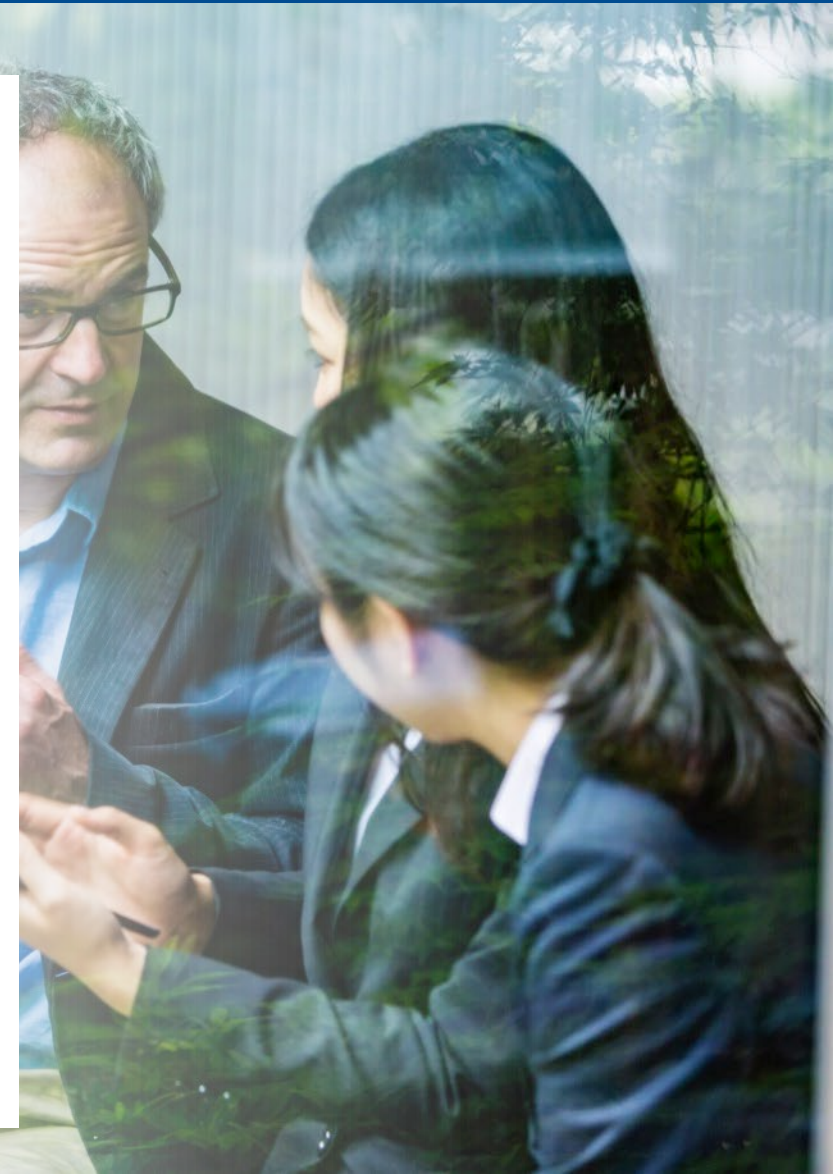


# Medicinal Cannabis Reform

Single Licence Reform Information Session

13 October 2021



Australian Government  
Department of Health

[www.odc.gov.au](http://www.odc.gov.au)

# Welcome

- Q&A session will occur at the end of the presentation
- To ask a question to the panel, please use the **Q&A function**
  - Q&A are visible only to the panel and speakers
- Relevant links will be sent to you via the chat function
- Live poll, at the end of this event
- The event is being recorded for internal data analytics use only
- A copy of today's presentation will be emailed to you by the Medicinal Cannabis team post the event



