

**MINISTRY OF HEALTH AND MINISTRY OF PUBLIC SAFETY
DECISION BRIEFING NOTE**

Cliff # 1061671

PREPARED FOR: Honourable Terry Lake, Minister of Health and
Honorable Mike Morris, Solicitor General & Minister of Public
Safety - **FOR DECISION**

TITLE: Regulation of Pill Presses

PURPOSE: To brief the Ministers on options for the regulation of pill presses.

BACKGROUND:

British Columbia has had a significant increase in opioid overdose deaths related to illegal drug use since 2012 and, under the *Public Health Act*, the Provincial Health Officer declared a public health emergency on April 14, 2016. From January to July 2016, there were 433 illicit drug overdose deaths (an average of 62 per month) in BC.¹ The proportion of overdoses and deaths related to illegal drugs in pill versus powdered form is not known.

The federal government role in pill press regulation is important and Ministers Lake and Morris wrote letters to Minister Philpott in June and July 2016 encouraging federal regulation (Appendices B & C). In her response to Minister Lake, Minister Philpott states that "work is underway to develop, in an expedited fashion, a series of potential legislative amendments that would support the important role of law enforcement in combatting the opioid crisis" (Appendix D). The federal Minister has stated that "We also intend to bring forward legislative options for consideration on the issue of pill presses."² Health Canada officials confirmed that they are researching this issue.

Pill presses/tablet presses/drug encapsulators and tablet punches/dies are used to make medications, natural health products, and food supplements for humans and animals. They are also used to make pills for the illegal market, such as "ecstasy" tablets or counterfeit oxycodone pills containing fentanyl. Pill presses are not regulated in BC or federally, and law enforcement agencies have limited authority to investigate or seize the devices unless they are directly implicated in making illegal drugs.

Alberta's Bill 205 (under the *Alberta Pharmacy and Drug Act*), tabled in May 2016, prohibits the purchase and possession of equipment used in the manufacture of pills and tablets unless licensed to do so. Fines range from \$50,000 for a first offence up to \$375,000 and one year jail time for conviction of a third offence under that Act (Appendices E & F). Australia has state and national laws that work jointly to restrict pill presses in that country—an individual can be guilty of an offence if there is no lawful or reasonable excuse for having one of these devices (Appendix G).

On July 27, 2016, a Private Member's Bill tabled by BC MLA Mike Farnworth, proposed legislation to regulate pill presses (Appendix H) by amending the *Pharmacy Operations and Drug Scheduling Act*. It is similar to the approach taken in Alberta.

DISCUSSION:

There is little evidence to suggest that regulating pill presses will directly contribute to improved public health outcomes, and little likelihood regulation would have a public health effect due to the ready availability and use of powdered illegal drugs, and the great difficulty in stopping traffic of illegal drugs in pill form to BC. However regulating pill presses would provide law enforcement with additional tools to investigate and disrupt these criminal activities, similar to how the BC *Body Armour Control Act*, the *Armoured Vehicle and After-Market Compartment Control Act* and the *Metal Dealers and Recyclers Act* operate. Hence regulating the equipment used in the manufacture of illegal drugs in BC, while forming part of the overall response to the current overdose emergency, should be considered public safety rather than public health legislation. The extent of legitimate use of these devices BC is unknown, and the impact and unintended consequences of regulating legitimate use will need to be considered.

OPTIONS:

Option 1 – Continue advocating for pill press regulation by the federal government. On September 2, 2016, Health Canada staff have confirmed they are exploring options on this matter, but were explicit that any federal restrictions on pill presses would be legislative, not regulatory, and thus would require federal cabinet approval before they can comment further on developments.

Option 2 – s.13,s.14
s.13,s.14

Option 3 – Support the private members bill. Development of a licensing scheme could require a significant amount of resources.

Option 4 – s.13,s.14
s.13,s.14

FINANCIAL IMPLICATIONS: Will include costs if BC legislation developed.

RECOMMENDATION:

Options 1 - Work with the federal government on federal legislation. If they do not appear to be taking action, then consider option 4.



