

Feedback template: *Consideration of proposed listing changes to antibiotic repeats on the Pharmaceutical Benefits Scheme*

Responses due back by: **21 December 2018**

Please also refer to the consultation paper for more information.

Organisation: Medicines Australia

General comments:

Medicines Australia applauds the Australian Government for taking steps to address the growing risks associated with antimicrobial resistance (AMR) and welcomes the opportunity to respond to the Department of Health consultation paper on 'Consideration of proposed listing changes to antibiotic repeats on the Pharmaceutical Benefits Scheme (PBS)'.

Medicines Australia and the medicines industry strongly support initiatives that encourage the Quality Use of Medicines (QUM) in order to make a positive contribution to the health of Australians and the efficiency of the healthcare system, whilst at the same time maintaining the important step of prescriber choice of the most appropriate treatment. QUM means:

- Selecting management options wisely
- Choosing suitable medicines if a medicine is considered necessary
- Using medicines safely and effectively

QUM applies equally to decisions about medicine use by individuals and decisions that affect the health of the population. It reinforces the central importance of a patient and their healthcare professional having access to accurate, evidence-based and balanced information to inform decisions about medicines and their use. Therefore, any changes to prescribing restrictions will require prescribers and their patients to receive appropriate support and education to ensure that the best possible patient-centered care is maintained.

The medicines industry has a key role to play in the Quality Use of Medicines (QUM) with the main responsibilities being:

- The development of safe and effective products
- Marketing products in a way that facilitates QUM
- Providing high quality, evidence-based information relevant to all stakeholders
- Discouraging any activities that are not conducive to QUM.

Industry has a history of implementing activities that promote QUM and this includes playing a role in early patient access to innovative medicines; partnering with Government and other stakeholders to shape healthcare policy which supports QUM; and pursuing new opportunities that add value and address unmet needs of healthcare professionals and patients.

The discovery of antibiotics and their development to treat bacterial infections was one of the most important achievements of the 20th Century. Since antimicrobials were first commercially produced, initially for use in human medicine and subsequently in veterinary medicine and agriculture, their use has been associated with the risk of emergence of AMR. At the same time as the world has observed accelerated emergence of resistance, the discovery and development of new antimicrobial drugs has slowed down. Today, AMR is recognized as one of the world's most pressing global health priorities.

The World Health Organization (WHO) has acknowledged that "AMR is a complex problem that affects all of society and is driven by many interconnected factors. Single, isolated interventions have limited impact. Coordinated action is required to minimize the emergence and spread of antimicrobial resistance."¹

¹ <https://www.who.int/en/news-room/fact-sheets/detail/antimicrobial-resistance>

It is clear from this that multiple approaches involving many stakeholders are required to build a comprehensive strategy to respond to the threat of AMR. The pharmaceutical industry has a key role in building this strategy and Medicines Australia is proud of the work it has been doing through its involvement in the development of Australia's next Antimicrobial Resistance Strategy. To this, the following needs to be considered.

1. **Representation:** Industry should have a seat at the table in developing AMR Policy
2. **Regulatory Framework:** Ensure the regulatory framework supports the approval of novel antibiotics
3. **Reimbursement Framework:** Ensure the availability of innovative funding models for new antibiotics to support further R&D and a sustainable marketplace
4. **Surveillance:** Support local and global surveillance programs, and ensure there is a national, standardised approach to supporting key pathogens
5. **Stewardship:** Support stewardship to conserve antimicrobials for those who really need them
6. **Vaccines:** Support use of vaccines to reduce infection and protect our antimicrobials
7. **Manufacturing:** Reduce the environmental impact from the manufacture of antimicrobials
8. **Collaboration:** Work collaboratively across sectors and stakeholders to support a robust response to AMR

Medicines Australia looks forward to further engagement on this highly important issue. If you would like any further information, please contact Betsy Anderson-Smith on banderson-smith@medaus.com.au.

Yours Sincerely,



Elizabeth de Somer
CEO, Medicines Australia

Amoxicillin + clavulanic acid			
Listing	Proposed change	Agreed : yes / no	Comments:
<p>Listing 01891M – amoxicillin + clavulanic acid - tablet 500mg amoxicillin (as trihydrate) with 125mg clavulanic acid (as potassium clavulanate) Max quantity: 10 Repeats: 1</p>	<p>Noting that the same formulation is listed separately on the PBS with zero repeats, it is proposed that a streamlined authority is applied to the entire listing (01891M) for the following indications that have been identified as requiring a repeat:</p> <ul style="list-style-type: none"> • Mild pyelonephritis; and • non-sexually acquired pelvic inflammatory disease. 		
<p>Listing 08254K – amoxicillin + clavulanic acid - tablet 875mg amoxicillin (as trihydrate) with 125mg clavulanic acid (as potassium clavulanate) Max quantity: 10 Repeats: 1</p>	<p>Noting that the same formulation is listed separately on the PBS with zero repeats, it is proposed that a streamlined authority is applied to the entire listing (08254K) for the following indications:</p> <ul style="list-style-type: none"> • Mild pyelonephritis; • non-sexually acquired pelvic inflammatory disease; and • bite wounds. 		

