UNIVERSITY CENTRE FOR RURAL HEALTH
NORTH COAST
education research workforce

2.3.21

The Secretary
Medicines Scheduling Secretariat
Therapeutic Goods Administration

With regard to TGA Interim Decisions on Psilocybin and MDMA

I am Professor of Mental Health and Wellbeing at the University of Sydney (University Centre for Rural Health) and am writing to you as one of the leading researchers in the field of psychotherapist training (I am one of the three most published researchers in this area). Recently I have turned my attention to the study of therapist training in psychedelic-assisted psychotherapies. Amongst other things, I was a reviewer for the most comprehensive paper on psychedelic-assisted psychotherapy training to date (Tai et al., 2020 – as attached). In addition I have corresponded with key researchers to collect training data from the UK's leading centre, Imperial College; from USA's leading centre, John Hopkins University; and with MAPS, the leader in therapist training for PTSD.

Having carefully read your interim decisions on psilocybin and MDMA, I feel it is important that some misleading statements about training are corrected in your final report. In essence, the implication in your report is that:

1. Psychedelic-assisted psychotherapy is conducted only by psychiatrists and physicians;
2. That any training programs should be directed at them predominantly or exclusively;
3. These will take a long time to be developed.

Please note that none of these implications are true.

What is clear from the Tai et al. (2020) study of 65 psychedelic-assisted psychotherapists across multiple countries, as well as the data I have gathered from three world-leading psychedelic-assisted psychotherapy research centres is:

1. The vast majority of therapists are psychologists, counsellors and other trained (usually to at least Masters level) mental health professionals. Psychiatrists and physicians are sometimes part of the therapist dyad in a minority of cases. For instance, Tai et al. (2020) report that of the 65 therapists already trained to use psilocybin-assisted therapy in trials in USA and Europe, "The therapists currently working on the phase IIb study includes predominantly psychologists, as well as psychiatrists, masters level practitioners, nurses, diploma level CBT therapists and PhD mental health specialists (p.4)." John Hopkins University, the world leading research centre, report (pers comm, 11.11.20) that the trials "rarely include psychiatrists unless we have one or more as a research fellow." Imperial College reports (pers.comm 4.11.20): "In our first depression trial, we always had a psychiatrist as one of the dyads but not in our second trial. I think the latter is better/more feasible."
2. The predominance of psychologists and other health professionals in the therapist dyad is due to a mixture of (i) greater level of specialist training as psychotherapists than psychiatrists (only a minority of psychiatrists practice psychotherapy); (ii) cost (psychiatrists are too expensive) and (iii) relative availability – for instance in Australia there are around 30,000 psychologists vs. c. 3,500 psychiatrists.

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3. However, it is important that psychiatrists or other physicians are on site close by, in case of emergencies. This is a core part of all protocols

4. The training required to be an 'on site' psychiatrist or physician is not extensive (in contrast to the implication of your report).

5. The training required to be a therapist is much more extensive and should include supervision in the role as assistant or second therapist on a clinical trial prior to assuming a lead therapist role.

6. The statement "It will take years to develop a curriculum and accredited training process for psychiatrists" is inaccurate at a number of levels:

   (i) As above, it depends what role they are being trained for

   (ii) A clear distinction needs to be made between training as a psychedelic-assisted psychotherapist and training for availability in the case of onsite emergencies. The latter could easily be encompassed in one day's training.

   (iii) If referring to training as a psychedelic-assisted psychotherapist, then your decision needs to reflect that therapists are likely to be psychologists, counsellors and other suitably qualified mental health professionals – in other words, not just psychiatrists.

   (iv) The statement that "it will take years to develop a curriculum and accredited training …" is quite inaccurate. There are now a number of well regarded, accredited programs in the USA, UK and elsewhere, some of which are now being adapted for use in Australian clinical trials. Designing a program for the Australian context, or simply adapting existing well-developed programs such as the MAPS program, is a relatively simple exercise that could be easily achieved within a year. As well as training, clinical supervision of patients in clinical trials by an experienced psychedelic-assisted psychotherapist would be a core requirement.

I suggest the following statements (italicised) are modified in the light of this feedback:

For psilocybin:

It will take years to develop a curriculum and accredited training process for psychiatrists

Having considered the risks to consumers, *the lack of training for physicians*, and the current state of research, I am of the view that Schedule 9 remains appropriate for psilocybin.

For MDMA

It will take time to develop *a curriculum and accredited training process for psychiatrists*.

Having considered the risks to consumers, *the lack of training for physicians*, and the current state of research, I am of the view that Schedule 9 remains appropriate for MDMA.

Kind regards
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