The Australasian College of Dermatologists

Submission to TGA consultation: Obstacles and incentives to repurposing prescription medicines

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THE AUSTRALASIAN COLLEGE OF DERMATOLOGISTS
Suite 2A, Level 2, 9 Blaxland Road,
Rhodes NSW 2138
PO Box 3785 Rhodes NSW 2138
Telephone +61 2 8765 0242
Email admin@dermcoll.edu.au
Website www.dermcoll.edu.au

ABOUT THE ACD

The Australasian College of Dermatologists (ACD) is the sole medical college accredited by the Australian Medical Council for the training and continuing professional development of medical practitioners in the specialty of dermatology. As the national peak membership organisation, we represent over 550 dermatologist Fellows (FACD) and 100 trainees.

In Australia, dermatologists are registered medical practitioners who have undertaken a minimum of four years of specialist training in dermatology. They specialise in the diagnosis, treatment and management of all skin diseases and conditions, including skin cancer. With skills and expertise spanning medical, surgical and procedural dermatology, dermatologists are at the forefront of diagnosis, treatment, research and innovation in skin health.

ACD RESPONSE

The ACD thanks the Therapeutic Good Administration for the opportunity to provide feedback on obstacles and incentives to repurposing of medicines in Australia.

All Australians should be able to access the highest standard of skin health and the dermatology care. With more than 3,000 cutaneous diseases that may be treated by dermatologists, there is a wide gap between the number of possible presenting symptoms and the number of effective therapies. As such, the use of off-label, unsubsidised drugs has become valuable in the management of dermatology patients with challenging conditions unresponsive to conventional therapy.

In dermatology there are many drugs used for non-approved conditions including mycophenolate, azathioprine, methotrexate for eczema, and other immune modulated conditions; TNF blocking agents for toxic epidermal necrolysis (TEN) and pyoderma gangrenosum (PG); dapsone, doxycycline for blistering diseases; and hydroxychloroquine for Lichenoid conditions and other uses; to name but a few.

Off-label prescribing provides the opportunity for serendipitous discovery - for example propranolol is highly effective in the treatment of infantile haemangioma which has been a game changer both in avoiding the need for high dose steroids and preventing the need for tracheostomies in neonates. The fact that dermatologists were able to use it off label as soon as the discovery was published has been a major health benefit.

While dermatologists are very comfortable with prescribing off-label, we are also highly cognisant that while beneficial in terms of treatment options, the financial costs to the patient are high. Off-label prescribing also comes with medicolegal risk for the prescriber.

Yet as recognised in the consultation paper, often industry has little to gain from a listing application and the logistical hurdles are significant. We are highly supportive of steps that can help reduce regulatory burden for repurposing medicines, such as that outlined in Option 1, to allow patients with challenging conditions more affordable and continued access to therapy.

We also support any steps that can be taken to facilitate open-access to “real-world” Australian medicines usage data as outlined in Option 2, for example by expanding data sets like MedicineInsight to capture specialist data. Such data collection would be of useful for a multitude of reasons and would be a valuable complement to measures outlined in Option 1.

We do have concerns about putting the onus on non-commercial entities to sponsor new indications of a medicine, as described in Option 3. Our sense is that this would likely fail, not due to a lack of interest, but simply because most non-commercial organisations do not have the resource capacity to undertake such a task. There is also a risk that this could disincentivise industry.

Indeed, any of the reforms proposed would need to be undertaken with care so as not to have any unintended consequences that may inadvertently limit the ability of specialists to continue to use medicines off label where appropriate and necessary taking into account clinical and individual patient's circumstances.

The ACD would be well placed to inform which medicines would be suitable for repurposing should these reforms proceed.