MDMA and Psilocybine

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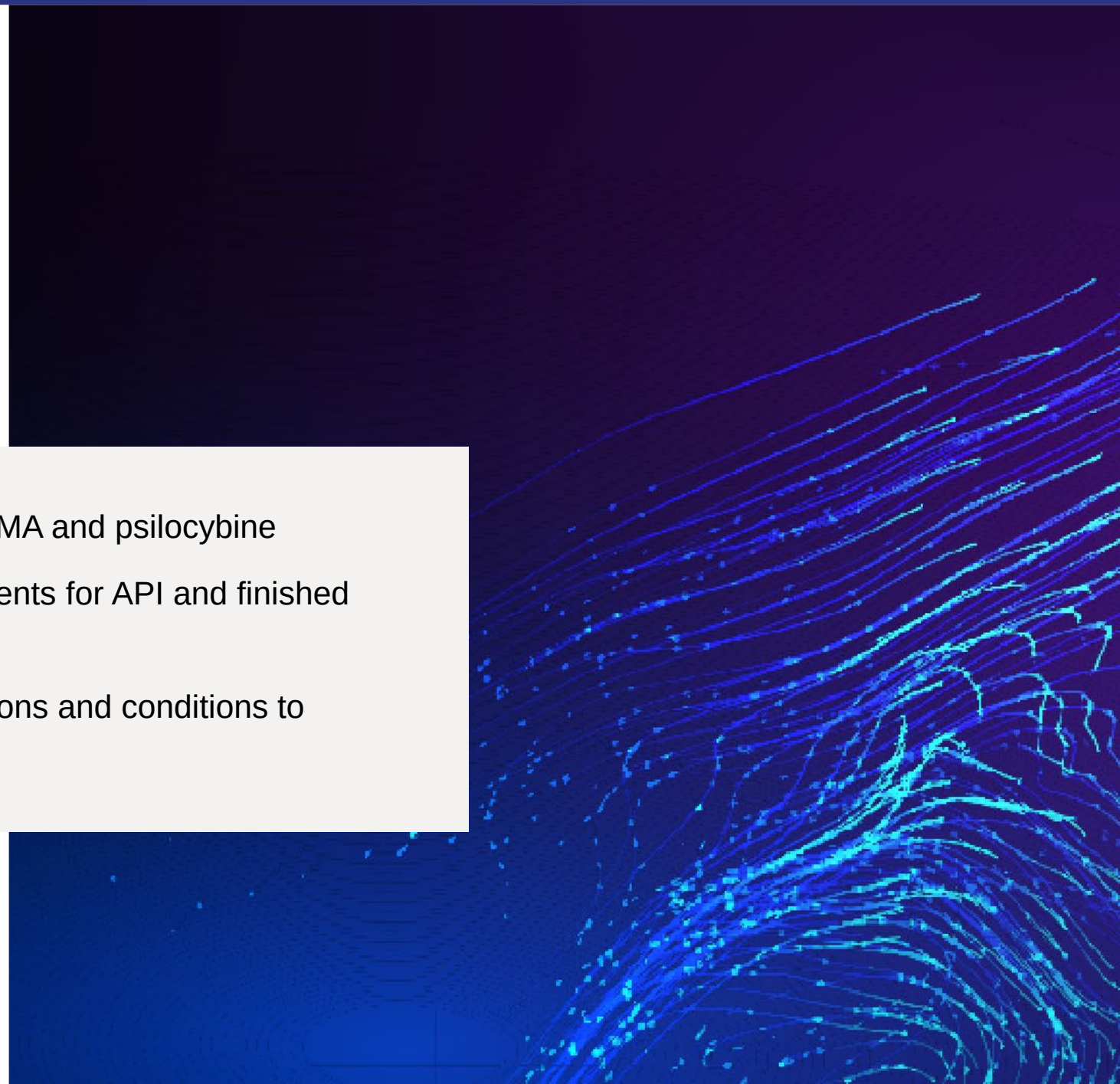
GMP FORUM 2024