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# Medicinal Cannabis Reform

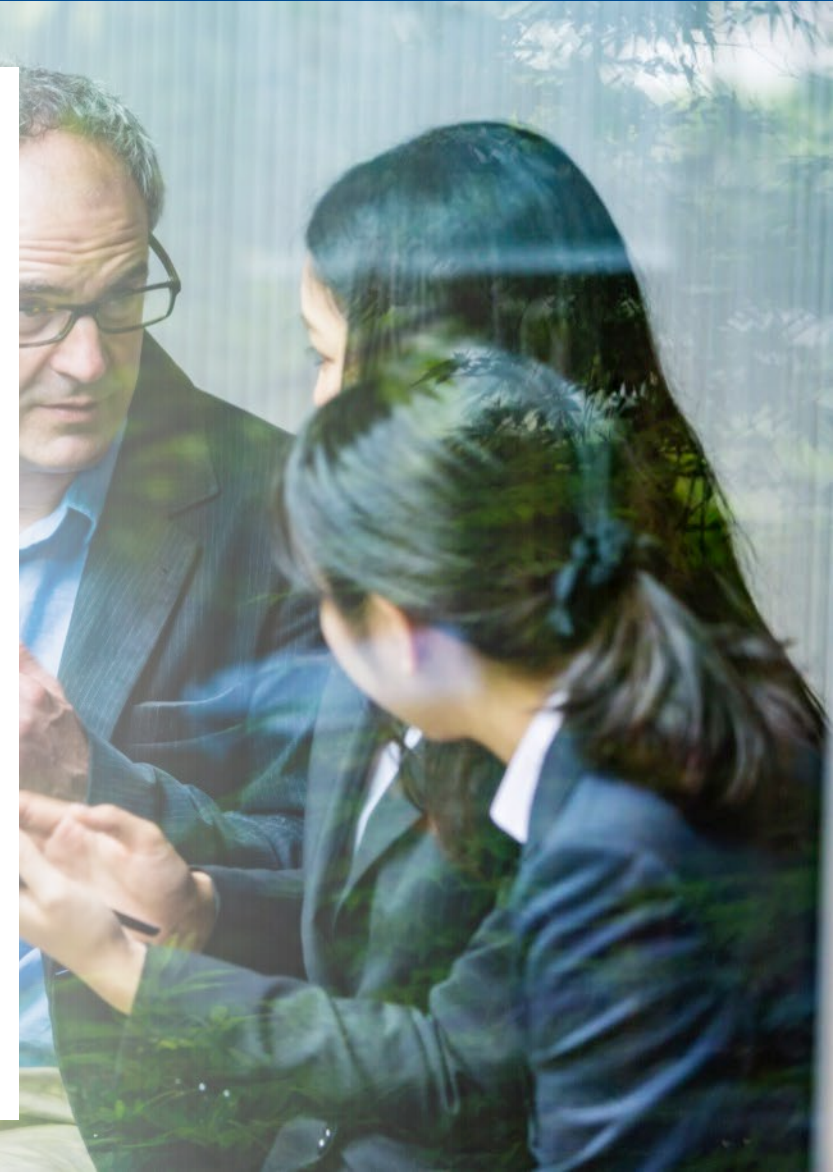
Single Licence Reform Information Session  
13 October 2021



**Mr Avi Rebera**  
Assistant Secretary  
Regulatory Services and Drug Control  
Branch, Health Products Regulation Group

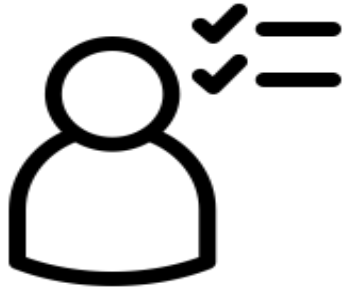


**Ms Danielle Chifley**  
Director  
Medicinal Cannabis Section,  
Health Products Regulation Group



# Objectives of this Session

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- Overview of amendments to the current licences and permit requirements.
- Highlight key aspects of the revised licence and new permits.
- Overview of changes to the *Narcotic Drug Regulations 2016*.
- Summary of reporting requirements for permit holders.
- Update on fees and charges.

# Narcotic Drugs Amendment (Medicinal Cannabis) Act 2021 (Amendment Act) Overview

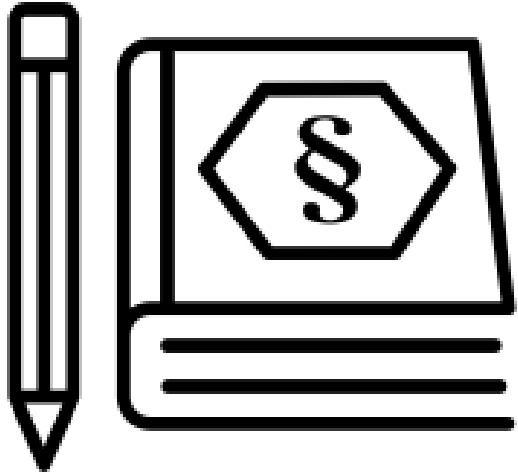
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- The Amendment Act received Royal Assent on 24 June 2021 and will commence on 24 December 2021.
- It provides for reforms to the *Narcotic Drugs Act 1967* (the ND Act) to support an innovative Australian medicinal cannabis industry for the benefit of Australian patients.
  - Gives effect to recommendations of the Review of the ND Act carried out by Professor John McMillan AO in 2019.
- The changes will reduce regulatory burden and provide benefits to businesses.
- New licences granted on and from the commencement date will be single licences under the Amendment Act.

# Amendments to the *Narcotic Drugs Act 1967*

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- Single licences to undertake one or more activities, in accordance with a permit.
- Most licences will have perpetual operation.
- Permits will be used to manage the specific activities of each site, including the volume and type (high/low THC) of cannabis material.



# Amendments to the *Narcotic Drug Regulations 2016*

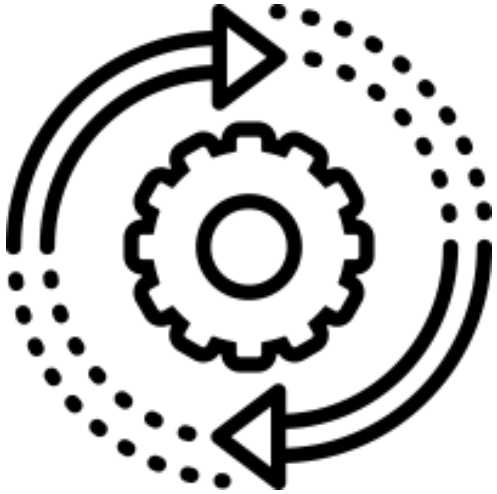
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- Consequential amendments to the *Narcotic Drug Regulations 2016* will:
  - complement changes to the Act for the single licence model,
  - simplify or clarify existing requirements, and
  - provide for transitional requirements.
  
