

# Tasmanian Government Submission

Legislative Council Select Committee Inquiry:  
Tasmanian Poppy Industry

November 2012

Tasmanian Government Submission to the Legislative Council Select  
Committee Inquiry into the Tasmanian Poppy Industry

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## Introduction

The Tasmanian Government welcomes the opportunity to provide a submission to the Select Committee's Inquiry into the Tasmanian Poppy industry and, in particular:

*(1) The effects upon the Tasmanian Poppy Industry as a consequence of the Tasmanian Government's decision to allow the importation of raw poppy capsules from Turkey, in the first instance, and possible importations from any other areas into the future; and.*

*(2) And other matters incidental thereto.*

As the world's largest producer of licit narcotic raw material, supplying around half of the world's demand, Tasmania is a significant supplier to the international pharmaceutical market. With a processing industry that grosses in excess of \$100 million per annum and farm gate returns to growers estimated at between \$70 and \$90 million in recent years, the Tasmanian poppy industry benefits not only farmers and processors, but the entire local economy.

Tasmania's geographical isolation and climate, together with the expertise of our farmers and processors, have enabled the industry to grow and develop over the last 40 years to the extent that it is now internationally recognised for export growth and manufacture of products, innovation and best practice regulation.

In an increasingly competitive international market, it is vital that Tasmania continues to strengthen and expand the industry to achieve its full potential. With just over half of the annual sustainable area of suitable land in Tasmania utilised for poppy growing, there is potential to expand the industry further. Strategic investment by Government and private land owners in irrigation infrastructure in recent years is opening up opportunities for expansion. To support industry investment, the Government is working with growers and processors to develop a strategic framework to guide the industry over the next five to ten years. In addition, the Government and Poppy Growers Tasmania have jointly invested in a social research project which will better define the area of land suitable for poppy production and the social factors affecting its use for this crop.

In order to secure manufacturing jobs in the industry and underpin further investment, the Government has indicated that it will support an application by TPI Enterprises Ltd (TPI) to vary its licence so that it can import 2 000 tonnes of poppy straw from Turkey in 2013 on a one-off basis. This will enable TPI to meet significant contracts, following a shortfall in reserves of local material. Further information about the Government's decision is set out in the body of this submission.

The Government will continue to work with poppy growers and processors to strengthen and expand the industry as well as to protect and enhance its reputation as a world leader in poppy production.

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## 1. Industry overview

Tasmania is the world's largest producer of raw narcotic material, supplying around half of the world's demand for use in pharmaceuticals. The Tasmanian poppy processing industry, which manufactures concentrate of poppy straw (CPS), currently grosses in excess of \$100 million per year and the farm gate return to growers is estimated at between \$70 and \$90 million per year.

Approximately 1 000 licences to grow opium poppies are issued each year to over 750 poppy-growers to grow approximately 30 000 hectares of opium poppies on contract for the three licensed processors:

Processor	Location of processing facilities
GlaxoSmithKline (GSK)	Tasmania (pellets) and Victoria (CPS)
Tasmanian Alkaloids Pty Ltd	Tasmania (CPS)
TPI Enterprises Ltd (TPI)	Tasmania (CPS)

Growers' licences are conditional on the grower having a contract with one of the three processors. The three processors provide the seed, assist in the growing process, arrange for harvesting and take the capsules for processing.

Poppy crops are grown throughout the State except for the Bass Strait Islands and south of Hobart. According to the most recent figures, the industry employs approximately 1 000 people<sup>1</sup>.

Tasmania is considered the world's most efficient producer of poppies with the highest yield per hectare of any opiate-producing country. This is largely due to ongoing plant breeding by the processing companies and adoption of well-established agronomic practices by farmers.

## 2. Regulatory framework

### International

The opium poppy industry is highly regulated under international and domestic law. As a signatory to the United Nations' *Single Convention on Narcotic Drugs 1961* (the Convention), as amended by the *Protocol Amending the Single Convention 1972*, Australia is required to carefully control and supervise all stages of the growing and production of opium poppies as well as the import and export of narcotic material.

Implementation of the Convention is overseen by the International Narcotics Control Board (INCB), which determines annual quotas for the growing of narcotic plants based on estimates of worldwide production needs.

