**Editors Note: There are multiple references to 'Marijuana' or 'Marihuana' and or Cannabis within this document and broadly within the media and community. For future reference in all respects, the most accurate term to use is the botanical name of Cannabis. Historically, the term 'Marijuana or Marihuana' was a pejorative racial term inherited during the Colonial years. Marihuana was a compressed grassy plant circulated into American & widely used by Mexican workers and popularised by African American jazz musicians.**

**Introduction**

Australia has a unique opportunity to embrace the example of more progressive countries like Israel and Canada and deliver the most exceptional Medical Cannabis System possible. We must learn from the mistakes of nations that initiated these types of systems. After a promising media campaign & full support by the Italian Government, the Italian Medical Cannabis system was shutdown after 3 years in operation. With only 12 registered patients sourcing medicine at unsustainable prices for 40 Euro a gram, the National Government took control of the system and reformed it. To engineer a cheaper retail price, the Italian military now produces & extracts Cannabis on a military base in Florence.

Today, Israel and Canada have effective legal access regulations for Cannabis and a wide range of prescribed conditions that respond to Cannabis Medicines added to their Medical Cannabis systems. Patients can be prescribed for and received various types delivery methods to titrate Cannabis Medicines, which suit their needs as patients or carers. These systems are easy to navigate through and their local doctor provides the patient or carer clinical advice & overall guidance through this process. However, both systems experienced 'teething' issues in their evolution before they were effective. In Israel, after 85% of new patient applications were rejected, the regulations were reformed. Canadian MMAR (Medical Marijuana Access Regulations) were a complex exhaustive process; comprising of a 30 page application process for patients and doctors to navigate through.
**Australian Senate Bill**

Our team have analysed this proposed Australian federal bill and identified some very concerning elements. Interestingly, the 'bureaucratic duplication' that exists with the current bill does not occur in any current regulated system in the world. This would significantly impact not how many potential patients are approved but the ongoing success of this proposed system.

**A closer examination**

Broadly speaking, the two Sections proposed a complicated process of a single patient applying to their doctor & regulator (and prescribed) for a single product for a single condition, which reflects the current TGA system and is not 'a new type of system'. If accepted without reforms, the current regulations would only favor foreign owned conglomerates like the United Kingdom's GW Pharmaceuticals with their standardized mouth spray 'Sativex'. *Sativex* is an expensive ($800 per unit) Cannabis extract product, that potentially can treat spasticity associated with Multiple Sclerosis.

This TGA type pharmaceutical product, if approved solely, would only benefit a narrow percentage of potential Australian patients. If too complex or restrictive, this new regulated system would suffer terminally & desperate patients driven offshore & relocate to legal markets to access a wider range of Medicines. Patients & carers who are limited financially may just resort back to sourcing untested, black market derived Cannabis and continue treating their various conditions with a cheaper but less effective method of treatment by vapourising or smoking the Cannabis flower.

A Medical Cannabis system delivered very narrow in scope wouldn't serve the large and growing number that the ACIA estimates to be in excess of 200,000 Australian patients and carers with multiple conditions that can respond to treatments with Cannabis oil like pain, glaucoma, Cancer, wasting syndrome, intractable epilepsy, MS & up to 25 other conditions. A new Regulated system also needs to embrace the "Entourage" effect of Cannabis outlined by Mara Gordon, a therapeutic Cannabis clinician who spoke at the 2014 Tamworth Symposium about the Cannabis plant's remarkable ability to treat & possible even prevent, a variety of conditions, as a panacea or 'cure all.'

**Economic Obstacles and Opportunities**

Will this new Regulator deliver this new industry in so much red tape that commerce simply can't happen? This current draconian policy of the NZ Food & Drug Administration to not allow the human consumption of Hemp seeds & protein in Australia & NZ is utterly ridiculous and needs to be reformed immediately; Hemp outperforms Soy, Rice & Corn & has a full branch chain of amino acids and is great source of Omega 3&6's, its a superfood! This ignorant & backwards which occurs nowhere in the world except Australia & New Zealand, is costing this region jobs, economic growth & investment. The policy achieves nothing; Hemp Foods Australia still supplies Australia by placing a sticky label on their domestic range promoting the use of external Hemp 'scrubs'. The global demand for food is huge & Hemp Foods Australia's $100 million dollar investment is at risk of going offshore where enterprise conditions are more favourable. Australian grown Hemp is in-demand & currently supplying hungry nations like Korea & India with a high performing Hemp seed much better than rice, soy or corn.
An Exporting Nation

The regulators of this new system must consider not only the wide range of medical benefits Cannabis can have for desperate Australian patients and families but the huge economic opportunity that exists before our country. We must embrace our agricultural heritage and capabilities to produce and export exceptional Cannabis Medicines to meet global demand, which is currently exceeding supply.