- Examples include:
  - licence application processes made obsolete by single licence will be repealed,
  - some documents to be provided with permit application (instead of licence application),
  - terminology revised in the Amendment Act will be updated,
  - standing licence conditions updated, and
  - Introduce reporting requirements for all permit holders.

# Transition arrangements

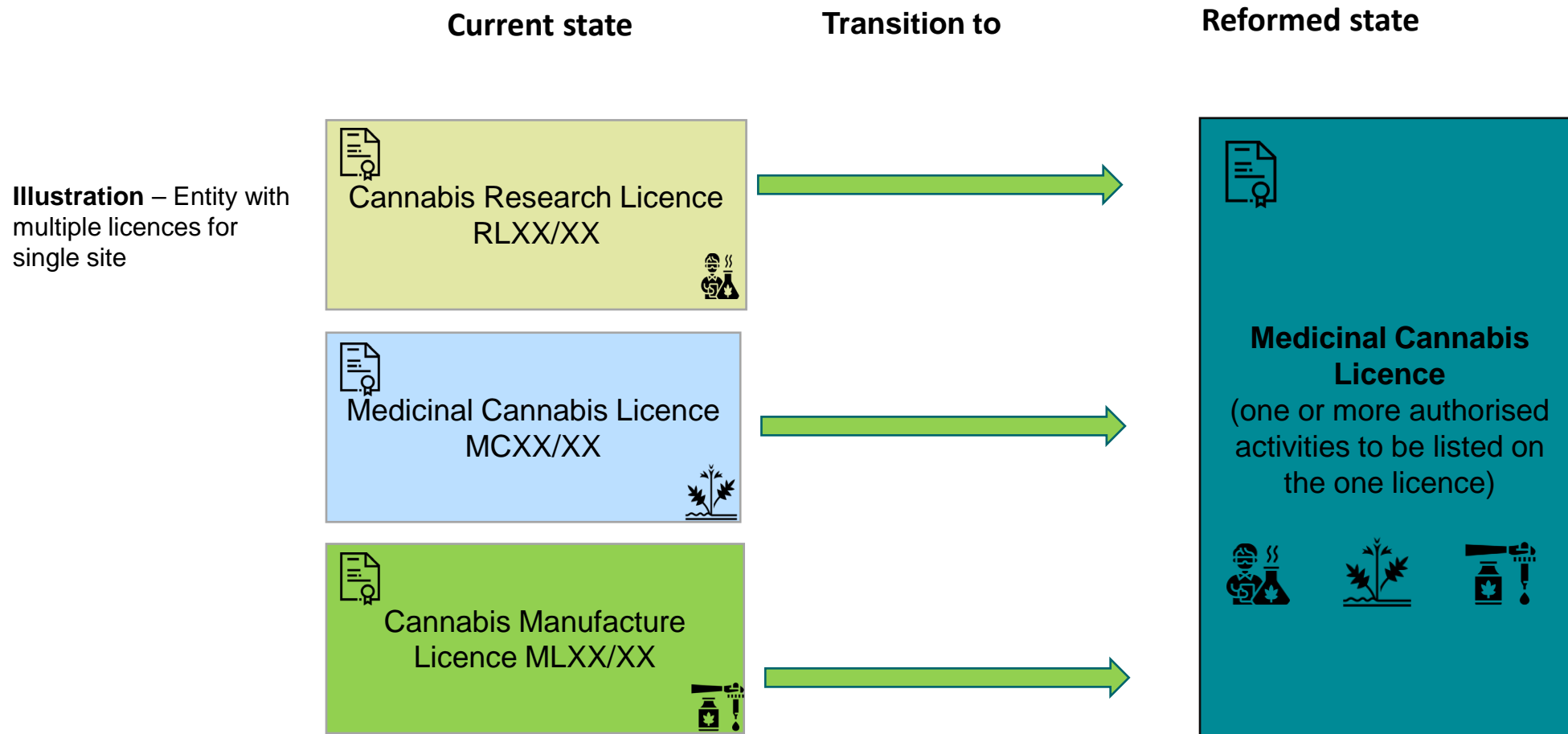
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- Current approved licences will be reissued in new single licence format.
  - The new licence template will look different, but still authorises the same activities.
  - The new licence will be clearer with regards to the location of authorised activities, and people listed on the licence as 'authorised persons'.
- The number of licence conditions on each licence will decrease, as many of these will be moved into the Regulation.
- Licence and permit documents issued under current arrangements will continue to be in force until updated paperwork is received

