AUSTRALIAN SOCIETY FOR ANTIMICROBIALS

Australasian Society for Infectious Diseases

Submission to the TGA Consultation on Proposed criteria for Appendix M of the Poisons Standard to support rescheduling of substances from Schedule 4 (Prescription only) to Schedule 3 (Pharmacist only)

The memberships of the Australian Society for Antimicrobials and the Australasian Society for Infectious Diseases wish to express their concern about the lack of criteria to address the critical issue of worsening antimicrobial resistance in Australia as part of the criteria for transfer of any antimicrobial agents to Appendix M. In particular, they wish to express their concern about the potential transfer of trimethoprim from Schedule 4 to Schedule 3, Appendix M. While it is recognised that the potential transfer is well-intentioned, the effect of such a transfer is fraught for the following reasons:

- Australia is already a very high user of antimicrobials in the community when compared to other nations with similar standards of healthcare (AURA 2016 and 2017 reports).
- Transferring any antimicrobial agent to Schedule 3 sends the wrong message to the community; it runs counter to all the work put in by multiple groups over the last 15 years to reduce unnecessary antimicrobial prescribing.
- One of the great benefits of the Australian healthcare system is the separation of prescribing from dispensing, thereby eliminating the risk of perverse financial incentives when prescribing. Avoidance of perverse financial incentives is highlighted by the World Health Organisation policy on promoting rational use of medicines (WHO Policy 2002). We believe that there would be significant risk of creating this perverse incentive with re-scheduling of any agents to S3, Appendix M, and yet this does not appear to have been addressed in the "Proposed criteria".
- In the context or management of uncomplicated urinary tract infection (uUTI):
    - Multi-resistance rates in *E. coli* are continuing to worsen in Australia (AURA 2019, to be released in early May 2019)
    - We do not consider it good clinical practice in these days of rising resistance to prescribe for uUTI without access to some form of testing, at a minimum a urine dipstick but ideally a midstream urine specimen for microbiological testing. Approximately one quarter of all patients presenting with lower UTI symptoms do not have bacterial uropathogens detected, so antibacterial therapy is not required. Pharmacists do not have the power to order such investigations. Furthermore, pharmacists do not have access to previous culture results which may indicate that trimethoprim will be ineffective.
    - If the motive is to reduce the risk of pyelonephritis and hospitalisation by administration of an antibacterial agent from a pharmacy, one recent study suggests that the number needed to treat to prevent pyelonephritis is 22, and to prevent hospitalisation is 133 (Kronenberg et al., 2017). In our opinion, the high rates of multi-resistance selection or amplification in individuals in the community outweigh the benefit of preventing these complications.

We believe that the move to consider any antimicrobial agents within the purview of Appendix M re-scheduling should be brought to the attention of the Australian Scientific and Technical Advisory Group on antimicrobial resistance. This Group was set up across both the Department of Health and the Department of Agriculture and Water Resources to advise government of scientific and technical matters in support of its National AMR Strategy. The Therapeutic Goods Administration is a member of this Group. It is likely that this Group would reject the notion of re-scheduling antimicrobial agents in human medicine, especially following the implementation of the JETACAR recommendation to re-schedule all veterinary and agricultural antibacterial agents as S4.

29 March 2019

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References

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Kronerberg A, Bütokofer L, Odutayo A. et al. Symptomatic treatment of uncomplicated lower urinary tract infections in the ambulatory setting: randomised, double blind trial. BMJ 2017; 359:j4784

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