Approved/Not Approved
Honourable Terry Lake
Minister of Health

NOV 20 2016

Date Signed



Approved/Not Approved
Honourable Mike Morris,
Solicitor General & Minister of Public Safety

Nov 21, 2016

Date Signed

Program ADM/Division: Arlene Paton, Population and Public Health & Clayton Pecknold, Assistant Deputy Minister and Director of Police Services
Telephone: Arlene Paton, 250 952-1731; Clayton Pecknold, (250) 387-1100
Program Contact (for content): Brian Emerson, Kathleen Perkin (Health); Kjerstine Holmes (PSSG)
Drafter: Brian Emerson
Date: September 2, 2016

Appendix A - End Notes

¹ The Coroners Service. Statistical Reports into BC fatalities. Accessed July 28, 2016. Reports available at <http://www2.gov.bc.ca/gov/content/safety/public-safety/death-investigation/statistical-reports>.

² Available at: <http://news.gc.ca/web/article-en.do?mthd=index&crtr.page=1&nid=1105179>.

Appendix B - 1061671

1056290

June 15, 2016

The Honourable Jane Philpott, PC, MP
Minister of Health
Health Canada
70 Colombine Dr, Tunney's Pasture
Postal Location: 0906C
Ottawa ON K1A 0K9

Dear Minister Philpott:

I am writing to encourage Health Canada to consider the regulation of pill presses.

As you know, British Columbia is dealing with an epidemic of overdose deaths caused by illicit opioid use. The situation is so concerning that, on April 14, 2016, Provincial Health Officer Dr. Perry Kendall took the unprecedented step of declaring a public health emergency.

The illegal drug market is being supplied by clandestine labs producing illegal pills. We are aware that pill presses with the capacity to produce thousands of pills in a short time are readily available and that these presses facilitate the manufacture, distribution and consumption of illegal drugs.

While we recognize that regulating the sale and use of pill presses will not in itself eliminate the overdose epidemic, we feel that the most effective way to address the use of these presses for the production of illegal drugs is through national regulation by Health Canada. This would lead to a consistent and enforceable response across the country and would be a meaningful contribution to the fight against opioid overdoses.

Sincerely,

A handwritten signature in black ink, appearing to read "Terry Lake".

Terry Lake
Minister of Health

A handwritten signature in black ink, appearing to read "Mike Morris".

Mike Morris
Minister of Public Safety and Solicitor General



1059790

July 27, 2016

The Honourable Jane Philpott, P.C., M.P.
Minister of Health
House of Commons
Ottawa ON K1A 0A6

The Honourable Ralph Goodale, P.C., M.P.
Minister of Public Safety and Emergency Preparedness
House of Commons
Ottawa ON K1A 0A6

Dear Ministers Philpott and Goodale:

As you are aware, on April 14, 2016, British Columbia's Provincial Health Officer, Perry Kendall, declared a Public Health Emergency under BC's *Public Health Act* due to unprecedented rates of opioid overdose fatalities in British Columbia.

We appreciate the federal government's willingness to collaborate on the response to date, including issuance of an emergency importation order for intranasal naloxone and participation by Health Canada staff in an Overdose Action Exchange meeting hosted by the BC Centre for Disease Control on June 9, 2016.

The provincial government has now established an Overdose Response Joint Task Force to lead the health and public safety response to British Columbia's overdose crisis. We are asking for the federal government's priority assistance in effectively addressing our Public Health Emergency, specifically in the following five areas:

1) **Improving the Scheduling of Substances and Equipment under the *Controlled Drugs and Substances Act* (CDSA) and Precursor Control Regulations (PCR)**

Background: Pill presses, sorters, tableting machines and pill dyes are routinely discovered by police in drug investigations. Improvement to the CDSA and the PCR would allow legitimate pharmaceutical companies to hold licenses to import, possess and use these machines but would allow the monitoring and control of access to non-legitimate users. Similarly, law enforcement has noted seizures of precursor chemicals used in the manufacture of illegal, dangerous drugs that are not scheduled as controlled substances under federal law. Fentanyl and related drugs and their precursors are often volatile and law enforcement are requesting seamless processes be instituted authorizing the early destruction of these drugs for safety purposes and to reduce risks while storing the seized drugs, without jeopardizing prosecution.

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Request: The federal government is in the best position to lead a coordinated national effort commencing with changes to the CDSA and PCR. It is requested that the chemicals that can be used to manufacture fentanyl and its analogs, and all W series compounds (e.g., W-18) be regulated as well as pill presses, sorters, tableting machines and pill dyes, which can be used in the production of pills for the illegal market.

