Importance Ratings and Summary of Antibacterial Uses in Humans in Australia

Version 1.1

Australian Strategic and Technical Advisory Group on AMR (ASTAG)

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Version control

The Importance Ratings and Summary of Antibacterial Uses in Humans in Australia document (the "Antibacterial Importance Ratings") was reviewed by the Australian Strategic and Technical Advisory Group on AMR (ASTAG) in February 2015. Some amendments were made, which are reflected in this version 1.1.

Australian Antimicrobial Resistance	Standing Committee (AMRSC	c) Version 1.0, July 2014
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Revisions by the Australian Strategic and Technical Advisory Group on AMR (ASTAG) Version 1.1, February 2015

Purpose

The purpose of the Antibacterial Importance Ratings tables is to provide guidance to clinicians and the pharmaceutical industry about the importance of antibacterial agents available for human use in Australia (refer table 1), as well as those agents not used in human health but that have the potential to select for cross resistance to antibacterials listed in table 1 (refer table 2).

Details are also given on the current ways in which all antibacterials are used in humans. This list is for guidance only, and does not include every use of the agent or class. All agents with significant antibacterial activity are included in the table, even if their primary use is for other than treatment of bacterial infections (e.g. pyrimethamine, a dihydrofolate reductase inhibitor whose main role is treatment of malaria and toxoplasmosis, but with the same antibacterial activity as trimethoprim, and therefore has the potential to select for resistance to this class).

ASTAG uses this information as a guide in providing advice to regulatory agencies and government committees including the Australian Pesticides and Veterinary Medicines Authority (APVMA), Therapeutic Goods Administration (TGA), Advisory Committee for Medicines Scheduling (ACMS), Advisory Committee for Chemicals Scheduling (ACCS) and Pharmaceutical Benefits Advisory Committee (PBAC), as a method of assessing the risk to human health after exposure of susceptible humans to either an antibacterial or antibacterial-resistant bacteria. In risk assessment terms, this table is relevant to the "severity of impact" which is an important element to overall risk characterisation. As an example, if an antibacterial is rated as 'High', ASTAG would consider that the severity of impact caused by bacteria resistant to that antibacterial is high, as there are few or no alternatives to many infections. Rating in this table does not affect other parts of risk assessment including hazard, exposure, impact or probability of disease as a result of exposure.

Background

The previous version of this document was released by the Antimicrobial Resistance Standing Committee (AMRSC), a former standing committee of the Australian Health Protection Principal Committee (AHPPC), building on earlier versions developed by the Expert Advisory Group on Antimicrobial Resistance (EAGAR) of the National Health and Medical Research Council (NHMRC). The document is intended to provide advice on risk assessments for new antibacterial agents and extensions of indications of currently registered antibacterials. The term 'antibacterial' is preferred in this document as the more common term 'antimicrobial' technically includes agents without antibacterial properties (e.g. antifungals), and such agents are not addressed here. The importance of the antibacterial or class of antibacterials in human medicine is taken into account in these risk assessments.

The ASTAG was formed in 2014, to provide advice to the Australian Antimicrobial Resistance Prevention and Containment Steering Group. It has assumed many of the roles of AMRSC, including the regular updating of the Antibacterial Importance Ratings. ASTAG is aware of documents with similar purposes including the WHO document 'Critically Important Antimicrobials for Human Medicine, 3rd rev, 2011' and the OIE 'List of Antimicrobials of Veterinary Importance', January 2014. ASTAG takes these documents into consideration when allocating its ratings, but has in some circumstances given a different rating because of the Australian context.

A note to readers

The Antibacterial Importance Ratings capture the knowledge of experienced professionals and is based upon the best available evidence at the time of completion. Readers should not rely solely on the information contained within this document. Antibacterial Importance Ratings is not intended to be a substitute for advice from other relevant sources including, but not limited to, the advice from a health professional. Clinical judgment and discretion may be required in the interpretation and application of this information.

The Antibacterial Importance Ratings will change over time as resistance levels change, new drugs are introduced, and optimum drug choices alter because of new medical evidence. Consequently the table will be updated at regular intervals.

