

Supplementary Material for

Clinical indications treated with unregistered antimicrobials: regulatory challenges of antimicrobial resistance and access to effective treatment for patients

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Table S1. Indications for category A applications for access to unregistered antimicrobials

Table S2. Indications for category B applications for access to unregistered antimicrobials

Table S3. Antimicrobial drugs included in Category C of the Special Access Scheme as at 1 June 2018

Table S1. Indications for category A applications for access to unregistered antimicrobials

Unregistered antimicrobial	Number of requests
amoxicillin/clavulanate (IV)	
Perforated diverticulitis	1
amphotericin B (IV)	
<i>Aspergillus fumigatus</i> infection of surgical wound - IV product used topically	1
Fungal infection of eye (endophthalmitis or keratitis) - IV product used to prepare eye drops	9
Invasive fungal sinusitis - IV product used intranasally	1
artesunate	
Malaria	3
aztreonam	
Cystic Fibrosis - infective exacerbation	3
bedaquiline	
Multi-drug resistant tuberculosis (TB) - pulmonary & central nervous system (CNS)	1
chloramphenicol (oral)	
Infected EVAR (Endovascular aneurysm repair) graft with Extended-spectrum beta-lactamase (ESBL) <i>E.coli</i>	1
cidofovir	
Adenovirus in immunocompromised patient	1
BK virus nephropathy	2
BK virus ulcerative cystitis	1
Laryngeal papillomatosis	8
Indication not provided	1
clofazimine	
Leprosy	2
Multi-drug resistant TB	2
<i>Mycobacterium abscessus</i> infection causing cavitating lung lesions	1
<i>Mycobacterium avium complex</i> (MAC) abscesses (in Cystic Fibrosis)	4
<i>Mycobacterium chelonae</i> cutaneous infection	2
Spinal osteomyelitis secondary to MAC	1
cycloserine	
Multi-drug resistant TB	5
flucytosine (oral)	
Cryptococcal pneumonia	3
Cryptococcal meningitis	8
<i>Cryptococcus</i> - disseminated	2
fosfomycin	
ESBL bacteraemia / septicaemia or urosepsis	4
ESBL Urinary tract infection (UTI)	37
Infected aortic graft	1
UTI prophylaxis (ureteric stent / metastatic colorectal cancer/ history of VRE UTIs)	1
isavuconazole (oral)	
Invasive fungal infection - <i>Zygomycetes rhizopus</i>	1
ketoconazole	
Cushing syndrome	4

moxifloxacin (eyedrops)	
Mycobacterial keratitis	1
natamycin (eyedrops)	
Fungal (<i>Fusarium</i> spp.) corneal ulcer	1
Fungal keratitis	13
nitazoxanide	
<i>Clostridium difficile</i>	1
<i>Cryptosporidium</i> diarrhoea	15
Recurrent <i>Giardia</i> spp. infection	1
paromomycin	
<i>Entamoeba histolytica</i> infection	1
primaquine	
Malaria	6
Malarial prophylaxis	1
Pneumocystis pneumonia	1
pristinamycin	
Chronic intra-abdominal infection	3
Chronic septic joint infection	2
Deep wound infection (Vancomycin-resistant enterococci (VRE) / Methicillin-susceptible <i>Staphylococcus aureus</i> (MSSA) / Coagulase-negative staphylococci)	2
ESBL UTI	1
Prosthetic joint infection	12
Osteomyelitis	4
Bacteraemia (Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) &/or VRE)	3
prothionamide	
TB - miliary or multi-drug resistant	7
pyrazinamide	
TB - pulmonary and / or extra-pulmonary, including multi-drug resistant TB	176
ribavirin	
Respiratory syncytial virus (RSV)	1
RSV (on background of bilateral lung transplant)	1
sulfadiazine	
Toxoplasmosis	3
triclabendazole	
Fascioliasis	1
Total:	368

Table S2. Indications for category B applications for access to unregistered antimicrobials

Unregistered antimicrobial	Number of requests
bismuth subcitrate	
Refractory <i>Helicobacter pylori</i> infection	24
chloroquine	
Uncharacterised connective tissue disease	1
clofazimine	
Chronic drug-resistant <i>Mycobacterium avium</i> lung disease	2
Miliary tuberculosis, CNS involvement	1
Multi-drug resistant TB	1
<i>Mycobacterium chelonae</i> cutaneous infection	1
fosfomycin	
ESBL Urosepsis	1
ESBL UTI (recurrent)	1
Multi-drug resistant Gram-negative prostatitis	1
ketoconazole	
Cushing syndrome / disease	6
levofloxacin	
Refractory <i>Helicobacter pylori</i> infection	1
miltefosine	
Cutaneous leishmaniasis (New World leishmaniasis)	1
nitazoxanide	
<i>Cryptosporidium</i> gastroenteritis	1
Giardiasis	2
paromomycin	
<i>Blastocystis hominis</i>	1
<i>Dientamoeba fragilis</i> infection	6
<i>Entamoeba histolytica</i>	2
pristinamycin	
Abdominal infection, following percutaneous drainage	1
Chronic osteomyelitis	6
Chronic prosthetic infection	9
<i>Mycoplasma genitalium</i> infection	6
Pacemaker infection (drug-resistant <i>Staphylococcal</i> infection)	3
VRE bacteraemia with aortic root abscess (palliation)	2
prothionamide	
Multi-drug resistant TB	1
pyrazinamide	
TB	1
sulfadiazine	
Cerebral toxoplasmosis	1
tetracycline	
Refractory <i>Helicobacter pylori</i> infection	23
Total:	106

Table S3. Antimicrobial drugs included in Category C of the Special Access Scheme as at 1 June 2018

Ingredient & dosage form	Indication(s)
Bismuth subcitrate tablet	Resistant <i>Helicobacter pylori</i> infection
Clofazimine capsule	Leprosy
Clofazimine capsule	Granulomatous cheilitis
Clofazimine capsule	Melkersson Rosenthal Syndrome
Clofazimine capsule	<i>Mycobacterium avium</i> paratuberculosis in immunocompromised patients, recommended by an infectious disease specialist
Clofazimine capsule	Erythema nodosum leprosum
Furazolidone tablet	Resistant <i>Helicobacter pylori</i> infection
Levofloxacin tablet	Resistant <i>Helicobacter pylori</i> infection
Moxifloxacin 0.5% eye drops	Refractory bacterial conjunctivitis
Natamycin 5% eye drops	Refractory fungal blepharitis, conjunctivitis or keratitis
Nitazoxanide oral suspension	Giardiasis
Nitazoxanide oral suspension	Cryptosporidiosis
Nitazoxanide oral suspension	Blastocystis
Nitazoxanide tablet	Giardiasis
Nitazoxanide tablet	Cryptosporidiosis
Nitazoxanide tablet	Blastocystis
Paromomycin capsule	<i>Blastocystis hominis</i>
Paromomycin capsule	<i>Dientamoeba fragilis</i>
Paromomycin capsule	<i>Entamoeba histolytica</i>
Paromomycin capsule	Parasite infection
Pristinamycin tablet	MRSA and VRE infection where there is history of failed therapy with the other available antibiotics, at sites in relation to bone / joint / prosthesis
Pristinamycin tablet	Refractory or resistant <i>Mycoplasma genitalium</i> infections
Pristinamycin tablet	Other infections as prescribed by an ID specialist
Pyrazinamide tablet	Tuberculosis
Tetracycline capsule	Resistant <i>Helicobacter pylori</i> infection
Tetracycline tablet	Resistant <i>Helicobacter pylori</i> infection

Reference: <https://www.tga.gov.au/form/special-access-scheme>