Specifically, the federal government is requested to:

- introduce controls on the sale and importation of certain equipment used in the production of illicit drugs, notably fentanyl, e.g., pill presses and tableting machines;
- classify two precursors used in the production of the fentanyl (Propionyl chloride and N-(1-phenethyl)-piperidin-4-one) as controlled substances; and
- Provide mechanisms and authorities for early and safe destruction of Fentanyl, its related compounds and their precursors without jeopardizing prosecutions.

2) **Improving Federal Enforcement Strategies**

Background: Public Safety Canada oversees the RCMP and Canada Border Services Agency (CBSA). Enforcement related to drug laws and importation is primarily a federal responsibility.

Request: Prioritise federal (RCMP and CBSA) enforcement strategies, including focusing interdiction of imported products, packages and precursors, and implement stronger and escalating penalties under the CDSA and the Criminal Code for those who import and traffic Fentanyl and related compounds.

3) **Expanding Supervised Consumption Services**

Background: Supervised consumption services prevent overdose deaths by providing a supervised context in which medical care can be given immediately in the event of an overdose. Federal requirements for a section 56 exemption under the CDSA are hindering efforts to expand supervised consumption services in BC.

Request: Work with the province to accelerate exemptions for the establishment and operation of supervised consumption services on the basis of the prescribed purpose of public safety in response to BC's Public Health Emergency declared under the provincial *Public Health Act*, should a municipality desire safe consumption services.



4) Establishing Drug Checking Services

Background: Drug checking is a public health intervention available in some European countries that allows people who use drugs to test samples of drugs to find out their contents, including adulterants or contaminants. If available in Canada, this kind of service would allow people to know before potentially taking a drug whether it contains Fentanyl or other compounds, and at the same time would enhance surveillance of illegal drug markets.

Request: Work with the province to ensure the granting of any necessary exemptions under the CDSA for the purposes of drug checking conducted as a public health service.

5) Increasing Availability of Treatments for Opioid Use Disorder

Vivitrol & Probuphine

Background: Vivitrol is the trade name for injectable extended release naltrexone, a drug marketed for treatment of alcohol and opioid use disorders. This injectable extended release formulation is approved for use in the United States, but only available in Canada for research purposes or through the Special Access Program. The Special Access Program requires patients to have tried other treatments first before being approved for Vivitrol. However, for some patients Vivitrol may be a more effective first-line treatment option than currently available medications, such as methadone and suboxone.

Similarly, Probuphine is the trade name for a subdermal implant formulation of buprenorphine, a drug approved and available for the treatment of opioid use disorders in the United States, but not yet in Canada.

Request: Work with the province to facilitate access to these long-acting formulations of medications that can be used to treat some of those patients most vulnerable to opioid overdose.

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We look forward to working with you on these key actions to address unprecedented numbers of opioid overdose deaths in our province, and trust that you are able to commit full federal cooperation in facilitating an effective multi-system response to British Columbia's Public Health Emergency.

Sincerely,

Terry Lake
Minister of Health

Mike Morris
Minister of Public Safety and
Solicitor General

Minister of Health



Ministre de la Santé

AUG 22 2016

Ottawa, Canada K1A 0K9

The Honourable Terry Lake, M.L.A.
Minister of Health
Province of British Columbia
Room 337, Parliament Buildings
Victoria, British Columbia V8V 1X4

Dear Minister:

Thank you for your letter of July 27, 2016, as well as your previous correspondence respecting problematic opioid use.

I too am very concerned about the crisis of opioid overdoses and deaths in British Columbia and across Canada. I applaud BC's ongoing work to address this crisis, including your Government's recent announcement of the creation of a Joint Task Force on Overdose Response. I also recognize the important role of the federal government in combatting the opioid crisis in Canada, which is why I recently announced Health Canada's Action Plan on Opioid Abuse. This action plan focuses on the following key areas:

- better informing Canadians about the risks of opioids;
- supporting better prescribing practices;
- reducing easy access to unnecessary opioids;
- supporting better treatment options for patients; and
- improving the national evidence base upon which policy decisions are made.

Work on this action plan is well under way, and it will be updated and modified over time as required.

As you know, this opioid crisis is complex and there is no single step that is going to solve this problem. However, I am committed to taking action and to working with partners across Canada on this important issue.