Antibacterial class and antibacterial	Importance Rating ¹	Uses P, T, R	Comments ²	APVMA registered
Narrow-spectrum penicillins				
Benzylpenicillin (pen G), phenoxymethylpenicillin (pen V)	Low	P2, T3, R1	Primary agents in pneumococcal and streptococcal infection	Yes (Benzylpenicillin)
Procaine penicillin	Low	P2, T3, R1	Intramuscular – occasional substitute for benzylpenicillin	Yes
Benzathine penicillin	Low	P3, T3, R1	Intramuscular – syphilis treatment and rheumatic fever prophylaxis	Yes
Moderate-spectrum penicillins				
Amoxycillin, ampicillin	Low	P2, T3, R1	Principal role in respiratory tract infections; widespread IV hospital use in combination for a range of moderate and serious infections. Surgical and endocarditis prophylaxis	Yes
Antistaphylococcal penicillins				
Flucloxacillin, dicloxacillin	Medium	P3, T3, R1	Standard treatment for <i>Staphylococcus</i> <i>aureus</i> infections (not MRSA) Surgical prophylaxis, especially orthopaedics	
ß-lactamase inhibitor combinations				
Amoxycillin-clavulanate	Medium	P1, T3, R1	Second line agent for respiratory tract infections; role in certain types of skin/soft tissue infections and mixed staphylococcal/Gram-negative infections and aerobic/anaerobic infections.	Yes
Piperacillin-tazobactam, Ticarcillin-clavulanate	High	P1, T2, R2	Valuable agents for a range of severe mixed aerobic-anaerobic infections including intra-abdominal infections, aspiration pneumonia, skin/soft tissue infections. Primary agents for Pseudomonas aeruginosa Neutropenic sepsis	
1st Generation Cephalosporins				
Cephalexin, cephalothin, cefazolin	Medium	P3, T3, R1	Treatment of minor and staphylococcal infections in penicillin allergic patients. Prophylaxis in orthopaedic and other surgery	Yes (Cephalexin)
2nd Generation Cephalosporins				
Cefaclor, cefuroxime-axetil	Medium	P0, T2, R1	Treatment of respiratory infections in penicillin-allergic patients	Yes (Cefuroxime)

TABLE 1 Antibacterial agents used in human health in Australia

Antibacterial class and antibacterial	Importance Rating ¹	Uses P, T, R	Comments ²	APVMA registered
Cephamycins				
Cefoxitin	Medium	P3, T1, R2	Useful anti-anaerobic activity, major role in surgical prophylaxis	
3rd Generation Cephalosporins				
Ceftriaxone	High	P2, T3, R2	Major agent in severe pneumonia and meningitis. Used in selected cases for treatment of gonorrhoea and alternative for prophylaxis of meningococcal infection	
Cefotaxime	High	P0, T3, R2	Major agent in severe pneumonia and meningitis	
4th Generation Cephalosporins				
(and anti pseudomonal)				
Ceftazidime and cefepime	High	P1, T3, R3	Restricted role in pseudomonal infection and neutropenic sepsis	
Anti-MRSA Cephalosporins				
Ceftaroline	High	P1, T1, R3	Restricted role in MRSA infection	
Carbapenems				
Imipenem, meropenem, ertapenem	High	P0, T3, R4	Very broad-spectrum reserve agents for multi-resistant and serious Gram-negative and mixed infections	
Monobactams				
Aztreonam	High	P0, T3, R4	Reserve agents for resistant Gram-negative infections or patients with severe ß-lactam allergy	
Tetracyclines				
Tetracycline, doxycycline, minocycline	Low	P2, T3, R1	Major agents for minor respiratory tract infections and acne. Supportive role in pneumonia for treating <i>Mycoplasma</i> and <i>Chlamydia pneumoniae</i> . Malaria prophylaxis (doxycycline)	Yes (Doxycycline) (Tetracycline)
Glycylcyclines				
Tigecycline	High	P0, T1, R4	Reserve agent for multi-resistant gram-positives and some multi-resistant gram-negatives	
Glycopeptides				
Vancomycin	High	P2, T3, R2	Drug of choice for serious methicillin-resistant staphylococcal infections. Reserve agent for enterococcal infection when there is resistance or penicillin allergy	