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<sup>1</sup> Food Industry Sub Sector Review Poppy Profile Oct 2009.

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## Commonwealth and state

International obligations, based on quotas determined by the INCB, are implemented through Commonwealth and state legislative frameworks which regulate the importation, possession, cultivation and processing of opium poppies.

Commonwealth and state legislative frameworks impose separate importation and licensing requirements. While these processes operate concurrently, consultation processes between Commonwealth and state government agencies support a coordinated approach to importation and licence applications.

In 1972 a joint decision of Commonwealth and state governments restricted the growing of opium poppies to Tasmania for security reasons. Cultivation, possession or refining of opium poppies are all criminal offences under Tasmania's *Misuse of Drugs Act 2001* unless the activity is licensed under Tasmania's *Poisons Act 1971*.

Under Commonwealth law, opium poppies are a scheduled substance under the *Therapeutic Goods Act 1989*, which is also referenced under Tasmania's *Poisons Act*. Licencing requirements for the importation and manufacture of poppy materials and products apply under Commonwealth law under the *Narcotic Drugs Act 1967* (manufacturing) and *Customs (Prohibited Imports) Regulations 1956 (Importation)*. These requirements must be met before importation or manufacturing can occur.

In addition, separate licencing requirements must also be met under the *Poisons Act* before the possession, cultivation, manufacture or supply of narcotic substances is permitted under Tasmanian law. Biosecurity, public health and security clearances also apply under licencing processes.

The Poppy Advisory and Control Board (PACB) is established under the *Poisons Act* to oversee and manage the poppy industry in Tasmania, including providing advice to the Minister on any matter relating to the poppy industry. However, the Board's role is advisory only and the final determination on licence applications is made by the Minister, and may include broad public interest considerations.

Licences to grow poppies in Tasmania have been issued annually since 1966.

## 3. Current issues facing the Tasmanian poppy industry

The Tasmanian poppy industry has grown rapidly since it began in the 1960s and is now entering a new phase of growth and development.

### Scope for expansion

In recent industry consultations conducted by the Department of Economic Development, Tourism and the Arts (DEDTA), all three poppy processors have indicated that they expect

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the global market for poppy products to grow in the medium to long term at between three to eight per cent per annum, depending on the product<sup>2</sup>. This is due to:

- increased use in key consumer countries;
- changing population demographics;
- new product development; and
- emerging pain management markets in developing countries.

As the world's leading poppy producer, Tasmania is well positioned to benefit from that growth.

All three processors have indicated in consultations that they consider that the Tasmanian poppy industry has a strong future and have advised that they remain committed to Tasmania as their primary source of raw poppy material into the future. In particular, processors have indicated that, over the next five to seven years, they are considering investing up to \$100 million to increase processing capacity in this State. According to processors, parent companies and boards will be making decisions around medium term investments, including investment locations, over the next one to two years.<sup>3</sup>

## Processor caution

It has emerged from industry consultations that some structural adjustment may be necessary to enable the industry to respond to changing market demands to maximise the opportunities available.

Processors have indicated that if the investment environment in Tasmania is not suitable, the state could lose a 'once in ten year' investment opportunity. Loss of that potential investment would have significant long-term implications for the industry, including the scale of industry, Tasmania's global standing and competitiveness and overall industry contribution to economic growth, with flow on effects for investment by related businesses.

According to processors, key considerations in investment decision making and overall growth prospects are:

- changes in international markets; and
- any actual or perceived limitations on the capacity of Tasmanian processors to meet customer requirements.

## Competition and surety of supply

Competition is increasing in international markets, particularly from other producer nations such as France and Spain. Consolidation of customers for raw narcotic material has placed increased

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<sup>2</sup> Industry consultation July 2012

<sup>3</sup> Industry consultation July 2012

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price pressures on processors. The high Australian dollar has reduced profitability for companies selling into a market where contracts are denominated in US dollars.

The productivity of the Tasmanian industry remains a key competitive advantage. While Tasmania is a relatively high cost producer, it has higher levels of productivity than other production areas. Despite this, as production moves into new and more marginal cropping areas in response to growing demand, it is noted that reliability and productivity risks increase.