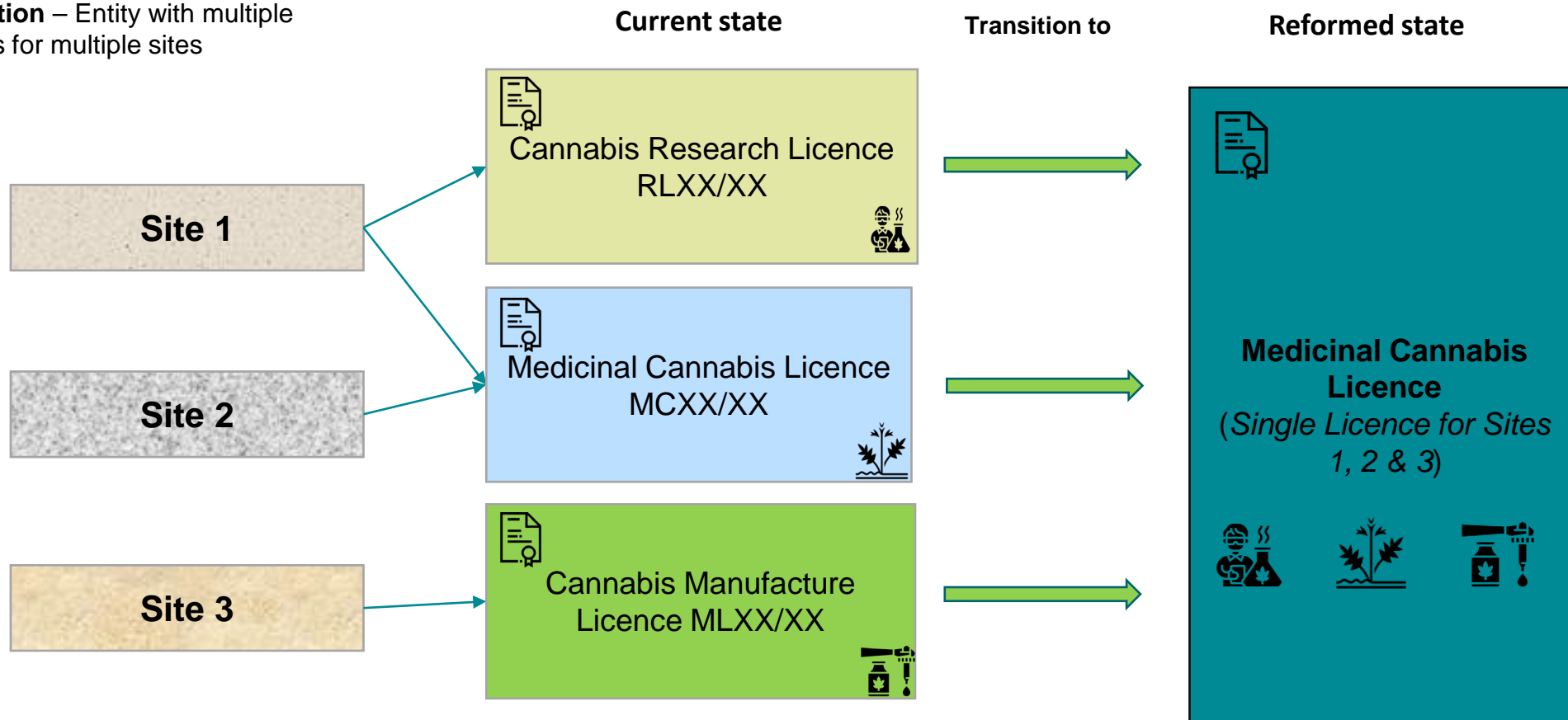


# Transition of multiple licences for single site



# Transition of entity with multiple licences for multiple sites

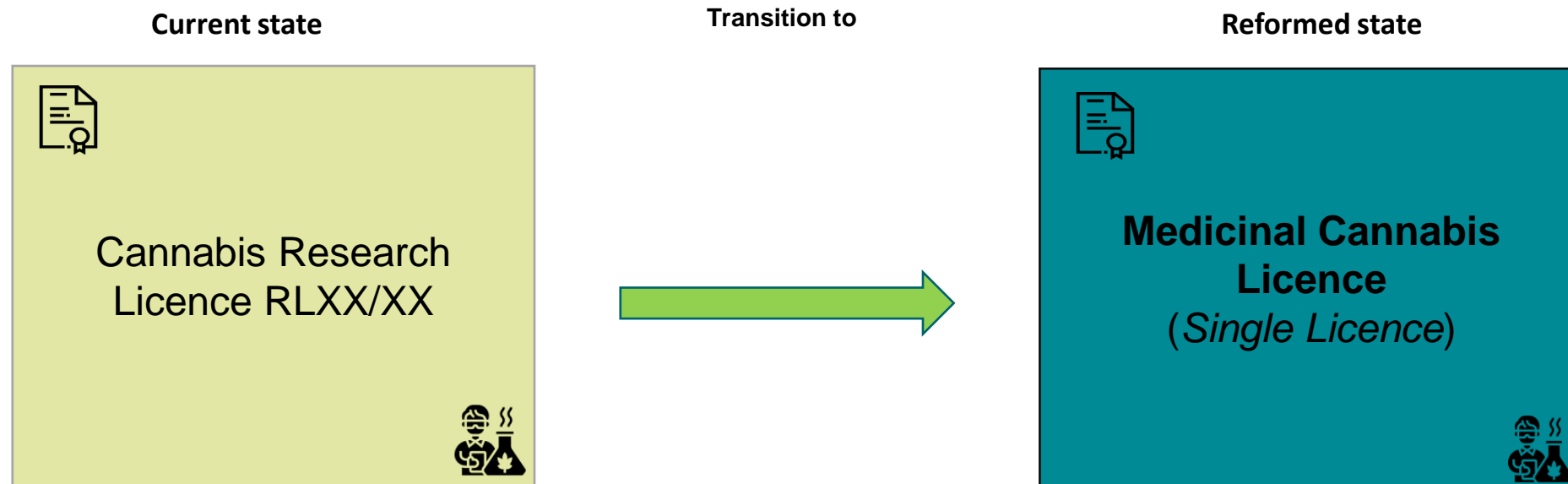
**Illustration** – Entity with multiple licences for multiple sites