Antibacterial class and antibacterial	Importance Rating ¹	Uses P, T, R	Comments ²	APVMA registered
Teicoplanin	High	P1, T1, R4	Substitute for vancomycin if intolerance or outpatient IV therapy	
Aminoglycosides				
Neomycin (including framycetin)	Low	P1, T2, R1	Topical agent for skin infection and gut suppression	Yes
Gentamicin, tobramycin	Medium	P2, T3, R1	Standard agents in combination for serious and pseudomonal infection. Gentamicin used in combination for endocarditis	Yes (Gentamicin)
Amikacin	High	P0, T2, R4	Reserve agents for Gram-negatives resistant to gentamicin and tobramycin	
Spectinomycin ³	Medium	P0, T2, R5	Spectinomycin only used for gonorrhoea (infrequently)	Yes
Streptomycin ³	Low	P0, T1, R5	Rare use in treatment of TB and enterococcal endocarditis	Yes
Capreomycin	Low	P0, T1, R5	Rare use in TB	
Paromomycin ³	Low	P0, T1, R5	Rare use for Cryptosporidium and Dientamoeba infection	
Sulfonamides and DHFR inhibitors				
Sulfadiazine ³	Low	P0, T3, R5	Treatment of acute toxoplasmosis	Yes
Silver sulfadiazine	Low	P3, T1, R1	Prevention of wound infections, especially in burns	
Sulfacetamide	Low	P0, T3, R1	Treatment of conjunctivitis	Yes
Trimethoprim	Low	P2, T3, R1	Treatment and prophylaxis of UTI	Yes
Trimethoprim-sulfamethoxazole (=co-trimoxazole)	Medium	P2, T3, R1	Minor infections, especially treatment and prophylaxis of UTI. Standard for treatment and prophylaxis of <i>Pneumocystis jiroveci</i> infection and nocardiasis. Important for community-acquired MRSA infections	
Sulfadoxine-pyrimethamine	Low	P1, T1, R3	Treatment and prophylaxis of malaria	Yes (Sulfadoxine)
Proguanil	Low	P2, T1, R3	Malaria prophylaxis	
Pyrimethamine	Low	P0, T3, R1	Treatment of toxoplasmosis	

Antibacterial class and antibacterial	Importance Rating ¹	Uses P, T, R	Comments ²	APVMA registered
Oxazolidinones				
Linezolid	High	P0, T1, R4	Treatment of multi-resistant Gram-positive infections, especially MRSA and VRE	
Macrolides				
Azithromycin	Low	P3, T3, R2	Treatment of <i>Chlamydia trachomatis</i> infections. Major agent for treatment and suppression of atypical mycobacterial infection	
Clarithromycin	Low	P2, T2, R1	Treatment of minor Gram-positive infections. Major agent for treatment and suppression of atypical mycobacterial infection	
Erythromycin, roxithromycin	Low	P1, T3, R1	Treatment of minor Gram-positive, Chlamydia and Mycoplasma infections.	Yes (Erythromycin)
Spiramycin ³	Low	P0,T1,R5	Treatment of toxoplasmosis in pregnancy	Yes
Lincosamides				
Clindamycin, lincomycin	Medium	P1, T3, R2	Reserved for Gram-positive and anaerobic infections in penicillin-allergic patients. Clindamycin topical used for acne	Yes
Streptogramins				
Quinupristin with dalfopristin ³	High	P0, T1, R4	Reserve agent for multi-resistant Gram-positive infections (MRSA and vancomycin-resistant <i>Enterococcus</i> <i>faecium</i>)	
Pristinamycin ³	High	P0, T1, R5	As for quinupristin-dalfopristin	
Nitroimidazoles				
Metronidazole, tinidazole	Medium	P2, T3, R1	Major agents for the treatment and prevention of anaerobic infections in hospitals. Principal agents for the treatment of giardiasis and trichomoniasis	Yes (Metronidazole)
Quinolones				
Norfloxacin	High	P1, T3, R2	Treatment and prevention of complicated UTI	
Ciprofloxacin	High	P2, T3, R3	Major oral agent for the treatment of Gram-negative infections resistant to other agents. Minor role in Meningococcal prophylaxis	
Moxifloxacin	High	P0, T3, R4	Restricted role in the management of serious respiratory infections, especially pneumonia in patients with severe penicillin allergy	