According to processors, as Tasmania's dominance of poppy production has grown, their customers have become increasingly sensitive to risks around surety of supply. Customers want guaranteed supply, with their purchasing policies generally preventing them from sourcing their supply from one geographic area.

## **4. Industry Development Framework**

In response to the potential investment opportunities and risks identified above, DEDTA is working with representatives of the Tasmanian poppy industry to reach agreement on an Industry Development Framework to guide the industry over the next five to ten years. This will include a range of strategies to increase the likelihood of the next cycle of investment occurring in Tasmania, enabling the state to retain its position as the world's leading producer of raw narcotic material. Discussions, which began in April 2012, are progressing with a view to agreeing a framework in the first half of 2013.

Participants in the meetings include Poppy Growers Tasmania (PGT), the Tasmanian Farmers and Graziers Association (TFGA), Tasmanian Alkaloids, GlaxoSmithKline (GSK), TPI Enterprises, and the Secretaries of the DEDTA and the Department of Primary Industries, Parks, Water and Environment (DPIPWE).

Discussions have focussed on encouraging cooperation and a shared approach to achieving industry growth and have identified:

- an agreed vision for the industry;
- agreed priority topics; and
- key issues to be addressed.

To date participants have agreed in-principle on the areas of common interest which need to be addressed to support growth and address the surety of supply issue. These include alternate contractual models between growers and processors and changes to raw material stockholding limits. Areas requiring significant negotiations are largely centred on the issue of importation of raw material for processing.

A key factor which needs to be better understood by all parties is the supply and demand picture over the past ten years. There is disagreement within industry as to whether Tasmania has always had sufficient supply to meet full demand.

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Work on the Industry Development Framework is ongoing and is expected to result in a written agreement between stakeholders on contributions and actions to grow the value and size of the Tasmanian poppy sector.

## Processor activity

In recent discussions between representatives of DEDTA and the three processors, all processors have emphasised that Tasmania remains their preferred location to source product. They remain committed to working with local growers to ensure that they can continue to source the majority of raw material from Tasmania.

During these discussions, all processors have also indicated that they support allowing the importation of poppy material to augment local supply when required. They are actively pursuing alternative sources of supply to address actual and perceived supply risks, as set out below:

Processor	Activity
Tasmanian Alkaloids	Commenced poppy growing trials in New Zealand in 2009 and is conducting trials in Victoria.
GSK	Conducting poppy growing trials in Victoria in 2012.
TPI Enterprises	Investigating growing trials in Victoria. Has sought approval to import 2 000 tonnes of Turkish poppy straw in 2013.

This indicates that the poppy processing sector is already actively managing its production risks to ensure it can secure contracts of sale by investigating alternative sources of supply.

The Victorian Government is conducting an inquiry into establishing a poppy growing industry and is actively encouraging existing businesses to consider Victoria for production.<sup>4</sup> At present Victoria has no regulations around poppy production.

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<sup>4</sup> DEDTA advises that the Victorian Government recently commissioned consultants to look into the possibility of establishing a poppy growing industry in Victoria. The Victorian Government wrote to DPIPWE and the PACB earlier in 2012 requesting a meeting with the consultants. Relevant officers then met with the consultants for a fact finding tour and they will now report back to the Victorian Government.

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## Growers' views

A key element identified by processors in consultations to date has been the issue of surety of supply, with all processors agreeing that there is a need for greater flexibility to allow the importation of poppy material where there is insufficient local supply.

Understandably, this a sensitive issue for growers and there are concerns that allowing the importation of poppy materials could undermine their position as growers of choice and have broader implications for Tasmania's reputation as a reliable source of supply to international markets. They are also concerned that the local Tasmanian price for poppies will be driven down by the price of imported material from countries with lower production and overhead costs.

The table below sets out in broad terms the concerns of the two bodies representing Tasmanian poppy growers:

Body	Concerns raised
PGT	<p>Concern about importation of poppy product in general, including the following risks:</p> <ul style="list-style-type: none"><li>• quarantine and biosecurity;</li><li>• disadvantage to Tasmanian growers by allowing importation of cheaper raw product; and</li><li>• negative impact on Tasmania's reputation as a reliable supplier.</li></ul> <p>While PGT is opposed to importation of poppies from international sources it is supportive of importation from other Australian production areas if Tasmania cannot supply the required demand at an acceptable level of surety.</p>
TFGA	<p>Concern around the potential loss of growing contracts to local growers. Acknowledges the need for the poppy processors to be able to secure supply and operate effectively in an increasingly competitive environment.</p>

The Government takes these concerns very seriously and is highly conscious of protecting Tasmania's international reputation. However, it is becoming increasingly clear that in order to support the industry to expand, there is a need to have a range of strategies in place to mitigate risks associated with local supply shortages. While a measure of last resort, there are circumstances where it is in the best interests of the industry as a whole to allow the importation of poppy material.