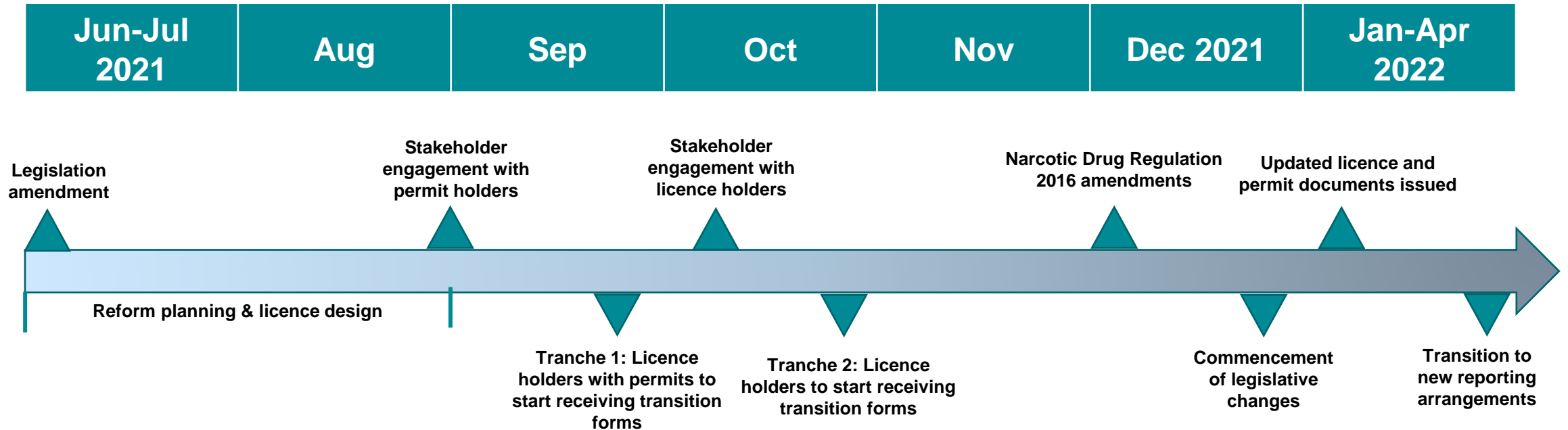
In total entity holds 3 licences for 3 sites

# Transition of entity with cannabis research licence only

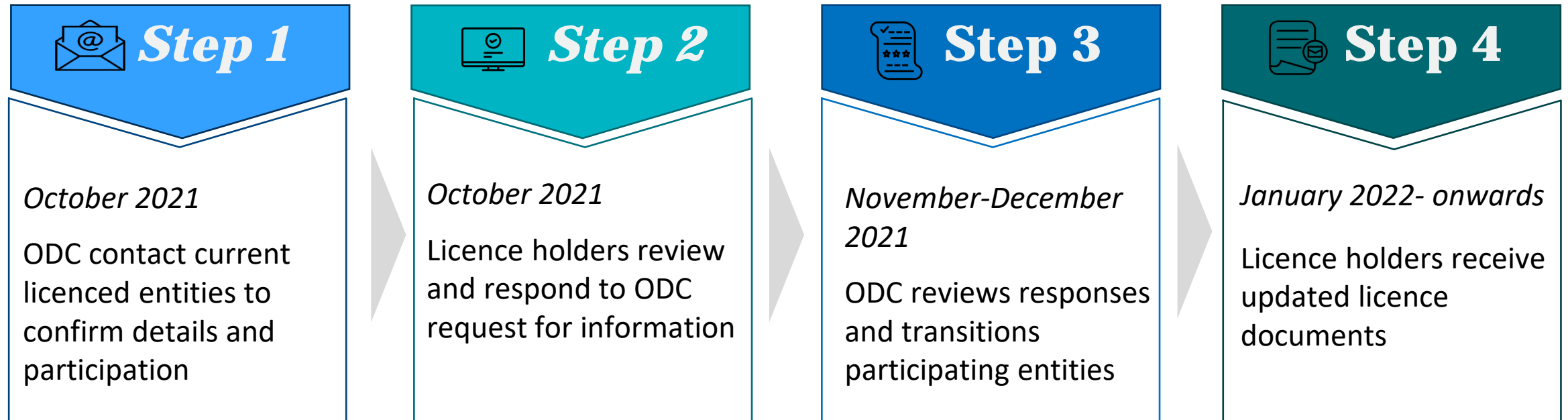
Illustration – Entity with cannabis research licence only