Antibacterial class and antibacterial	Importance Rating ¹	Uses P, T, R	Comments ²	APVMA registered
Ofloxacin	High	P0, T2, R3	Topical treatment of severe eye infections	
Levofloxacin ³	High	P0, T1, R5	Reserve treatment for <i>Helicobacter pylori</i> infection	
Antimycobacterials				
Isoniazid	High	P2, T3, R4	Primary agent for treatment and prevention of tuberculosis	
Ethambutol, pyrazinamide ³	High	P1, T3, R4	Primary agent for treatment of TB	
Cycloserine, p-aminosalicylic acid ³ , prothionamide ³	High	P0, T1, R4/R5	Reserve agents for complicated or resistant TB	
Antileprotics				
Clofazimine ³ , dapsone	High	P0, T3, R4	Usage predominantly for treatment of leprosy	
Rifamycins				
Rifampicin (Rifampin)	High	P3, T3, R2	Meningococcal and <i>H. influenzae</i> type b prophylaxis; Standard part of TB regimens. Important oral agent in combination for MRSA infections	Has been available under permit since 1998 for <i>Rhodococcus</i> <i>equi</i> infection. Permit not renewed since Sept 2012 but is available to veterinarians through Bova Compounding Chemist
Rifabutin	High	P3, 12, R4	I reatment and prophylaxis of Mycobacterium avium complex infections	
Rifaximin	High	P1, T0, R4	Prevention of hepatic encephalopathy	
Polypeptides				
Bacitracin, gramicidin	Low	P0, T2, R1	Topical agents with Gram-positive activity	Yes (Bacitracin)
Polymyxins				
Polymyxin B	High	P0, T2, R1	2, Topical agent with Gram-negative activity Ye	
Colistin	High	P0, T1, R4	Reserve agent for very multi-resistant gram-negative infection (both inhaled and intravenous)	

Antibacterial class and antibacterial	Importance Rating ¹	Uses P, T, R	Comments ²	APVMA registered
Amphenicols				
Chloramphenicol	Low	P0, T2, R1	Usage largely as topical eye preparation. Occasional need for the treatment of bacterial meningitis	Yes
Nitrofurans				
Nitrofurantoin	High	P2, T2, R1	Treatment and prophylaxis of urinary tract infections only	
Furazolidone ³	High	P0, T1, R5	Reserve treatment for <i>Helicobacter pylori</i> infection	
Fusidanes				
Sodium fusidate	High	P0, T3, R2	Used in combination therapy with rifampicin for MRSA	Yes ⁴
Fosfomycins				
Fosfomycin	High	P0,T1,R5		
Pseudomonic acids				
Mupirocin	Medium	P1, T3, R1	Topical treatment of skin infections and clearance of <i>S. aureus</i> nasal carriage (including MRSA)	
Lipopeptides				
Daptomycin	High		Reserve agent for serious MRSA and VRE infections	
Macrocyclic lactones				
Fidaxomicin	High	P0, T1, R4	Reserve agents for refractory <i>C. difficile</i> infection	

1 The importance of the drug class to the treatment of infections in humans, and the seriousness of the consequences of emergence of resistance.

- 2. Listed uses don't necessarily align with the TGA-registered uses, due to the slow evolution of indications after registration. Most closely aligned with Therapeutic Guidelines—Antibiotic
- 3. Not TGA-registered, but used through the Special Access Scheme
- 4. Generally for topical use in companion and recreational animals

<u>Abbreviations</u>: UTI = urinary tract infections; TB = tuberculosis; MRSA = methicillin-resistant *Staphylococcus aureus*; VRE = vancomycin resistant *Enterococcus* species

LEGEND for TABLE 1

AMRSC Importance Rating

High

These are essential antibacterials for treatment of human infections where there are few or no alternatives for many infections. Also have been called "critical", "last-resort" or "last line" antibacterials.

Medium

There are other alternatives available but less than for those classified as Low.

Low

There are a reasonable number of alternative agents in different classes available to treat most infections even if antibacterial resistance develops.

Human Uses

These reflect the current use of these antibacterials in Australia in human medicine.