## Factors influencing growing choices

DPIPWE advises that the 2011-12 season was a record planting year for poppy production with close to 24 000 hectares harvested state-wide. The 2012-13 season will be another record planting year with a combined area over 30 000 hectares approved by the Poppy Advisory and Control Board (PACB).

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Understanding the factors influencing the decision of farmers to grow poppies in newly established irrigation areas may help ensure the economic viability of these areas. In contrast, significant areas of traditional and well proven high value cropping soils along the North Coast are not used for poppy production.

These observations suggest that a range of factors are influencing farmers' decision to grow poppies. In an effort to understand these factors and develop strategies to address them, DPIPW and PGT have co-funded a study into what influences farmers' decisions whether to grow poppies on suitable land.

The results of this study may ultimately lead to increased land area becoming available for poppy production. The study will also provide an assessment of the area annually available for poppy production taking into account sociological and microclimatic factors. This project will be completed by 31 December 2012.

## **5. TPI's application**

Prior to and concurrent with discussions between the industry and the Government on how best to grow the industry, TPI sought approval to import a quantity of Turkish poppy straw. This proposed importation was to supplement shortages in local supplies and enable TPI to meet orders from overseas pharmaceutical manufacturers.

TPI first approached the PACB in August 2011 seeking approval to import a quantity of poppy capsules from Turkey due to a shortfall in local supply following two poor harvesting seasons. According to advice provided by the Board, the Board subsequently met with TPI to discuss its request, with TPI providing further information to support its application. TPI's request was based on concerns that it would not be able to fulfil contracts to supply concentrate of poppy straw (CPS) in 2011 and 2012.

According to the PACB, TPI further advised that it also had additional contracts for the supply of CPS thebaine and that these contracts were also potentially at risk. TPI also indicated to the Board that it intended to commit to further orders in 2013, with the Board expressing concerns that TPI would be unlikely to meet these commitments based on the quantity of growing area likely to be allocated to TPI at that time.

In September 2011, the PACB wrote to the Attorney-General, Brian Wightman MP, expressing concerns with TPI's request and recommending that the Government oppose it on a number of grounds, including concerns about the potential impact on Tasmania's national and international reputation as reliable supplier of poppy extracts, potential implications for local growers and biosecurity risks<sup>5</sup>.

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<sup>5</sup> A redacted copy of the PACB's letter was tabled in Parliament on 29 August 2012.

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The PACB's advice was forwarded to the Minister for Health, Michelle O'Byrne MP - as Minister responsible for issuing licences under the Poisons Act - for consideration in late October 2011. Given that the request had potential whole of industry impacts, the Minister for Primary Industries and Water, Bryan Green MP, and the Minister for Economic Development, David O'Byrne MP, were also consulted on the request.

The Government then initiated discussions with TPI, growers and the other processors to explore the request. Concurrent with these discussions, DEDTA commenced discussions with the industry to examine the potential to develop a broader Industry Development Framework given the industry's status as a priority sector under the Economic Development Plan. These discussions continued into mid-2012, with ongoing discussions on the Framework.

TPI's initial request for importation was not supported by the Minister for Health. However, following further consultation with the company, including consideration of additional material provided by TPI, the Minister for Health wrote to TPI in July 2012 providing in-principle support on behalf of the Government for TPI to import 2 000 tonnes of Turkish poppy straw in 2013 on a one-off basis. It is important to note that this support was conditional on all Commonwealth and state legislative requirements for importing raw narcotic material, as well as biosecurity and freedom from genetically modified material conditions, being met. These requirements include:

- obtaining a licence under the Poisons Act to allow the possession and manufacture of narcotic materials from imported material;
- obtaining a licence and associated permit to import narcotic substances, administered by the Australian Department of Health and Ageing;
- obtaining a Commonwealth licence to manufacture and export narcotic material. This is in addition to the state licence;
- ensuring that any biosecurity conditions imposed by the Australian Department of Agriculture, Fisheries and Forestry (DAFF) are met; and
- ensuring State biosecurity requirements administered by the DPIPW are satisfied.