It’s no coincidence that Australian climate is perfectly suited to produce Cannabis. In fact, The first Cannabis seeds arrived to Australia in 1788 at the request of head botanist, Sir Joseph Banks. On the side of the cargo were two words. "For Commerce." In fact, the blueprint for this new colony envisaged Australia as a commercial agriculture colony producing Cannabis Hemp. So good was Australia's climate for growing this cash crop that for 150 years of settlement, Governments in Australia actively supported & rewarded the growing of cannabis hemp with land, gifts and grants. Even Queen Victoria, where the Victorian state derives its namesake, used Cannabis to treat her menstrual cramps.

In the 1960's Australia pioneered the poppy industry and now controls 50% of the world's market for morphine based pharmaceuticals. The Cannabis plant is a robust, sustainable & carbon capturing agricultural product our farmers and horticulturalist could be easily arranged to produce.

While we examine the use and supply of Cannabis Medicines, The Australian Government has the unprecedented opportunity 'future proofing' our economy. By re-organising our economy to be producers and exporters instead of importers and consumers, we can leverage our agricultural expertise and supply the exponential global demand for Cannabis & Hemp products. Cannabis might be the world's most versatile & relevant plants of the future. It can be grown cheaply and rotated easily, produced organically with limited water or use of harmful pesticides or herbicides. It can serve multiple sectors from food, biofuels, textiles, medicine to high performance energy storages devices and has enormous potential for innovation. This one plant has it all! If the old adage, 'the harder we work, the luckier we get' is true, the Australian Government must work feverishly hard to open this promising industry up and allow it to flourish if we are to maintain our 'lucky' country moniker.

The Lucky Country

We have the chance to create another successful Australian exporting brand like Woolmark & Woolmark Gold, and supply legal markets of the world with exceptional Australian grown Cannabis. We have the skills, personnel, and infrastructure to have this in-demand product grown, processed & extracted and exported globally by Australian owned & operated businesses. These legitimate & responsible businesses will drive our economy forward, create jobs and significant economic growth. The State of Colorado recently hauled in $63 million in tax revenue as well as $13 million from licenses in 2014 from its pioneering legal Marijuana industry. This money has already been allocated to public health, schools & hospitals. With more US states & other progressive nations like Uruguay, Spain, Jamaica, Netherlands & Canada recognising the growing acceptance of Cannabis, the global industry is destined to double in size every year & could grow globally to $100 billion AUD dollars by 2030, rivaling the Tobacco industry.
'Regulator of Medical Cannabis Bill': Sections requiring reform

Section 19(3) requires that authorisation for patients be given by the new regulator (or a State/Territory authority). This is similar to the current system in Israel and the old Canadian system, under which Health Canada was the gatekeeper to the medical cannabis scheme. The result in Israel has been a rejection of close to 85% of applicants, whilst in Canada it has meant significant bureaucratic costs and delays in processing applications. Canada is currently transitioning away from this approach – under the new scheme, coming into effect next year, patients only require the support of an authorised medical practitioner.

Section 13 of the bill requires that for a cannabis product to be included in the register of regulated products a person must make an application for that product. There are significant requirements for registration of a product, particularly with regard to suitability for medical use. Further, it appears that the product will then be registered only in 'relation to the person' who made the application. This would mean that patients wishing to become part of the scheme will have to register not only for authorisation to possess cannabis, but also to have their particular cannabis product (or products) registered with the regulator. There does not appear to be another method for getting products onto the register.

Together these provisions would likely prevent any substantial domestic market and growth in registered patients numbers for cannabis products from developing. However, the bill leaves significant scope for the production and export of cannabis products to more open markets overseas, but this system should be primarily geared around serving Australians with a certified legal medicine as soon as possible.
REPORT: MARIHUANA FOR MEDICAL PURPOSES REGULATIONS (MMPR)

Introduction

The following report on the MMPR by the Australian Cannabis Industry Association, draws out the key points for a consideration by the Committee. Australia has the opportunity to embrace the lessons & evolutions of overseas regulations and deliver the most effective Medical Cannabis System in the world. We have included our report of the Canadian system to offer the Committee the most relevant information possible about the 'best practices' in this global industry. It is particular useful to consider how other countries' systems have suffered for years and in some instances still do.