P: prophylactic use

0 = not recommended for prophylactic use; 1 = rarely used; 2 = moderate; 3 = frequent or major use

T: therapeutic use

0 = not used for treatment; 1 = infrequently used for listed indications; 2 = moderate use for listed indications; 3 = used frequently for listed indications

R = Restriction on use (Pharmaceutical Benefits Scheme or hospitals)

- 1 = readily available
- 2 = some extra rules on use e.g. 'Restricted benefit' in the Pharmaceutical Benefits Scheme (PBS) or not listed on the PBS and therefore not subsidised
- 3 = higher level of restriction e.g. needs an 'Authority required' prescription on the PBS or not listed on the PBS and therefore not subsidised; often restricted use in hospitals
- 4 = use severely restricted (e.g. not available for prescription under PBS, available in major hospitals but only with permission from microbiologist or infectious diseases consultant, or in a special clinic)
- 5 = not TGA registered but imported under the SAS scheme

Antibacterial drug classes which are not used in humans and with no cross-resistance known to classes of antibacterials used in humans include arsenicals (roxarsone, 3-nitro-4-hydroxyphenylarsonic acid, sodium arsenilate), bambermycins (flavophospholipol, flavomycin), bicozamycin, coumermycins (including novobiocin), ionophores (lasalocid, maduramycin, monensin, narasin, salinomycin, semduramycin), orthosomycins (avilamycin), quinoxalines (carbadox, olaquindox), coumermycins (novobiocin) and nisin.

Pleuromutulins (tiamulin, valnemulin in animals) for human use are undergoing development; one agent, retapamulin, is registered for topical use in the USA and EU.

TABLE 2Antibacterials not included in Table 1, but with potential to select for cross resistance to
antibacterials used in Table 1

Antibacterial class	Importance	APVMA registered	Not registered in Australia for any
	rating		purpose
Narrow-spectrum penicillins	Low	Penethamate hydriodide	Phenoxyethylpenicillin (phenethicillin)
Moderate spectrum penicillins	Low	Nil	Aspoxicillin
			Azidocillin
			Bacampicillin
			Clometocillin
			Epicillin
			Hetacillin
			Metampicillin
			Penamecillin
			Pivampicillin
			Propicillin
			Sultamicillin
			Talampicillin
			Temocillin
			Tobicillin
Broad-spectrum penicillins	High	Nil	Azlocillin
(anti-pseudomonal and/or			Carbenicillin
β-lactamase stable)			Carindacillin
			Mecillinam
			Mezlocillin
			Piperacillin
			Pivmecillinam
			Sulbenicillin
			Temocillin
			Ticarcillin
Antistaphylococcal penicillins	Medium	Cloxacillin	Methicillin
			Oxacillin
			Nafcillin
ß-lactamase inhibitor	Medium-High	Nil	Ampicillin-sulbactam
combinations			Cefoperazone-sulbactam
1st Generation	Medium	Cephalonium	Cefacetrile
Cephalosporins (Medium)		Cephapirin	Cefadroxil
			Cefatrizine
			Cefazedone
			Ceforanide
			Cefroxadine
			Ceftazafur
			Ceftezole
			Cephaloglycin
			Cephaloridine
			Cephradine

Antibacterial class	Importance	APVMA registered	Not registered in Australia for any
	rating	A 11	purpose
2nd Generation	Medium	INII	
Cephalosporins			
			Cetotiam
			Cefprozil
			Cefroxadine
			Ceftezole
			Loracarbef
Cefamycins	Medium	Nil	Cefbuperazone
			Cefmetazole
			Cefminox
			Cefotetan
			Flomexef
3rd Generation	High	Cefovecin	Cefcapene
Cephalosporins		Ceftiofur	Cefdinir
			Cefditoren
			Cefetamet
			Cefixime
			Cefmenoxime
			Cefodizime
			Cefoselis
			Cefazopran
			Cefniramide
			Cefpodoxime
			Ceffizovime
			Ceftibuten
			Latamovef
			Cefquinome
4th Generation	High	Nil	Cefsulodin
Cephalosporins (and anti	5		Cefoperazone
pseudomonal)			Cefpirome
Anti-MRSA Cephalosporins	High	Nil	Ceftobiprole
Penems	High	Nil	Faropenem
Carbapenems	High	Nil	Biapenem
	5		Panipenem
Monobactams	Hiah		Carumonam
			Norcardicin A
			Tigemonam
Tetracyclines	Low	Chlortetracycline	Clomoclocycline
	LOW	Oxytetracycline	Demeclocyline
			Penimepicycline
			Rolitetracycline

Antibacterial class	Importance	APVMA registered	Not registered in Australia for any
	rating		purpose
Glycylcyclines	High	Nil	Nil
Glycopeptides	High	Nil	Avoparcin
			Dalbavancin
			Oritavancin
			Ramoplanin
			Telavancin
Aminoglycosides	Low-Medium-High	Apramycin	Arbekacin
	Ŭ	Dihydrostreptomycin	Bekanamycin
		Spectinomycin	Dibekacin
		. ,	Isepamicin
			Kanamycin
			Netilimicin
			Ribostamycin
			Sisomicin
			Streptoduocin
Sulfonamides and DHER	Low-Medium	Sulfacetamide	Baquiloprim
inhibitors		Sulfadimidine	Brodimoprim
		Sulfaquinovaline	Iclanrim
		Sulfamerazine	Ormetanrim
		Sulfathiazolo	Pyrimethamine
		Dhthalyleulfathiazolo	Sulfachlorpyridazipo
		Filliaryisullatillazoie	Sulfadimorazin
			Sulfadimethovazolo
			Sulfadimethoving
			Sulfacuanidina
			Sulfaisamidina
			Sulfalono
			Sulfamozono
			Sulfamethazina
			Sulfamethizala
			Sulfamethoxazole (alone)
			Sulfamethoxine
			Sulfametermidine
			Sulfametomidine
			Sulfametrolo
			Sullamida
			Suitapyridine
			letroxaprim
			Ormosulfathiazole

Antibacterial class	Importance	APVMA registered	Not registered in Australia for any
	rating		purpose
Oxazolidinones	High	Nil	Tolezolid
Macrolides	Low	Kitasamycin	Dirithromycin
		Oleandomycin	Flurithromycin
		Tilmicosin	Gamithromycin
		Tulathromycin	Josamycin
		Tylosin	Midecamycin
			Miocamycin
			Mirosamycin
			Rokitamycin
			Telithromycin
			Terdecamycin
			Tildipirosin
			Troleandomycin
			Tylvalosin
Lincosamides	Medium	Nil	Pirlimycin
	Wooddin		
Streptogramins	High	Virginiamycin	Nil
Nitroimidazoles	Medium	Dimetridazole	Ordinazole
	Modium	Ronidazole	
Quinclones	High	Enrofloxacin	Cinovacin
Quintiones	riigri	Ibaflovacin	Danoflovacin
		Marboflovacin	Difloyacin
		Orbiflovacin	Energein
		Orbinoxacin	Eloroyacin
			Flumoquino
			Correnovasin
			Garenoxacin
			Germalevesin
			Lomenoxacin
			Naliulixic aciu
			Pazunoxacin
			Piperilaid acid
			Prioriticic acia
			Pradonoxacin
			Trovafloxacin

Antibacterial class	Importance	APVMA registered	Not registered in Australia for any
	rating	• ····	purpose
Antimycobacterials	High	Nil	Calcium aminosalicylate
			Capreomycin
			Morinamide
			Sodium aminosalicylate
			Terizadone
			Tiocarlide
Antileprotics	High	Nil	Aldesulfone
Rifamycins	High	Nil	Rifapentine
-	ů,		Rifamycin
Polypeptides	Low	Thiostrepton	Enramycin
Polymyxins	Hiah	Nil	Nil
	g.i		
Amphenicols	Low	Florfenicol	Thiamphenicol
	2011		
Nitrofurans	High	Nitrofrurazone	Furaltadone
			Nifurtoinol
			Nitrofural
Fusidanes	High	Nii	Nil
rusidanes	riigii	INII	INII
Eastomyaina	High	Nii	Nil
Fosiomycins	піуп	INII	INII
Dogudomonio goido	Modium	Niji	Nil
Pseudomonic acids	wealum	INII	INII
		N 11	N 1
Lipopeptides	High	NII	NII
Macrocyclic lactones	High	Ní	