This in-principle support was provided on the basis of TPI having strategies in place to increase the area of land available for poppy production in Tasmania, as well as various commitments by TPI aimed at increasing Tasmanian supply.

On 1 August 2012, the Minister for Primary Industries and Water publicly announced that the Government would support TPI's application as a one-off measure on 2013, noting that work on the Industry Development Framework was continuing.

## **Factors relevant to the TPI application**

The Government notes that TPI Enterprises has sought permission to import Turkish poppy straw on a one-off basis to enable it to fulfil contracts worth in excess of \$25 million over two

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years. It is expected that TPI Enterprises will do all it can to secure local growing contracts in subsequent seasons.

While the Minister for Health has not yet formally approved a variation to TPI's licence to enable the importation to occur, set out below are a number of factors considered by the Government in reaching the decision to provide in-principle support for a variation of TPI's licence to enable the importation of Turkish poppy straw:

- TPI's immediate situation is, in part, because of unfavourable cropping weather over the past two years that prevented it from accumulating raw material reserves to buffer against shortfalls.
- TPI is the smallest and newest processor in Tasmania, and is less likely to be able to secure local supplies in 2013 sufficient to fulfil its contracts with alkaloid buyers.
- One-off approval to vary its licence for 2013 will assist TPI to continue with its capital raising activities to fund its longer term value-adding plans, which involve manufacture of generic tablets in Tasmania and additional technical and professional jobs at its Tasmanian processing facility.
- Supporting a third player in the poppy processing sector in Tasmania has increased competition, presented growing alternatives for farmers and provided a market for new growers likely to start production once the newly developed irrigation schemes come on line and new tracts of land become available for poppy production.
- Tasmania Police advises that there are no additional security risks because the poppy industry is well regulated by the PACB.
- Variations of licence have previously been granted to another processor to allow for importation when supply did not meet demand, with no adverse outcomes reported.
- Sale of raw poppy material across borders for processing is common practice in Europe and other areas, indicating that if done properly the International Narcotics Control Board (INCB) which regulates production and movement of narcotic products is unlikely to be concerned.

## **6. Potential longer term considerations**

The work currently being undertaken in relation to an Industry Development Framework will provide a stronger basis for the Government to consider some of the longer term factors for the Tasmanian poppy industry.

Pending the outcome of this work, the Government notes that the long term future of the Tasmanian poppy industry will likely depend on its ability to expand production by accessing a share of the larger raw narcotic materials market in an increasingly competitive market place. As the market for narcotics grows, Tasmania will be less likely to be able to dominate

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production. There is no guarantee of long term certainty for poppy production and processing in Tasmania, as these operations can be carried out in other states of Australia and other countries, such as New Zealand. The industry must remain competitive to be sustainable.

Processors with an interest in Tasmania have all clearly stated that the extent of their investment in Tasmania into the longer term will be impacted by the ability of the local industry to respond to the changing industry environment. This may include a more flexible and responsive approach to importation of raw material for processing.

Given the projected growth of the global market and Tasmania's dominant position within that market, formulation of the Industry Development Plan will be critical to ensuring continuing reliability of supply and underpin further growth and investment in the Tasmanian industry.

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**Appendix I: Tasmanian Poppy Industry Roles and Responsibilities**