Agenda

Learning outcomes

- Understand the changes to access for MDMA and psilocybine
- Overview of the minimum quality requirements for API and finished product
- Understand the specific licence authorisations and conditions to manufacture these substances



MDMA and psilocybine

Changes to access

1 July 2023 entries created for MDMA and psilocybine under Schedule 8 to the Poisons Standard.

MDMA and psilocybine are approved for specific mental health conditions:

- MDMA for post-traumatic stress disorder (PTSD)
- psilocybine for treatment-resistant depression (TRD)

To access, you must be a registered psychiatrist, that:

- completed a Fellowship with the Royal Australian and New Zealand College of Psychiatrists (RANZCP)
- Has approval under the Authorised Prescriber scheme

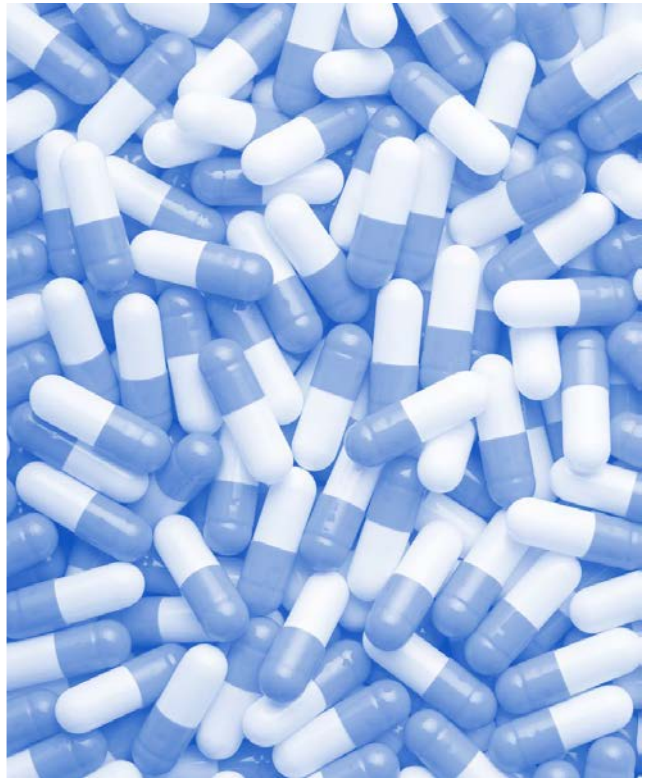
MDMA and psilocybine

Therapeutic Goods Orders

- Therapeutic Goods (Standard for MDMA) (TGO 112) Order 2024
- Therapeutic Goods (Standard for Psilocybine) (TGO 113) Order 2024
- Commence 6 January 2025
- Manufacturers and testing laboratories should plan for the commencement of the standards and develop and validate methods for testing the APIs and finished products.

