy in children including neonates with MDR Gram-negative infections (10)*.

60 **Table 1. TPP for therapy of severe infections caused by MDR Gram-negative bacteria**
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	Minimal TPP	Preferred TPP
Indication for use	Severe infections, including BSIs, caused by prioritized MDR Gram-negative bacteria: 3GCRE, CRE, CRAB and/or CRPA.	All criteria in the minimal TPP, including HABP/VABP.
Target population	Hospitalized patients with severe community- or hospital-acquired infections, including BSIs.	Critically ill patients, including intensive care unit (ICU) patients, with HABP/VABP.
Mechanism of action (MoA)	Any MoA is acceptable.	Novel or differentiated MoA compared to existing antibiotics.
Access and affordability	Dose, regimen, cost of goods and health system delivery costs should enable affordable supply and delivery and should not be a barrier to access in LMICs.	Analyses of the cost-effectiveness and acceptability from an LMIC perspective should be conducted.
Safety	Any adverse events are reversible and manageable in the targeted patient population.	Same as minimal TPP, plus no need for routine therapeutic drug monitoring (TDM).
In vitro activity	Activity against prioritized MDR Gram-negative pathogens: 3GCRE, CRE, CRAB and CRPA. Low degree of cross-resistance to existing antibiotics and low propensity for resistance development.	Same as minimal TPP, plus activity against isolates with acquired resistance to new BL/BLI combinations and cefiderocol.
Efficacy	Proven clinical efficacy in adults through randomized clinical trials in patients with Gram-negative infections, including patients with BSIs and infections caused by MDR Gram-negative pathogens.	Same criteria as minimal TPP, with demonstrated efficacy for HABP/VABP and optimized dosing for PK/PD target attainment in critically ill patients.
Formulation or presentation	Formulation for intravenous administration.	Formulations for intravenous and oral administration.
Dose regimen	1–4 times daily dosing.	1–2 times daily dosing.
Route of administration	Intravenous injection or infusion.	Intravenous or oral.
Product stability and storage	Heat-stable, 3-year shelf life in hot tropic/humid climate (30°C and	Same as minimal TPP except no need for refrigeration.

	65% relative humidity). Need for refrigeration (4 ^{0}C) is acceptable.	
Pharmacokinetics (PK)	PK data available to support use in adult patients with severe Gram-negative infections. Adequate drug concentrations in plasma and in tissue of infection site.	Same as minimal TPP, for critically ill patients with HABP/VABP. Adequate drug concentrations in epithelial lining fluid (ELF) with standard or adapted dosing.
Co-administration	Minimal interactions with drugs commonly used in hospitalized patients and in the ICU setting.	No interactions with drugs commonly used in hospitalized patients and in the ICU setting.

Note: *minimal* profile reflects the essential requirements for development, while the *preferred* profile outlines the ideal characteristics for broader impact and clinical utility.

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Target product profile for therapy of antibiotic-resistant Gram-positive infections in immunosuppressed and critically ill patients

Focus: novel antibiotics for severe infections, including bloodstream infections, caused by vancomycin-resistant Enterococcus faecium and other Gram-positive bacteria, such as methicillin-resistant Staphylococcus aureus and coagulase-negative staphylococci

Immunocompromised and critically ill patients face substantially increased risk of severe bacterial infections. Bloodstream infections (BSIs) affect 5–7% of intensive care unit (ICU) admissions and are estimated to cause approximately 2 million cases and 250,000 deaths annually across North America and Europe *(1–3)*. The incidence of Gram-positive pathogens, including the WHO bacterial priority pathogens vancomycin-resistant *Enterococcus faecium* (VRE) and methicillin-resistant *Staphylococcus aureus* (MRSA) is increasing, driven by demographic shifts towards older and chronically ill and immunosuppressed patient populations, the increased use of invasive devices, and widespread use of broad-spectrum antibiotics *(4,5)*. MRSA prevalence increased from 13.4% in 2016 to 32.2% in 2022 *(6)*, while VRE remains associated with high mortality (25–50%) *(7,8)*, limited treatment options, and emerging resistance to the last-resort agents linezolid and daptomycin, both of which carry toxicity concerns *(9,10).* The antibiotic R&D pipeline is equally concerning, with only two traditional antibiotics in development targeting both VRE and MRSA, and none currently in Phase 3 trials, underscoring the urgent need for innovative therapeutics for high-risk patient populations *(11)*.

This TPP aims to guide the development of novel antibiotics with activity against vancomycin-resistant *E. faecium*, MRSA, and other Gram-positive pathogens causing severe infections in immunosuppressed and critically ill patients, featuring novel mechanisms of action, suitable pharmacokinetic profiles, and both intravenous and oral formulations, while carefully considering equitable global access, affordability, and stewardship.