Entity	Short Title	Role
<b>International</b>		
International Narcotics Control Board	INCB	<ul style="list-style-type: none"> <li>• An independent, quasi-judicial expert body established by the <i>Single Convention on Narcotic Drugs of 1961</i></li> <li>• Meets annually in Vienna to determine growing quantities.</li> </ul>
<b>Commonwealth Government</b>		
Department of Agriculture, Fisheries and Forestry (DAFF) (Biosecurity)	DAFF	<ul style="list-style-type: none"> <li>• Undertakes an Importation Risk Analysis</li> </ul>
Department of Health and Ageing (DOHA)	DOHA	<ul style="list-style-type: none"> <li>• Administers the <i>Narcotic Drugs Act 1967</i> and issues licences and permits to manufacture narcotic drugs</li> <li>• Determines whether to issue a <i>Licence to Import Narcotic Substances</i> <ul style="list-style-type: none"> <li>– Note that a CW licence cannot be issued without a valid Tasmanian licence to possess and manufacture in relation to the imported material</li> </ul> </li> </ul>
<b>State Government</b>		
Department of Economic Development, Tourism and the Arts	DEDTA	<ul style="list-style-type: none"> <li>• Undertakes a range of activities to support growth in the poppy industry, in particular, development of an industry development framework (Future Outlook)</li> </ul>
Department of Health and Human Services	DHHS	<ul style="list-style-type: none"> <li>• Administers the licensing of manufacturers and growers under the <i>Poisons Act 1971</i> on behalf of the Minister for Health</li> <li>• Enforces licensing</li> <li>• Is consulted by DPIPWE in respect of biohazard issues</li> <li>• Needs to be satisfied that product does not pose a risk to human health from hazards such as microbial pathogens or spores</li> </ul>
Department of Primary Industries, Parks, Water and the Environment (DPIPWE)	DPIPWE	<ul style="list-style-type: none"> <li>• Undertakes a State Biosecurity Importation Risk Analysis.</li> <li>• Consults with DHHS on matters related to human health concerns</li> <li>• Agricultural policy advice</li> </ul>
Minister for Health	N/A	<ul style="list-style-type: none"> <li>• Is the decision-maker under the <i>Poisons Act 1971</i> in respect of licences to grow and manufacture scheduled substances, including poppies <ul style="list-style-type: none"> <li>– Licence stipulates what substances can be manufactured and from what material</li> </ul> </li> </ul>
Attorney General/ Minister for Justice		<ul style="list-style-type: none"> <li>• Receives advice from the Poppy Advisory and Control Board</li> </ul>
Minister for Primary Industries and Water	N/A	<ul style="list-style-type: none"> <li>• Minister with portfolio responsibility for primary industries, in which the poppy industry is a significant player</li> </ul>

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Entity	Short Title	Role
<i>Statutory</i>		
Poppy Advisory and Control Board	PACB	<ul style="list-style-type: none"> <li>• Established under the <i>Poisons Act 1971</i> to provide independent management and oversight of the poppy industry and ensure that practices are consistent with Australia's international obligations</li> <li>• Enforces grower licensing and other controls to ensure that obligations are met</li> <li>• Provides advice to the Minister for Health on any matter relating to the alkaloid poppy industry</li> </ul>
<i>Representative</i>		
Poppy Growers Tasmania	PGT	<ul style="list-style-type: none"> <li>• Representative body for poppy growers for Tasmanian Alkaloids and GlaxoSmithKline</li> </ul>
Tasmanian Farmers and Graziers Association	TFGA	<ul style="list-style-type: none"> <li>• Representative body for poppy growers for TPI Enterprises</li> </ul>

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**Appendix 2 – Glossary of technical terms<sup>6</sup>**

Term	Definition/use
Opium poppy	A plant of the species <i>Papaver somniferum</i> or <i>Papaver bracteatum</i>
Poppy straw	Poppy straw is the initial harvested material containing both seed and plant material. It is processed for the production of seed and concentrated poppy straw(CPS)
Poppy capsules	Poppy capsules are the heads of the opium poppy which contain alkaloid material as well as encapsulate the poppy seed. The seed is separated early in processing and the remaining material goes to concentrate of poppy straw production.
Concentrate of Poppy straw (CPS)	The material arising when poppy straw has entered into a process for the concentration of its alkaloids. Can be sold as a narcotic raw material, or utilised in the manufacture of active pharmaceutical ingredients (APIs)
Poppy seeds	Poppy seeds are separated early in the processing of poppy straw. They are retained for the sowing of future crops or sold as a food.
CPS thebaine	An important raw material used for the production of several opioids such as oxycodone and buprenorphine and the “nal-compounds” such as naloxone and naltrexone
Assay	Determination of the concentration of a specified element or compound in a material

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<sup>6</sup> These definitions have been prepared with the assistance of the Deputy Chief Pharmacist.