You have requested additional federal action in five areas. My colleague, the Honourable Ralph Goodale, Minister of Public Safety and Emergency Preparedness, will respond to Minister Morris on the issue of federal enforcement strategies and escalating penalties under the *Controlled Drugs and Substances Act* (CDSA) and the Criminal Code. I am pleased to be able to respond to your request in the other four areas.

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Canada

1) Pill Presses, Precursors and Disposition

Minister Goodale and I agree that addressing the supply side of the opioid crisis is an important part of a comprehensive response. That is why work is underway to develop, in an expedited fashion, a series of potential legislative amendments that would support the important role of law enforcement in combatting the opioid crisis.

With regard to the precursors to fentanyl, our Government has supported a Private Members Bill to schedule six fentanyl precursors. This Bill has made its way through the Senate and is currently awaiting introduction in the House of Commons. However, in an effort to ensure these substances are scheduled as quickly as possible, I have asked my officials to develop regulatory options to control these substances.

2) Supervised Consumption Sites

Harm reduction is an important part of our government's approach to drug policy. The evidence is clear: when properly established and managed, supervised consumption sites are an important component of a comprehensive approach to drug policy. I am pleased that two supervised consumption sites in BC were approved since January of this year. Departmental officials are committed to continuing to work closely with potential applicants across the country to facilitate and provide guidance on the application process. For example, my officials responded to questions and concerns from BC health authorities on a teleconference on July 12, 2016, and are available to continue this collaboration to support the application process for other sites in BC. A useful next step would be to discuss details of specific locations; staffing and regulatory structure; governance and sustainability; and community views. I look forward to learning more about proposed new sites in BC and can assure you of my Department's ongoing collaboration and support, which will help to ensure timely consideration of any new proposal.

3) Drug Checking Services

I have seen some reports of the positive impacts of drug checking services and how these services may help to reduce drug overdoses. I also understand that there are different operating models for these services, utilizing various types of equipment. My officials in our Drug Analysis Service Laboratory, as well as those involved in issuing exemptions under the CDSA, would welcome further discussion with your officials on this subject.

4) Medication-Assisted Treatment for Opioid Use Disorder

Treatment options, including opioid substitution therapy, are important tools in responding to the crisis. As you know, I announced in May 2016 my intention to reverse the

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regulations denying access to heroin for treatment purposes under the Special Access Program. In light of the opioid crisis, I have asked that work on the final amendments be accelerated.

My officials will also begin discussions in the fall with provincial/territorial ministries of health, regulators, and others about whether the current requirement for prescribers to obtain a section 56 exemption for methadone is needed to ensure patient safety or whether it presents an unnecessary barrier to treatment.

With respect to Vivitrol and Probuphine, Health Canada prescription drug review experts have begun discussions with your officials to better understand how to support this request.

Before concluding, I would also like to seek your views on work that can be done to support and promote responsible opioid prescribing. As you know, Canadians are the second highest per capita consumers of opioids in the world and a comprehensive solution must include lowering rates of prescribing. I am taking measures where I can to achieve this objective, but I feel there is more that could be done via provincial health ministries and the regulatory colleges. I would welcome your thoughts on creative approaches to this aspect of our collective response.

I recognize the severity of the opioid crisis within your province, and my Department is committed to continuing to work with you and your colleagues to address opioid overdoses and deaths. It is only by working together that we can hope to have the kind of lasting impact that will curb the opioid crisis and save lives. I can assure you that we will continue to work with partners in BC and across the country to combat this crisis.

Thank you again for writing to us on this very important issue.

Yours sincerely,

A handwritten signature in black ink, reading "Jane Philpott". The signature is fluid and cursive, with the first name "Jane" and last name "Philpott" clearly distinguishable.

The Honourable Jane Philpott, P.C., M.P.

c.c.: The Honourable Ralph Goodale, P.C., M.P.
The Honourable Mike Morris, M.L.A.



