Memorandum on ACT Legislation

The Chair of Mind Medicines Australia (MMA) Peter Hunt seeks advice about possible amendments to the *Medicines Poisons and Therapeutic Goods Act 2008* (ACT) (the Act) to deal with the fact this Act is narrower than the *Therapeutic Goods Act 1989* (Cth) (TGA) which allows access to Schedule 9 medicines for clinical purposes under Special Access Scheme -B. Mr Hunt advises there is no ability under the Act for the ACT Government to approve clinical use outside of a research trial even if the doctor has received approval from the TGA under Special Access Scheme – B.

Mr Hunt suggests an amendment to section 20(3) of the Act to allow in relation to a prohibited substance, either;

1. The automatic issue of a license to a doctor if that doctor had first obtained an approval to use the substance from the TGA under the Special Access Scheme, or the medical practitioner had been approved by the TGA to be an Authorised Prescriber in relation to that substance; or
2. The issue of a licence in the same circumstances if approved by the Chief Medical Officer of the ACT.

MMA seeks draft amendments to the *Medicines Drugs and Therapeutic Goods Act 2008* that would achieve this.

Section 20 of the Act allows an exemption at (2) such that a practitioner can gain access to the drugs under the TGA Act, but then at (3) states the authority for dealing with prohibited substance only exists for the purposes of research at a recognized institution (see s20 (5)) and with the approval of a human research ethics committee. This requirement was removed in July 2020 for certain drugs but not for the two substances we are dealing with here.

The Amendment

Any amendment should address that section of the Act and add a further exemption. It could add s20(3)(c) to read, after (2);

or

(c) (i) the dealing has been approved by the Therapeutic Goods Administration under the Special Access Scheme B;
or
(ii) the person is an Authorised Prescriber

The definition section of the Act would need to be amended to include definitions of “Special Access Scheme-B” and “Authorised Prescriber” which would simply be recognizing that they have the meaning attributed to them in the TGA Act and Regs.

The *Medicines, Poisons and Therapeutic Goods Regulations* 2008 (ACT) would need to be revised, and amended, to reflect s20(3) (c).

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