MDMA and psilocybine

Application and dosage



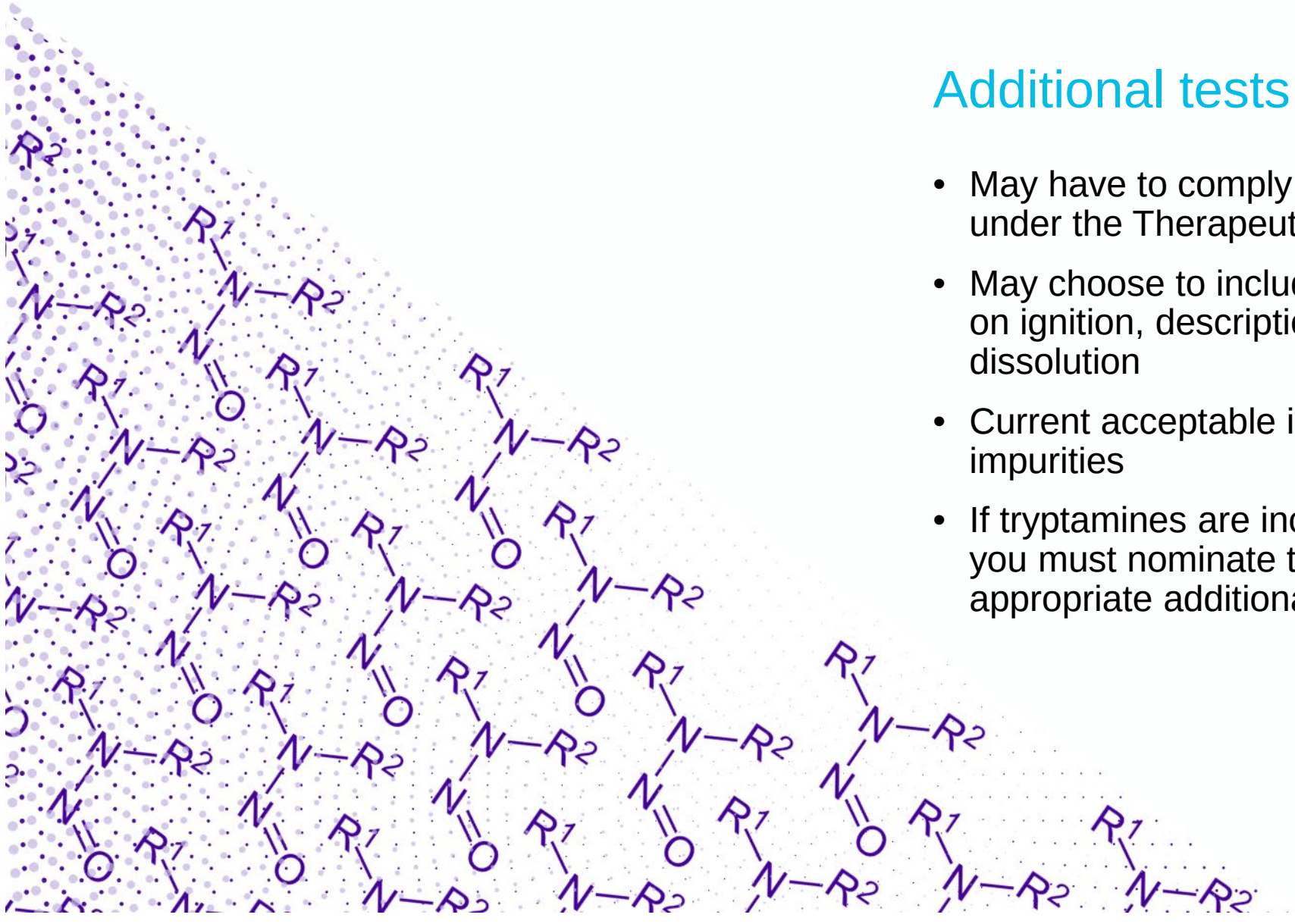
- TGOs apply to both the active pharmaceutical ingredient (API) and finished product
- Do not apply to goods supplied and imported for use under the clinical trial notification (CTN) and clinical trial approval (CTA) schemes; or to goods imported by certain groups of people subject to conditions
- MDMA limited to MDMA hydrochloride API and finished product.
- Psilocybine may be plant derived (extract or isolate from Psilocybe cubensis) or synthetically derived API or finished product.
- Dosage form of a capsule for human consumption

MDMA and psilocybine

Test methods

- API and finished product must be tested against and show compliance with the requirements.
- Test methods specified are considered most relevant and up to date to achieve a consistent API and finished product.
- May use:
  - equivalent methods in established pharmacopoeia, including the USP, or
  - suitably validated in-house tests
- In the event of a dispute, the test methods specified in the TGOs are the official methods for their respective therapeutic good and must be used

MDMA and psilocybine



Additional tests

- May have to comply with other quality standards under the Therapeutic Goods Act 1989
- May choose to include additional tests e.g. loss on ignition, description & appearance, dissolution
- Current acceptable intakes (AI) for nitrosamine impurities
- If tryptamines are included as part your extract, you must nominate them and conduct the appropriate additional tests