# Transition roadmap



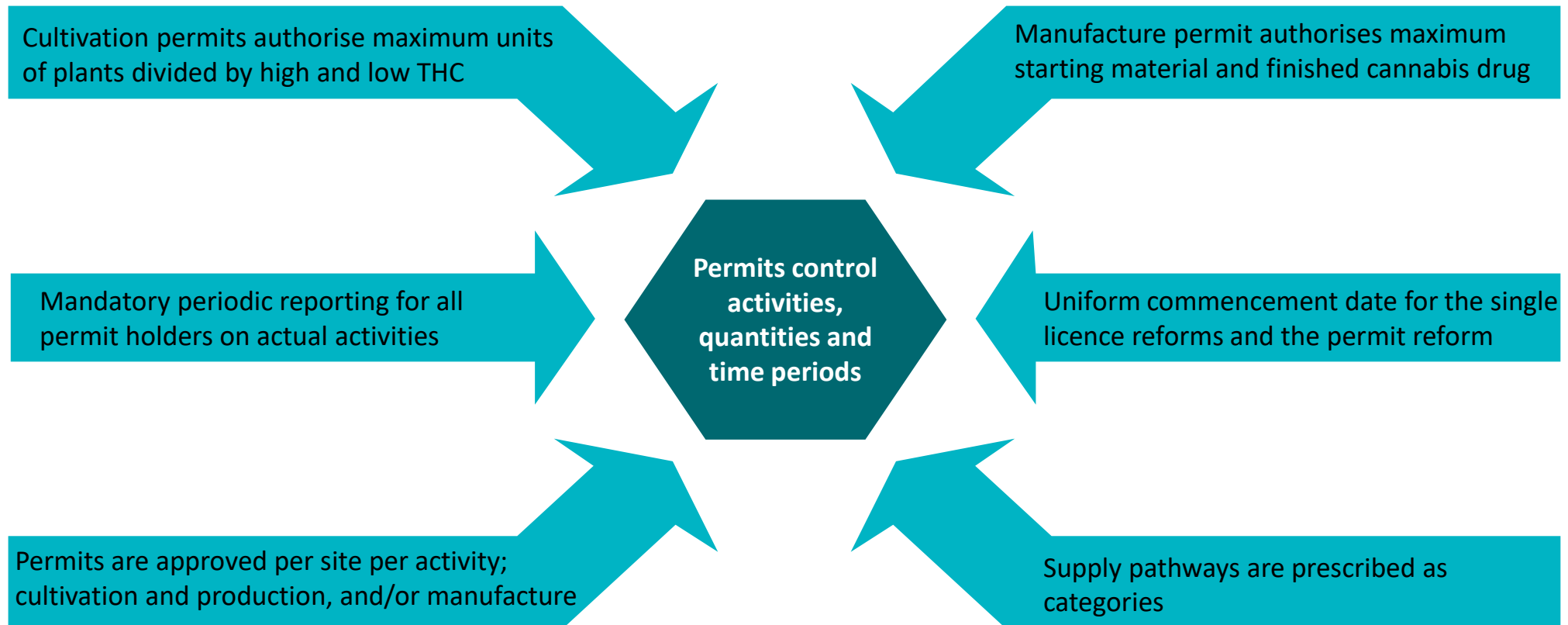
# Single Licence transition process



The ODC will be in touch with all licence holders about transition arrangements and next steps specific to their business needs

# Activities controlled by Permits

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# Benefits of permit reforms

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Permits will:

- be simplified with a consistent format for each of the primary licence activities
- be based on a 'one permit, per activity, per site' model
- be issued for 12 month periods
- be focussed on maximum amounts, not detailed crops and strains information
- support supply to recipients within categories, rather than entity to entity
- reduce the frequency that entities will need to apply for permit variations, and
- be more supportive of industry innovation, responsiveness and flexibility.

# New schedules for Cultivation and Production activities

Types and quantities of medicinal cannabis that may be obtained, cultivated or produced under the relevant licence

		Quantity	
		Low THC ≤ 1%	High THC > 1%
Genetics	Seeds	Total <b>units</b> authorised to be <b>obtained</b> from other sources over the life of the permit	
		Total <b>units</b> authorised to be <b>harvested</b> over life of permit	
		Maximum <b>units</b> authorised to be on the premises at <b>any one time</b>	

[Authorised activities](#) to include obtaining and generating tissue culture to support permitted cultivation

			Quantity	
			Low THC ≤ 1%	High THC > 1%
Cultivation	Plants	Total <b>units</b> of plants* authorised to be obtained from other sources over the life of the permit		
		Total <b>units</b> of plants* authorised to be <b>cultivated</b> over the life of the permit (from seed, tissue culture or cuttings)		
		Maximum <b>units</b> of plants* authorised to be on the premises at <b>any one time</b>		
Production	Cannabis	Total quantity of cannabis authorised to be produced over the life of this permit (kg) <b>dry weight at 10% moisture content</b> )		
		Maximum quantity of cannabis authorised to be on the premises at <b>any one time (kg) dry weight at 10% moisture content</b> )		
	Cannabis resin	Total quantity of cannabis resin authorised to be produced over the life of this permit (kg)		
		Maximum quantity of cannabis resin authorised to be on the premises at <b>any one time (kg)</b>		
Waste		Total waste <b>authorised to be stored</b> on the premises before authorised disposal (kg) <b>dry weight at 10% moisture content</b> )		

\* For this purpose, a plant unit is one that has formed roots

# New schedules for Manufacture activities

*Types and quantities of starting material and cannabis resin or cannabis drug that may be obtained or manufactured under the relevant licence*