Cefalexin			
Listing	Proposed change	Agreed : yes / no	Comments
Listing 02655R – cefalexin - capsule 250mg (anhydrous) Max quantity: 40 Repeats: 2	No change noting that the listing is already streamlined for prophylaxis of urinary tract infection.		
Listing 02655R – cefalexin - capsule 500mg (anhydrous) Max quantity: 40 Repeats: 1	No change noting that this listing is already streamlined for the treatment of osteomyelitis.		
Listing 03058Y –cefalexin – capsule 250mg (anhydrous) Max quantity: 20 Repeats: 1 <hr/> Listing 03119E – cefalexin – capsule 500mg (anhydrous) Max quantity: 20 Repeats: 1	Noting that the same formulations are listed separately on the PBS with zero repeats, it is proposed that a streamlined authority is applied to listings 03058Y and 03119E for the following indications: <ul style="list-style-type: none"> • Infected dermatitis (only for patients with hypersensitivity to penicillin) • Impetigo (only for patients dsfwith hypersensitivity to pesnicillin) • Cellulitis (only for patients with hypersensitivity to penicillin) 		

	<ul style="list-style-type: none"> • Acute pharyngitis caused by streptococcal infection (only for patients with hypersensitivity to penicillin) • Mild pyelonephritis • Cervical lymphadenitis; and • Perianal dermatitis caused by streptococcal infection. 		
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Amoxicillin			
Listing	Proposed change	Agreed : yes / no	Comments
Listing 01884E – amoxicillin capsule 250mg (as trihydrate) Max quantity: 20 Repeats: 1	Noting that the same formulation is listed separately on the PBS with zero repeats, it is proposed that a streamlined authority is applied to the entire listing for acute exacerbations of bronchiectasis.		
Listing 01889K – amoxicillin capsule 500mg (as trihydrate) Max quantity: 20 Repeats: 1			
Listing 08581P – amoxicillin tablet 1g (as trihydrate) Max quantity: 14 Repeats: 1	It is proposed that a streamlined authority is applied to the entire listing for the following indications: <ul style="list-style-type: none"> • community acquired pneumonia; and 		

	<ul style="list-style-type: none"> pneumonia in residents of a high level care nursing home (mild) 		
Doxycycline			
Listing	Proposed change	Agreed : yes / no	Comments
Listing 02708M - doxycycline - capsule 100mg (as hydrochloride) containing enteric coated pellets Max quantity: 7 Repeats: 1	No change as pack size is too small to justify removal of repeats, with repeats required in most cases to complete treatment.		
Listing 02709N – doxycycline – tablet 100mg (as hydrochloride) Max quantity: 7 Repeats: 1			
Listing 09105F – doxycycline – tablet 100mg (as monohydrate) Max quantity: 7 Repeats: 1			
Listing 02707L – doxycycline – capsule 50mg (as hydrochloride) containing enteric coated pellets Max quantity: 25 Repeats: 5	No changes are proposed for these listings noting that repeat prescriptions are appropriate for long term treatment of acne according to the <i>Therapeutic Guidelines: Antibiotic</i> .		
Listing 02711Q – doxycycline – tablet 50mg (as hydrochloride) Max quantity: 25 Repeats: 5			

Listing 09106G – doxycycline – tablet 50mg (as hydrochloride) Max quantity: 25 Repeats: 5			
Listing 10777F – doxycycline – capsule 100mg (as hydrochloride) containing enteric coated pellets Max quantity: 28 Repeats: 5	These listings are restricted for prophylaxis of severe acne. No changes are proposed to these listings as repeat prescriptions are appropriate for long term treatment of acne.		
Listing 10779H – doxycycline - tablet 100mg (as hydrochloride) Max quantity: 28 Repeats: 5			
Listing 10781K – doxycycline - tablet 100mg (as monohydrate) Max quantity: 28 Repeats: 5			

Roxithromycin			
Listing	Proposed change	Agreed : yes / no	Comments
Listing 8129W – roxithromycin – tablet 50mg Max quantity: 10 Repeats: 1	There are limited current recommendations for these listings in the Therapeutic Guidelines and none of the current listings need repeats. The 150mg dose is listed for prophylaxis but the current quantities are inadequate. It is		
Listing 01760P – roxithromycin – tablet 150mg Max quantity: 10 Repeats: 1			

<p>Listing 08016X – roxithromycin – tablet 300mg Max quantity: 5 Repeats: 1</p>	<p>therefore recommended that repeats are removed.</p>		
Paediatric antibiotic products			
Listing	Issue	Considerations	Comments
<p>All listings</p>	<p>Paediatric antibiotic products are widely used, particularly amoxicillin, cefalexin and amoxicillin + clavulanic acid.</p>	<p>Potential recommended change: Require streamlined authority based around weight of the patient for listings with repeats noting that identical formulations are available on the PBS with zero repeats.</p>	
		<p>Questions: What other options could be explored to address minimising unnecessary repeats to paediatric patients while still allowing access for heavier children or adults who require these formulations?</p> <p>Do you consider there to be any significant issues related to the implementation of streamlined authorities for repeats for paediatric antibiotic products?</p>	