



Australian Government

Department of Health

# FACT SHEET

## Medicinal Cannabis Scheme

### Introduction of Fees and Charges for Cannabis-related Manufacture

#### 1 November 2020

On 1 November 2020 cost recovery arrangements for the Medicinal Cannabis Scheme (the Scheme) in the *Narcotic Drugs Act 1967* (the Narcotic Drugs Act) will change to introduce fees and charges for cannabis-related manufacture licences and permits granted under the Scheme.

This is in addition to changes that were introduced on 15 July 2020. Together, these reforms are the result of an extensive activity based costing exercise undertaken by the Office of Drug Control (ODC) within the Australian Government Department of Health (the Department). These reforms provide the ODC with a robust cost recovery framework that will recover adequate costs for the activities associated with the regulation of the Scheme.

### What changes on 1 November 2020

- Introduction of new terminology
  - **Cannabis-related manufacture licence:** A manufacture licence that will authorise the manufacture of a drug that includes, or is from, any part of the cannabis plant.
  - **Cannabis-related manufacture permit:** A manufacture permit relating to the manufacture of a drug that includes, or is from, any part of the cannabis plant.
  - **Non-commercial cannabis-related manufacture licence:** Applicable to a licence when the Secretary of the Department of Health (the Secretary) decides that a licence holder undertakes manufacturing that is for research for non-commercial purposes, or primarily for research for non-commercial purposes. A licence holder must apply for the Secretary to make such a decision.
  - **Commercial cannabis-related manufacture licence:** All other cannabis-related manufacture licences.
- Introduction of **fees and charges for cannabis-related manufacture licences and permits**.
- Introduction of a new **triple application fee**, payable when an applicant submits three licence applications for assessment for the same site, at the same time.
- Extension of the concept of a **non-commercial licence for research related to medicinal cannabis** to cannabis-related manufacture licences which allows for some limit on the amount of annual charges that such licences holders must pay.

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These reforms do not apply to licences granted under the Narcotic Drugs Act for the manufacture of other narcotics.

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## What this means for cannabis-related manufacture licence holders and applicants on 1 November 2020

### **Applications for cannabis-related manufacture licences/permits received after 1 November 2020**

- An application fee is payable for any application for a cannabis-related manufacture licence or permit, or a variation to such a licence or permit, submitted on or after 1 November 2020.
- A planned inspection will be undertaken by the ODC before the first permit is granted.
- Once the first permit is granted, the licence holder will receive an invoice for the site charge.

### **Existing cannabis-related licence holders – transitional arrangements**

- All existing cannabis-related manufacture licence holders will receive an invoice in early November 2020 in relation to annual charges. The first annual charge will be calculated using a pro rata formula based on the anniversary date of the licence.
- Existing cannabis-related manufacture licence holders without permit/s on 1 November 2020 will be invoiced (pro rata) for the annual licence charge only.
- When the first permit is granted the licence holder will receive an invoice for the site charge. The first site charge will also be calculated using a pro rata formula based on the anniversary date of the licence.
- Existing cannabis-related manufacture licence holders with permit/s on 1 November 2020 will be invoiced (pro-rata) for both for the annual licence and site charge.

### **Other fees and charges**

- All cannabis-related manufacture licence holders should expect Authorised Inspectors from the ODC to undertake an unannounced inspection of the licenced premises at any time.
- Compliance follow-up charges will be payable by all holders of cannabis-related manufacture licences, including the reimbursement of ODC travel costs.

### **Non-commercial research**

- There will be a limit on the amount of annual charge payable by a cannabis-related manufacture licence holder conducting research for non-commercial purposes.
- Any cannabis-related manufacture licence granted on the basis of an application received before 1 November 2020, is a *commercial cannabis-related manufacture licence*.
- Existing commercial cannabis-related manufacture licence holders, or new applicants, seeking to have their licence designated as a non-commercial cannabis-related manufacture licence must apply to the Secretary for such a decision to be made and provide relevant information to support the decision.
- Licence holders or applicants interested to know more about the fees and charges payable for non-commercial research licences should contact the ODC at [MCS.Application@health.gov.au](mailto:MCS.Application@health.gov.au) as soon as possible.

## Contact the ODC

Licence holders are encouraged to email any queries, including transitional arrangements, relating to these amendments to the ODC at [MCS.Application@health.gov.au](mailto:MCS.Application@health.gov.au).

## Table of Fees and charges

Fee / Levy	Fees and charges from 01 November 2020 – 30 June 2021
<b>Licence Application Fees</b>	
Single Licence Application	<b>\$7,960</b>
Double Licence Application	<b>\$8,580</b>
Triple Licence Application <b>NEW</b>	<b>\$9,250</b>
<b>Permit Application Fee</b>	
Permit Application	<b>\$3,410</b>
<b>Licence Variation Fees</b>	
Licence Variation - Simple	<b>\$1,090</b>
Licence Variation - Complex	<b>\$5,460</b>
<b>Permit Variation Fee</b>	
Permit Variation - Simple	<b>\$120</b>
Permit Variation - Complex	<b>\$2,870</b>
<b>Planned Inspection Fee</b>	
Planned Inspection	<b>\$3,650</b>
<b>Charges</b>	
Annual Licence Charge	<b>\$11,570</b>
Annual Site Charge	<b>\$19,160</b>
<b>Follow-up of non-compliance charges</b>	
*Indicative only. Charge will be applied at \$107 per person per hour plus reimbursement of reasonable travel costs	
Follow-up Audit	<b>\$3,092</b>
Follow-up Inspection	<b>\$6,537</b>
Follow-up Sampling Assessment	<b>\$1,201</b>
Investigations	<b>\$8,799</b>
Investigation Inspections	<b>\$7,810</b>
Investigation - Sampling Assessment	<b>\$1,201</b>
Enforcement Action - Minor	<b>\$4,396</b>
Enforcement Action - Moderate	<b>\$5,099</b>
Enforcement Action - Major	<b>\$6,942</b>

### **Background information**

**Fees** – Charged when a good, service or regulation is provided directly to a specific entity or organisation. The *Narcotic Drugs Regulation 2016* was amended allow for the reforms to fees under the Scheme to come into force.

**Charges** – Also known as levies, are charged when a good, service or regulation is provided to a group of individuals or organisations. *The Narcotic Drugs (Licence Charges) Regulation 2016* was amended allow for the reforms to charges under the Scheme to come into force.

**Planned Inspection** – An inspection associated with an application. (This was previously described as a pre-commissioning inspection).

**Anniversary date** – The date a licence came into effect.

**Licence year** – This is the year for which the annual charges are applied and it applies to period from the anniversary date of a licence.

**First Permit** – The first permit to be granted to a licence holder that allows for activities authorised under the licence to commence

**Licence Charge** – A charge imposed on all licence holders on the anniversary date of the licence

**Site Charge** – A charge imposed from the date the first permit is granted to a licence holder, and then each year thereafter on the anniversary date of the licence

**Compliance Follow Up Charges** – Charges to recover costs for addressing compliance monitoring and specific matters of non-compliance directly from those that are the subject of such activities.