Mike Ellis
MLA Calgary-West

**Pharmacy and Drug
(Pharmaceutical Control) Amendment Act, 2016**

Executive Summary

Issue:

- Fentanyl is killing Albertans at an alarming rate. In 2016, 274 Albertans died due to a fentanyl overdose, the highest number in Canada. The Medical Examiner's first-quarter statistics for 2017 attribute 69 deaths to fentanyl, indicating the crisis is not abating.
- Pill and tablet presses are used to manufacture fentanyl – as well as other illegal drugs, such as W-18 and counterfeit OxyContin.
 - A \$750 pill press can produce 3,600 pills an hour.
 - A \$10,000 commercial tablet press can produce 10,000 to 18,000 tablets per hour.
 - Street price is \$20 to \$30 a pill.
- Police need more tools to deal with criminals producing fentanyl.
- Current restrictions in the *Criminal Code of Canada* and the *Controlled Drugs and Substances Act* do not address pill presses.

Pharmacy and Drug (Pharmaceutical Equipment Control) Amendment Act:

- Regulates pill and tablet presses, as well as capsule-filling machines.
- Regulates tablet punches and dies used to stamp pills and falsely legitimize them.
- Regulations (to be drafted) will establish a licensing system to possess pill and tablet presses and capsule-filling machines. Pharmacies are exempt in the legislation, with further exemptions to be addressed in the regulations.
- Penalties of up to \$50,000 for a first offence; a fine of up to \$125,000 for a second offence or up to six months in jail – or both a fine and jail time; and for a third offence, a fine of up to \$375,000 or one year in jail – or both a fine and jail time.

Benefits of the legislation:

- Directly saves lives by providing police with an enforcement tool that can take tens of thousands of pills off the streets.
- Other provinces may wish to use the Act as a framework for their own legislation.
- A groundswell of provincial legislation may convince the federal government include pill and tablet presses and capsule-filling machines as controlled equipment in the *CDSA*, as well the analogues and precursors for manufacturing fentanyl and W-18, which provinces cannot control.

Consultation on the Act included:

- RCMP, Calgary Police Service, Edmonton Police Service, Alberta Law Enforcement Response Team, Alberta Pharmacists' Association, Alberta College of Pharmacists, Natural Practitioners of Canada, members of the medical profession, addiction treatment community, legal counsel, Legislative Assembly Office parliamentary counsel, Minister of Health.

Timeline of legislation:

- Introduced as Bill 205 on April 20, 2016.
- Unanimously passed third reading on May 16, 2016, with a few agreed upon amendments, including higher penalties.
- Received Royal Assent on May 27, 2016.
- Regulations to be drafted in summer and fall of 2016.
- The Pharmacy and Drug (Pharmaceutical Equipment Control) Amendment Act, 2016, comes into force on January 1, 2017.

Appendix F - 1061671



Province of Alberta

PHARMACY AND DRUG (PHARMACEUTICAL EQUIPMENT CONTROL) AMENDMENT ACT, 2016

Statutes of Alberta, 2016
Chapter 12

Assented to May 27, 2016

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Alberta Queen's Printer
7th Floor, Park Plaza
10611 - 98 Avenue
Edmonton, AB T5K 2P7
Phone: 780-427-4952
Fax: 780-452-0668

E-mail: qp@gov.ab.ca
Shop on-line at www.qp.alberta.ca

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**PHARMACY AND DRUG
(PHARMACEUTICAL EQUIPMENT
CONTROL) AMENDMENT ACT, 2016**

Chapter 12

Preamble

WHEREAS the safety and security of the public is a paramount concern to the professions of pharmacists and pharmacy technicians and to all Albertans;

WHEREAS the illegal use of synthetic drugs such as fentanyl can have dangerous effects, including loss of life, and the illegal manufacture and distribution of these drugs has negatively impacted the lives of far too many Albertans;

WHEREAS the control of equipment used to illegally manufacture and distribute drugs will assist in the prevention of illegal drug manufacturing, trafficking and other forms of illegal drug activity; and

WHEREAS it is in the best interests of the public to regulate who is authorized under the law to own and operate certain types of pharmaceutical equipment;

THEREFORE HER MAJESTY, by and with the advice and consent of the Legislative Assembly of Alberta, enacts as follows:

Amends RSA 2000 cP-13

1 The *Pharmacy and Drug Act* is amended by this Act.

2 The following is added after section 18.7:



Province of Alberta

PHARMACY AND DRUG (PHARMACEUTICAL EQUIPMENT CONTROL) AMENDMENT ACT, 2016

Statutes of Alberta, 2016
Chapter 12

Assented to May 27, 2016

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Alberta Queen's Printer
7th Floor, Park Plaza
10611 - 98 Avenue
Edmonton, AB T5K 2P7
Phone: 780-427-4952
Fax: 780-452-0668

E-mail: qp@gov.ab.ca
Shop on-line at www.qp.alberta.ca

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Part 1.1 Pharmaceutical Equipment Control

Definition

18.8 In this Part, “designated equipment” means a pill or tablet press, tablet machine, capsule filling machine, pharmaceutical mixer or tablet punch or die, as those terms may be defined in the regulations, and any other equipment prescribed by the regulations.