MDMA and psilocybine

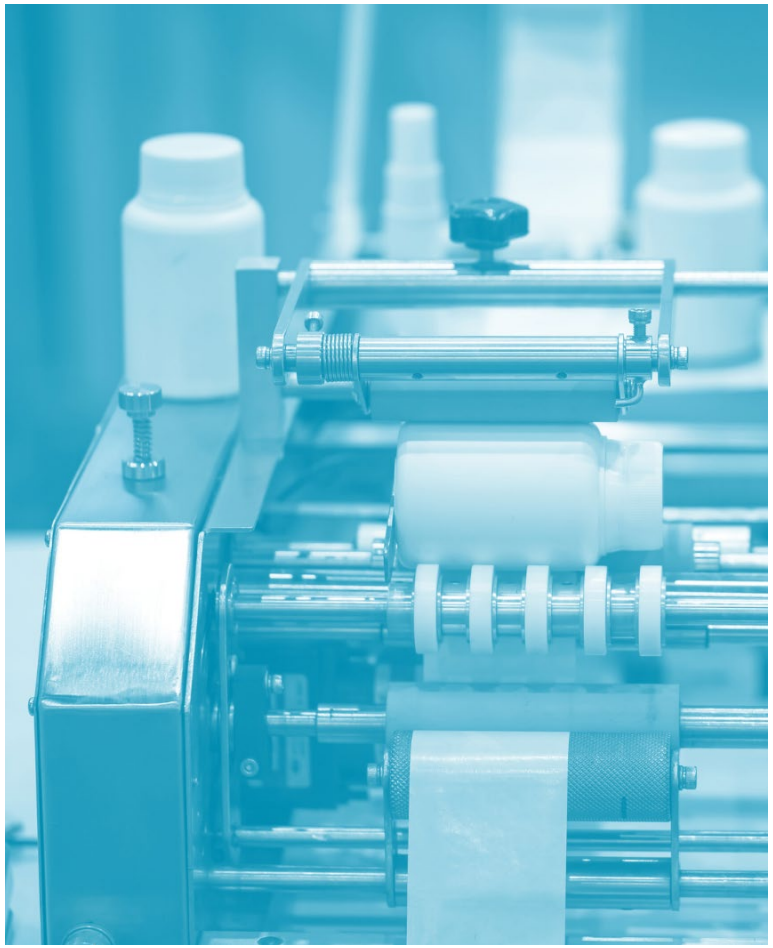
What to know if you compound

- Specific testing requirements apply to these medicines
- The API used to compound an MDMA or psilocybine finished product must be tested against and show compliance with the requirements of the TGO.
- Testing must be conducted at a site that holds a manufacturing licence from the TGA.

MDMA and psilocybine

Labelling

- Labels must comply with the requirements in the TGOs
- Labelling requirements in the Poison Standards also apply.
- Labelling requirements do not apply to compounded products.



MDMA and psilocybine

Manufacturing licence

- May only be manufactured for and supplied to:
  - Sponsor of a clinical trial
  - Authorised prescriber
- Requires a TGA manufacturing licence
- Specific authorisations on your licence
- **Manufacturers with a current licence will need to submit a licence variation application**

MDMA and psilocybine

Licence conditions

- Manufacturing licences will be conditioned.
- Comply with Office of Drug Control reporting requirements for the single convention.
- Reporting on the quantity of the goods held and supplied.
- Conditions will be the same format as those for medicinal cannabis

MDMA and psilocybine

Legislation

- Import, manufacture, possession and supply prohibited under the Commonwealth Criminal Code, unless authorised under a law of the Commonwealth or a State or Territory.
- Must ensure that the manufacture of goods containing MDMA and psilocybine (as Schedule 8 or Schedule 9 substances) is permitted by the law of the state or territory.

Questions?

Scan this QR code with your device to submit a question

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Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration