**Importance Ratings and Summary of**

**Antibacterial Uses in Humans in Australia**

**Version 1.1**

Australian Strategic and Technical Advisory Group on AMR (ASTAG)

**February 2015**

**Importance Ratings and Summary of Antibacterial Uses in Humans in Australia Version 1.1**

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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) Version 1.0, July 2014

Revisions by the Australian Strategic and Technical Advisory Version 1.1, February 2015

Group on AMR (ASTAG)

# 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.

# TABLE 1 Antibacterial agents used in human health in Australia

| Antibacterial class and antibacterial | Importance Rating1 | UsesP, T, R  | Comments2 | APVMAregistered |
| --- | --- | --- | --- | --- |
| **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.  | Yes |
|  |  |  | Surgical and endocarditis prophylaxis |  |
| **Antistaphylococcal penicillins** |  |  |  |  |
| Flucloxacillin, dicloxacillin | Medium | P3, T3, R1 | Standard treatment for *Staphylococcus aureus* 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 | Yes |
|  |  |  | and aerobic/anaerobic infections. |  |
| 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. | Yes(Cephalexin) |
|  |  |  | Prophylaxis in orthopaedic and other surgery |  |
| **2nd Generation Cephalosporins** |  |  |  |  |
| Cefaclor, cefuroxime-axetil | Medium | P0, T2, R1 | Treatment of respiratory infections in penicillin-allergic patients | Yes(Cefuroxime) |
| **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. | Yes(Doxycycline) |
|  |  |  | Supportive role in pneumonia for treating *Mycoplasma* and *Chlamydia pneumoniae.* | (Tetracycline) |
|  |  |  | Malaria prophylaxis (doxycycline) |  |
| **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 |  |
| 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. | Yes(Gentamicin) |
|  |  |  | Gentamicin used in combination for endocarditis |  |
| Amikacin | High | P0, T2, R4 | Reserve agents for Gram-negatives resistant to gentamicin and tobramycin |  |
| Spectinomycin3 | Medium | P0, T2, R5 | Spectinomycin only used for gonorrhoea (infrequently) | Yes |
| Streptomycin3 | Low | P0, T1, R5 | Rare use in treatment of TB and enterococcal endocarditis | Yes |
| Capreomycin | Low | P0, T1, R5 | Rare use in TB |  |
| Paromomycin3 | Low | P0, T1, R5 | Rare use for *Cryptosporidium* and *Dientamoeba* infection |  |
| **Sulfonamides and DHFR inhibitors** |  |  |  |  |
| Sulfadiazine3 | 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 *Pneumocystis jiroveci* 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 |  |
| **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 *Chlamydia trachomatis* 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) |
| Spiramycin3 | 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 dalfopristin3 | High | P0, T1, R4 | Reserve agent for multi-resistant Gram-positive infections (MRSA and vancomycin-resistant *Enterococcus faecium*) |  |
| Pristinamycin3 | 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. | Yes(Metronidazole) |
|  |  |  | Principal agents for the treatment of giardiasis and trichomoniasis |  |
| **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 |  |
| Ofloxacin | High | P0, T2, R3 | Topical treatment of severe eye infections |  |
| Levofloxacin3 | High | P0, T1, R5 | Reserve treatment for *Helicobacter pylori* infection |  |
| **Antimycobacterials** |  |  |  |  |
| Isoniazid | High | P2, T3, R4 | Primary agent for treatment and prevention of tuberculosis |  |
| Ethambutol, pyrazinamide3 | High | P1, T3, R4 | Primary agent for treatment of TB |  |
| Cycloserine, p-aminosalicylic acid3, prothionamide3 | High | P0, T1, R4/R5 | Reserve agents for complicated or resistant TB |  |
| **Antileprotics** |  |  |  |  |
| Clofazimine3, dapsone | High | P0, T3, R4 | Usage predominantly for treatment of leprosy |  |
| **Rifamycins** |  |  |  |  |
| Rifampicin (Rifampin) | High | P3, T3, R2 | Meningococcal and *H. influenzae* type b prophylaxis; Standard part of TB regimens.Important oral agent in combination for MRSA infections | Has been available under permit since 1998 for *Rhodococcus equi* infection. Permit not renewed since Sept 2012 but is available to veterinarians through Bova Compounding Chemist |
| Rifabutin | High | P3, T2, R4 | Treatment 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 | Topical agent with Gram-negative activity | Yes4 |
| Colistin | High | P0, T1, R4 | Reserve agent for very multi-resistant gram-negative infection (both inhaled and intravenous) |  |
| **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 |  |
| Furazolidone3 | High | P0, T1, R5 | Reserve treatment for *Helicobacter pylori* infection |  |
| **Fusidanes** |  |  |  |  |
| Sodium fusidate | High | P0, T3, R2 | Used in combination therapy with rifampicin for MRSA | Yes4 |
| **Fosfomycins** |  |  |  |  |
| Fosfomycin | High | P0,T1,R5 |  |  |
| **Pseudomonic acids** |  |  |  |  |
| Mupirocin | Medium | P1, T3, R1 | Topical treatment of skin infections and clearance of *S. aureus* 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 *C. difficile* 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