Pharmaceutical equipment

18.81(1) No person shall own, operate or possess designated equipment unless that person holds a licence or is a proprietor or is exempt under subsection (2).

(2) The following are exempt from subsection (1):

- (a) an institution pharmacy;
- (b) a person authorized to compound or manufacture drugs under an Act or regulation of Alberta or Canada;
- (c) any other person designated in the regulations as being exempt.

Regulations

18.82 The Lieutenant Governor in Council may make regulations

- (a) prescribing types of equipment as designated equipment for the purposes of section 18.8;
- (b) defining terms for the purposes of section 18.8;
- (c) respecting the granting, cancellation and suspension of permits for any activity under this Part;
- (d) respecting the charging of fees for any permit issued under this Part;
- (e) designating persons or classes of persons as being exempt from section 18.81(1);
- (f) respecting the seizure, removal, return, sale and destruction of designated equipment;
- (g) respecting any matter that the Lieutenant Governor in Council considers necessary and advisable to carry out effectively the content and purpose of this Part.

3 Section 38 is amended by adding “18.81(1),” after “12,”.

4 Section 39(1) is amended by adding “, other than an offence under section 18.81,” after “under this Act”.

5 The following is added after section 39:

Penalties – pharmaceutical equipment offences

39.1(1) A person who is guilty of an offence under section 18.81(1) is liable

- (a) for a first offence, to a fine of not more than \$50 000,
- (b) for a 2nd offence, to a fine of not more than \$125 000 or to imprisonment for a term of not more than 6 months or to both fine and imprisonment, and
- (c) for a 3rd and every subsequent offence, to a fine of not more than \$375 000 or to imprisonment for a term of not more than 1 year or to both fine and imprisonment.

(2) A prosecution under this section may be commenced within 2 years after the commission of the alleged offence, but not afterwards.

6 This Act comes into force on January 1, 2017.



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Appendix G: Australia legislation (excerpts from state legislation)

New South Wales

Drug Misuse and Trafficking Act 1985 No 226

<http://www.legislation.nsw.gov.au/#!/view/act/1985/226/full>

“drug encapsulator means a device that is capable of being used to produce a prohibited drug in a capsule or similar form, and includes a unique part of any such device.

tablet press means a device that is capable of being used to produce a prohibited drug in a pill, tablet or other similar form, and includes a unique part of such a device.

...

11B Possession of tablet press or drug encapsulator

- (1) A person who has in his or her possession a tablet press or drug encapsulator is guilty of an offence.
- (2) It is a defence to a prosecution for an offence under subsection (1) if the defendant establishes:
 - (a) that the tablet press or drug encapsulator is used in connection with an activity that is not unlawful, or
 - (b) that the defendant otherwise has a reasonable excuse for possessing the tablet press or drug encapsulator.”

Victoria, Australia Acts

Drugs, Poisons and Controlled Substances Act

[http://www.legislation.vic.gov.au/domino/Web_Notes/LDMS/LTObject_Store/ltobjst9.nsf/DDE300B846EED9C7CA257616000A3571/817FD2977F782488CA257FCC000FB362/\\$FILE/81-9719aa109B%20authorised.pdf](http://www.legislation.vic.gov.au/domino/Web_Notes/LDMS/LTObject_Store/ltobjst9.nsf/DDE300B846EED9C7CA257616000A3571/817FD2977F782488CA257FCC000FB362/$FILE/81-9719aa109B%20authorised.pdf)

“71C. Possession of tablet press

A person who, without being authorized by or licensed under this Act or the regulations (if any) to do so or otherwise without a lawful excuse, possesses a tablet press is guilty of an indictable offence and liable to a penalty of not more than 600 penalty units or level 6 imprisonment (5 years maximum) or both.”