World Health Organization

133 **Table 2a. TPP for therapy of antibiotic-resistant Gram-positive infections in immunosuppressed and**
134 **critically ill patients**
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	Minimal TPP	Preferred TPP
Indication for use	Severe infections, including BSIs, in immunosuppressed and critically ill patients, caused by antibiotic-resistant Gram-positive bacteria.	All criteria in the minimal TPP, plus more complicated infections, such as intravascular catheter-related infections and native or prosthetic valve endocarditis.
Target population	Hospitalized patients with immunosuppression and severe community- or hospital-acquired infections.	Critically ill patients, including patients treated in intensive care units (ICUs) and receiving haemodialysis.
Mechanism of action (MoA)	Any MoA is acceptable.	Novel or differentiated MoA compared to existing antibiotics.
Access and affordability	Dose, regimen, cost of goods and health system delivery costs should enable affordable supply and delivery and should not be a barrier to access in LMICs.	Analyses of the cost-effectiveness and acceptability from an LMIC perspective should be conducted.
Safety	Any adverse events are reversible and manageable in the targeted patient population.	Same as minimal TPP, plus no need for routine therapeutic drug monitoring (TDM).
In vitro activity	Activity against Gram-positive pathogens, including vancomycin-resistant *E. faecium*, and other enterococci and staphylococci with resistance to vancomycin and β-lactams (VRE, MRSA and methicillin-resistant coagulase-negative staphylococci). No cross-resistance to currently used antibiotics, and low propensity for resistance development.	Same as minimal TPP, and activity against strains with acquired resistance to linezolid and daptomycin.
Efficacy	Proven clinical efficacy in randomized controlled trials for severe Gram-positive infections, including patients with BSIs, immunosuppression, and infections caused by pathogens resistant to vancomycin and/or beta-lactams.	Same criteria as minimal TPP and with demonstrated efficacy for more complicated infections, and optimized dosing for PK/PD target attainment in critically ill patients.

Formulation or presentation	Formulation for intravenous administration.	Formulations for intravenous and oral administration.
Dose regimen	1–4 times daily dosing.	1–2 times daily dosing.
Route of administration	Intravenous injection or infusion.	Intravenous or oral.
Product stability and storage	Heat-stable, 3-year shelf life in hot tropic/humid climate (30°C and 65% relative humidity). Need for refrigeration (4 ^{0}C) is acceptable.	Same as minimal TPP except no need for refrigeration.
Pharmacokinetics (PK)	PK data available to support use in patients with severe Gram-positive infections in immunosuppressed patients. Adequate drug concentrations in plasma and in tissue of infection site.	Same criteria as minimal TPP, for more complicated infections and critically ill patients. Activity in biofilm for use against foreign body infections with standard or adapted dosing.
Co-administration	Minimal interactions with drugs commonly used in hospitalized immunosuppressed patients and in the ICU setting.	No interactions with drugs commonly used in hospitalized immunosuppressed patients and in the ICU setting.

136 **Note:** *minimal* profile reflects the essential requirements for development, while the *preferred* profile
137 outlines the ideal characteristics for broader impact and clinical utility.
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139 **Table 2b. Special considerations for children**

	Minimal TPP	Preferred TPP
Target population	Children (2–16 years old).	Neonates and infants (0–2 years old).
Efficacy & safety	When the course of infection is similar between children and adults and the product belongs to a well-established class of antibiotics, extrapolation of efficacy and safety should be applied in consultation with regulators. For first in class compounds a risk-based approach should be considered. When the course of infection is different, safety and efficacy should be compared to standard of care in a randomized controlled trial.	Same as minimal TPP.

Pharmacokinetics (PK)	PK data available to support use in the target patient population.	Same as minimal TPP.
Formulation or presentation	Formulation for intravenous administration.	Formulations for intravenous and oral administration. Oral formulations suitable for children, infants and neonates, e.g., functionally scored dispersible tablets and orodispersible multi-particulates (minitablets or sprinkles) or taste-masked suspensions.
Dose regimen	Weight-based dosing.	Weight-banded or age-banded dosing.

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Target product profile for treatment of community-acquired and healthcare-associated bacterial meningitis

Focus: novel antibiotics for community-acquired meningitis caused by penicillin- and cephalosporin-resistant bacteria, and healthcare-associated, e.g., neurosurgical meningitis, caused by multidrug-resistant Gram-negative bacteria and methicillin-resistant Staphylococcus aureus

Bacterial meningitis remains a major global cause of high mortality and morbidity, *with Streptococcus pneumoniae, Neisseria meningitidis, Haemophilus influenzae*, and Group B streptococci predominating in community-acquired meningitis, and MDR Gram-negative bacteria and MRSA more commonly seen in healthcare-associated infections *(1,2).* In 2019, *S. pneumoniae* accounted for 18.8% of meningitis-related deaths and *K. pneumoniae* for 12.2% *(2)*. Mortality remains disproportionately high in low-resource settings, particularly among neonates where case fatality rates can reach 43% *(3,4).* Escalating resistance to third-generation cephalosporins and carbapenems increasingly undermine treatment efficacy *(5,6).* Therapeutic options are further constrained by the limited ability of many antibiotics to efficiently penetrate the blood-brain barrier (BBB), and there are currently no agents in clinical trials specifically targeting meningitis. However, novel BL/BLI combinations and cefiderocol are under early investigation for activity against priority Gram-negative pathogens *(7,8)*.