Raw/Starting material		Quantity	Manufacture activities		Quantity
Cannabis	Total quantity of cannabis authorised to be <b>obtained</b> over the life of this permit (kg) ( <b>dry weight at 10% moisture content</b> )		Drugs manufactured from cannabis under this permit	Total quantity of delta-9 tetrahydrocannabinols (THC) <b>authorised to be manufactured</b> (kg)	
	Maximum quantity of cannabis authorised onsite at <b>any one time</b> (kg) ( <b>dry weight at 10% moisture content</b> )			Maximum amount of delta-9 THC <b>authorised on the premises</b> at any one time (kg).	
Cannabis extract	Total quantity of cannabis extract authorised to be <b>obtained</b> over the life of this permit (kg)			Total quantity of non-delta-9 THC (THC Isomers other than delta-9 THC) <b>authorised to be manufactured</b> onsite	
	Maximum quantity of cannabis extract authorised onsite at <b>any one time</b> (kg)			Maximum amount of non-delta-9 THC (THC Isomers other than delta-9 THC) <b>authorised on the premises</b> at any one time (kg).	
				Maximum amount of cannabidiol (CBD) <b>authorised to be manufactured</b> on site.	
				Maximum amount of CBD <b>authorised on the premises</b> at any one time (kg).	

# Supply pathways – cultivation and production

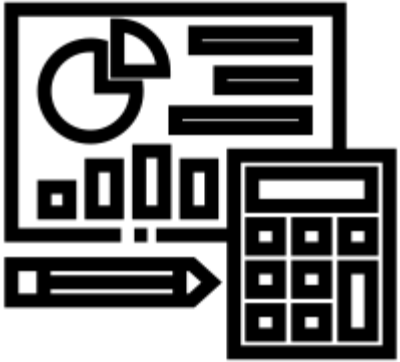
## Approved ways to transfer, supply, dispose or destroy cannabis or cannabis resin

ITEM	Column A SUPPLY OR TRANSFER	Column B CIRCUMSTANCES	Column C REQUIREMENT
1	Transfer to different premises (at which the relevant licence authorises activities)	The relevant licence authorises, at the different premises, one or both of the: <ul style="list-style-type: none"> <li>production of cannabis or cannabis resin</li> <li>manufacture of a cannabis drug</li> </ul>	The licence holder must ensure that this would not result in inconsistency or breach with any conditions or permits relevant to the different premises
2	Supply to another person ( <b>recipient</b> )	The recipient holds a licence granted under the <i>Narcotic Drugs Act 1967</i> which authorises the: <ul style="list-style-type: none"> <li>manufacture of a cannabis drug</li> </ul>	The licence holder must make and keep a record of the name of the recipient
3	Supply to another person ( <b>recipient</b> )	The recipient holds a licence under Part 3-3 of the <i>Therapeutic Goods Act 1989</i> , and the cannabis or cannabis resin is supplied for use by that person in the manufacture of a medicine	The licence holder must make and keep a record of the name of the recipient
4	Supply to another person ( <b>recipient</b> )	The recipient is authorised under state or territory legislation to obtain, possess, and hold cannabis material for purposes including testing or research	The licence holder must make and keep a record of the name of the recipient
5	Supply to another person ( <b>recipient</b> ) for disposal or destruction	The recipient is authorised under Commonwealth, state or territory legislation to undertake disposal or destruction activities	The licence holder must retain records of disposal
6	Supply by way of export	The licence holder has been issued an export licence pursuant to the <i>Customs (Prohibited Exports) Regulations 1958</i>	The licence holder must make and keep a record of: <ul style="list-style-type: none"> <li>the name of the importing country; and</li> <li>the export licence number</li> </ul>
7	Supply to a pharmacist in a public hospital	The cannabis or cannabis resin is supplied for use by that pharmacist or another pharmacist in that hospital	The licence holder must make and keep a record of the name of the hospital and the responsible pharmacist



# Reporting requirements

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- Templates and guidance material will be provided to assist with reporting.
- All permit holders to report quarterly and annually, with monthly breakdown of data.
- Key things to report on:
  - ❖ numbers of plants (#) generated each month
  - ❖ stock held (kg) and purpose, and
  - ❖ extract(s) manufactured (kg), as delta-9 THC, other THC, and CBD.
- You will not be required to report on:
  - ❖ numbers of seeds, or
  - ❖ individual supply transactions.

Licence holders will be required to maintain records to support their activities, and to supply information to the ODC on request.

# Fees and charges

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- Work is currently underway to review fees and charges as part of the transition to the new framework.
- There will be a transitional period from January - June 2022.
  - This will allow time for analysis of the cost recovery model against the new framework.
- Introduce new fees and charges structure in July 2022, following consultation.
- The Medicinal Cannabis Cost Recovery Implementation Statement will be updated in December 2021 to reflect the transitional arrangements (if applicable).