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

| Antibacterial class | Importance rating | APVMA registered | Not registered in Australia for any purpose |
| --- | --- | --- | --- |
| Narrow-spectrum penicillins  | Low | Penethamate hydriodide | Phenoxyethylpenicillin (phenethicillin) |
| Moderate spectrum penicillins | Low | Nil | AspoxicillinAzidocillinBacampicillinClometocillinEpicillinHetacillinMetampicillinPenamecillinPivampicillinPropicillinSultamicillinTalampicillinTemocillinTobicillin |
| Broad-spectrum penicillins (anti-pseudomonal and/or β-lactamase stable) | High | Nil | AzlocillinCarbenicillinCarindacillinMecillinamMezlocillinPiperacillinPivmecillinamSulbenicillinTemocillinTicarcillin |
| Antistaphylococcal penicillins | Medium | Cloxacillin | MethicillinOxacillinNafcillin |
| ß-lactamase inhibitor combinations | Medium-High | Nil | Ampicillin-sulbactamCefoperazone-sulbactam |
| 1st Generation Cephalosporins (Medium) | Medium | CephaloniumCephapirin | CefacetrileCefadroxilCefatrizineCefazedoneCeforanideCefroxadineCeftazafurCeftezoleCephaloglycinCephaloridineCephradine |
| 2nd Generation Cephalosporins | Medium | Nil | CefamandoleCefonicidCefotiamCefprozilCefroxadine CeftezoleLoracarbef |
| Cefamycins | Medium | Nil | CefbuperazoneCefmetazoleCefminoxCefotetanFlomexef |
| 3rd Generation Cephalosporins | High | CefovecinCeftiofur | CefcapeneCefdinirCefditorenCefetametCefiximeCefmenoximeCefodizimeCefoselisCefazopranCefpiramideCefpodoximeCeftizoximeCeftibutenLatamoxefCefquinome |
| 4th Generation Cephalosporins (and anti pseudomonal) | High | Nil | CefsulodinCefoperazoneCefpirome |
| Anti-MRSA Cephalosporins | High | Nil | Ceftobiprole |
| Penems | High | Nil | Faropenem |
| Carbapenems | High | Nil | BiapenemPanipenem |
| Monobactams | High |  | CarumonamNorcardicin ATigemonam |
| Tetracyclines | Low | ChlortetracyclineOxytetracycline | ClomoclocyclineDemeclocylineLymecyclineMetacyclineMinocyclinePenimepicyclineRolitetracycline |
| Glycylcyclines | High | Nil | Nil |
| Glycopeptides | High | Nil | AvoparcinDalbavancinOritavancinRamoplaninTelavancin |
| Aminoglycosides | Low-Medium-High | ApramycinDihydrostreptomycinSpectinomycin | ArbekacinBekanamycinDibekacinIsepamicinKanamycinNetilimicinRibostamycinSisomicinStreptoduocin |
| Sulfonamides and DHFR inhibitors | Low-Medium | SulfacetamideSulfadimidineSulfaquinoxalineSulfamerazineSulfathiazolePhthalylsulfathiazole | BaquiloprimBrodimoprimIclaprimOrmetaprimPyrimethamineSulfachlorpyridazineSulfadimerazinSulfadimethoxazoleSulfadimethoxineSulfafurazole = sulfisoxazoleSulfaguanidineSulfaisomidineSulfaleneSulfamazoneSulfamethazineSulfamethizoleSulfamethoxazole (alone)SulfamethoxineSulfamethoxypyridazineSulfametomidineSulfamethoxydiazineSulfametroleSulfamonomethoxineSulfamoxoleSulfanilamideSulfaperinSulfaphenazoleSulfapyridineSulfathioureaTetroxaprimOrmosulfathiazole |
| Oxazolidinones | High | Nil | Tolezolid |
| Macrolides | Low | KitasamycinOleandomycinTilmicosinTulathromycinTylosin | DirithromycinFlurithromycinGamithromycinJosamycinMidecamycinMiocamycinMirosamycinRokitamycinTelithromycinTerdecamycinTildipirosinTroleandomycinTylvalosin |
| Lincosamides | Medium | Nil | Pirlimycin |
| Streptogramins | High | Virginiamycin | Nil |
| Nitroimidazoles | Medium | DimetridazoleRonidazole | Ordinazole |
| Quinolones | High | EnrofloxacinIbafloxacinMarbofloxacinOrbifloxacin | CinoxacinDanofloxacinDifloxacinEnoxacinFleroxacinFlumequineGarenoxacinGemifloxacinGrepafloxacinLomefloxacinMiloxacinNalidixic acidOxolinic acidPazufloxacinPefloxacinPipemidic acidPiromidic acidPradofloxacinPrulifloxacinRosoxacinRufloxacinSarafloxacinSitafloxacinSparfloxacinTemafloxacinTrovafloxacin |
| Antimycobacterials | High | Nil | Calcium aminosalicylateCapreomycinMorinamideSodium aminosalicylateTerizadoneTiocarlide |
| Antileprotics | High | Nil | Aldesulfone |
| Rifamycins | High | Nil | RifapentineRifamycin |
| Polypeptides | Low | Thiostrepton | Enramycin |
| Polymyxins | High | Nil | Nil |
| Amphenicols | Low | Florfenicol | Thiamphenicol |
| Nitrofurans | High | Nitrofrurazone | FuraltadoneNifurtoinolNitrofural |
| Fusidanes | High | Nil | Nil |
| Fosfomycins | High | Nil | Nil |
| Pseudomonic acids | Medium | Nil | Nil |
| Lipopeptides | High | Nil | Nil |
| Macrocyclic lactones | High | Nil |  |