This TPP aims to guide the development of a novel antibiotic for bacterial meningitis with broad coverage of WHO bacterial priority Gram-positive and Gram-negative pathogens, a novel mechanism of action, sufficient CNS penetration, and formulations suitable for diverse clinical settings, while ensuring equitable global access, affordability, and stewardship in line with the WHO Defeating Meningitis by 2030 roadmap *(9).*

World Health Organization

237 **Table 3a. TPP for therapy of community-acquired and healthcare-associated bacterial**
238 **meningitis**
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	Minimal TPP	Preferred TPP
Indication for use	Patients with bacterial meningitis, where resistance to the current standard antibiotic treatment is suspected or proven.	All the criteria included in the minimal TPP, plus infections caused by multidrug-resistant pathogens, for which there is currently no optimal treatment.
Target population	Hospitalized patients with 1) community-acquired bacterial meningitis or 2) healthcare-associated bacterial meningitis, including patients treated in intensive care units (ICUs).	Same as for minimal TPP.
Mechanism of action	Any MoA is acceptable.	Novel or differentiated MoA compared to existing antibiotics.
Access and affordability	Dose, regimen, cost of goods and health system delivery costs should enable affordable supply and delivery and should not be a barrier to access in LMIC settings.	Analyses of the cost-effectiveness and acceptability from an LMIC perspective should be conducted. See section on Access and affordability section.
Safety	Any adverse events are reversible and manageable in the targeted patient population.	Same as minimal TPP, plus no need for routine therapeutic drug monitoring (TDM).
In vitro activity	Antibiotics for community-acquired bacterial meningitis: Activity against pathogens commonly causing these infections with acquired resistance to current standard treatment, including pneumococci resistant to third-generation cephalosporins. Antibiotics for healthcare-associate bacterial meningitis: Activity against Gram-negative bacteria with acquired resistance to current standard treatment (including CRE, CRAB and CRPA), and/or staphylococci (including MRSA). Both indications: No cross-resistance to currently used	Antibiotics for community-acquired bacterial meningitis: The same criteria included in the minimal TPP. Antibiotics for healthcare-associate bacterial meningitis: The same criteria included in the minimal TPP, plus activity against strains with acquired resistance to current last-resort antibiotics, such as Gram-negative bacteria resistant to newer BL/BLIs and cefiderocol, and/or staphylococci, including MRSA, resistant to glycopeptide antibiotics.

	antibiotics, and low propensity for resistance development.	
Efficacy	Proven clinical efficacy in randomized clinical trials including patients with bacterial meningitis caused by pathogens resistant to standard treatment (see above).	Same criteria as minimal TPP.
Formulation or presentation	Formulation for intravenous administration.	Formulations for intravenous and oral administration.
Dose regimen	1–4 times daily dosing.	1–2 times daily dosing.
Route of administration	Intravenous injection or infusion.	Intravenous or oral.
Product stability and storage	Heat-stable, 3–year shelf life in hot tropic/humid climate (30°C and 65% relative humidity). Need for refrigeration (4^0C) is acceptable.	Same as minimal TPP except no refrigeration needed.
Pharmacokinetics (PK)	PK data available demonstrating good central nervous system (CNS) penetration to support use in patients with bacterial meningitis.	Same as minimal TPP.
Co-administration	Minimal interactions with drugs commonly used in hospitalized patients and in the ICU setting.	No interactions with drugs commonly used in hospitalized patients and in the ICU setting.

Note: *minimal* profile reflects the essential requirements for development, while the *preferred* profile outlines the ideal characteristics for broader impact and clinical utility.

Table 3b. Special considerations for children

	Minimal TPP	Preferred TPP
Target population	Children (2–16 years old).	Neonates and infants (0–2 years old).
Efficacy & safety	When the course of infection is similar between children and adults and the product belongs to a well-established class of antibiotics, extrapolation of efficacy and safety should be applied in consultation with regulators. For first in class compounds a risk-based approach should be considered. When the course of infection is different,	Same as minimal TPP.

	safety and efficacy should be compared to standard of care in a randomized controlled trial.	
Pharmacokinetics (PK)	PK data available to support use in the target patient population.	Same as minimal TPP.
Formulation or presentation	Formulation for intravenous administration.	Formulations for intravenous and oral administration. Oral formulations suitable for children, infants and neonates, e.g., functionally scored dispersible tablets and orodispersible multiparticulates (minitablets or sprinkles) or taste-masked suspensions.
Dose regimen	Weight-based dosing.	Weight-banded or age-banded dosing.

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