# Next steps

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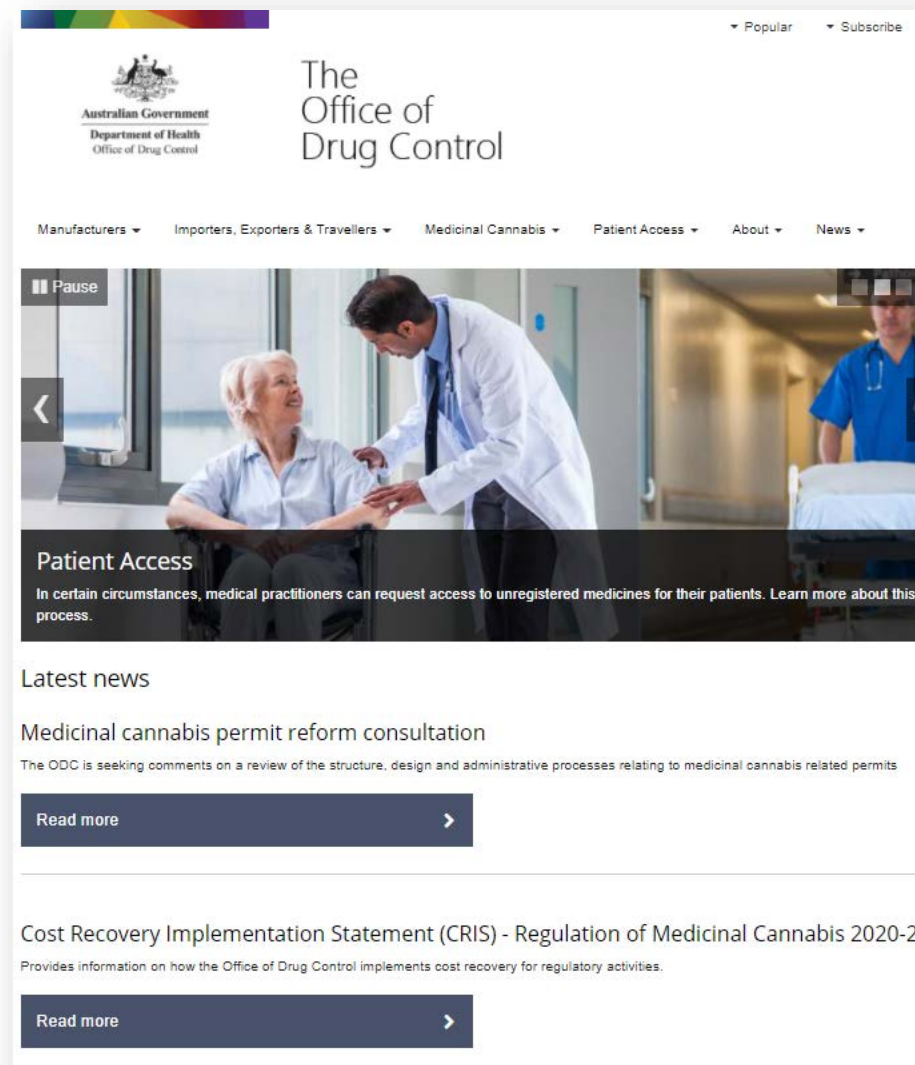
- ODC will contact licence holders directly to confirm individual transition arrangements.
- ODC will review responses and seek further information as required.
- Legislative amendments will come into force on 24 December 2021.
  - Existing licences and permits will continue until replacement documents are received- ‘no disadvantage’ model.
- Updated licence and permit documents will be issued from January 2022.
- Further documentation will be released on the ODC website from November 2021, including:
  - new licence, permit and variation application forms
  - reporting template, and
  - guidance material for templates and forms

# Further information and updates

## Contact us

**Website:** <https://www.odc.gov.au>

**Email:** [MCS@health.gov.au](mailto:MCS@health.gov.au)



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Patient Access

In certain circumstances, medical practitioners can request access to unregistered medicines for their patients. Learn more about this process.

Latest news

Medicinal cannabis permit reform consultation

The ODC is seeking comments on a review of the structure, design and administrative processes relating to medicinal cannabis related permits

Read more

Cost Recovery Implementation Statement (CRIS) - Regulation of Medicinal Cannabis 2020-21

Provides information on how the Office of Drug Control implements cost recovery for regulatory activities.

Read more

## Website and link references

Review of the *Narcotic Drugs Act 1967* - Final Report

[www.odc.gov.au/news-media/news/tabling-report-review-2016-medicinal-cannabis-amendments-narcotic-drugs-act-1967](http://www.odc.gov.au/news-media/news/tabling-report-review-2016-medicinal-cannabis-amendments-narcotic-drugs-act-1967)

Medicinal cannabis permit reform consultation

[www.odc.gov.au/news-media/news/medicinal-cannabis-permit-reform-consultation](http://www.odc.gov.au/news-media/news/medicinal-cannabis-permit-reform-consultation)

Current permit applications and guidance materials

[www.odc.gov.au/licence-and-permit-application-forms-0](http://www.odc.gov.au/licence-and-permit-application-forms-0)

We are currently reading over your submitted questions.

We'll be back shortly for Q&A  
We appreciate your participation in our  
LIVE POLL

# More information – Social media

	Website	<a href="https://www.tga.gov.au">https://www.tga.gov.au</a>
	Facebook	<a href="https://www.facebook.com/TGAgovau/">https://www.facebook.com/TGAgovau/</a>
	Twitter	<a href="https://twitter.com/TGAgovau">https://twitter.com/TGAgovau</a>
	YouTube	<a href="https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw">https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw</a>
	Topic blogs	<a href="https://www.tga.gov.au/blogs/tga-topics">https://www.tga.gov.au/blogs/tga-topics</a>
	LinkedIn	<a href="https://www.linkedin.com/company/therapeutic-goods-administration/">https://www.linkedin.com/company/therapeutic-goods-administration/</a>
	Instagram	<a href="https://www.instagram.com/tgagovau/?hl=en">https://www.instagram.com/tgagovau/?hl=en</a>

# Questions







**Australian Government**

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**Department of Health**