We have examined the MMPR and the Regulatory Impact Analysis Statement (RAIS). The RAIS was sponsored by the Health Canada and attached to the proposed regulations, prior to their adoption and implementation. Although some changes were made, the MMPR remains substantively the same to the proposed regulations considered in the RAIS.

Assuming that the MMPR is a model for any Australian legislation, the RAIS is particularly useful. The RAIS provides an excellent overview of the operation of the MMPR in a relatively accessible form. Rather than attempt to re-summarise the MMPR, we have included below two excerpts from the RAIS that are relevant to the industry. The first outlines the regulation of licensed producers; the second outlines market analysis and predictions for the industry under the MMPR.

Regulatory context

It is worthwhile explaining the regulatory context of the MMPR. Cannabis remains a controlled substance under the Controlled Drugs and Substances Act, which prohibits the possession, sale etc. of ‘marihuana’. The single reason for a legal access was a landmark High Court case which mandated the Canadian Government to make Cannabis legally available. The MMPR creates an exception to those prohibitions, but does not change the legal status of cannabis outside the MMPR context.

*Prepared by the Australian Cannabis Industry Association

1 http://gazette.gc.ca/rp-pr/p1/2012/2012-12-15/html/reg4-eng.html
2 Controlled Drug and Substances Act, SC 1996, c 19, Schedule II.
Throughout the MMPR and the RAIS, reference is made to the need to prevent ‘marihuana’ grown by licensed producers falling into the wrong hands and becoming part of the illicit drug trade: this appears to be a primary concern for legislators and stakeholders. Presumably this will be a similar concern for legislators in Australian jurisdictions considering medicinal marijuana reform. The ACIA’s members would be well advised to keep this in mind when considering which aspects of any proposed scheme they wish to alter or vary in an Australian model.

**Key issues**

There are a number of regulatory issues (regarding security, record keeping, production etc.) in the MMPR that are relevant to members of the ACIA, however most of these are adequately addressed in the RAIS excerpts. Given that legislators in Australia will also be concerned with the illicit drug trade, it is unlikely that any regulatory scheme here will be less stringent than the MMPR.

There are, however, three problematic issues which the MMPR creates and which I think the ACIA would hope to avoid in any Australian legislation based on the MMPR. First, licensed producers are limited to growing indoors: growing outdoors is not permitted. Outdoor growing has been prohibited under the MMPR for security reasons. Although permitting outdoor growing may entail stricter security requirements (and higher associated regulatory costs for outdoor growers), failure to take advantage of the superior outdoor growing conditions in Australia (as compared with Canada) would be a great loss for any emergent agricultural industry.

Second, licensed producers are only permitted to sell to clients ‘dried marihuana’. Dried marihuana must not be sold with any additives (which is defined as anything other than dried marihuana). This means that edibles, tinctures and oils etc. are not permitted. Again, there would likely be stricter quality control requirements (and again, higher associated costs) if producers in Australia wish to provide alternative forms cannabis consumption. However, given that cannabis would be used to treat a variety of medical conditions, it seems unreasonable to limit its availability to those willing to safely vaporize ‘dried marihuana’. The ACIA advocates for the permitted production and distribution of in demand edibles, oils and tinctures, as more ‘healthy’ options.

Third, licensed producers may only ship ‘dried marihuana’ to clients: face-to-face and shop-front sales are prohibited (except for hospitals and, potentially, pharmacists). Restricting delivery to shipping severely

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restricts the availability of and access to cannabis, but does little to prevent cannabis from entering the illicit drug trade, compared with properly regulated shop sales. Pharmacy sales may still permitted in Canada under the Narcotic Control Regulations, however it is unclear if and how a patient, who receives permission to possess medical marijuana under the MMPR, could buy from a pharmacy. The ACIA advocates for a broad range of access points of sale and delivery options, including both secure online shipping and shop-front sales as currently exists in Canada.
Excerpts from the “REGULATORY IMPACT ANALYSIS STATEMENT”

[OPERATION OF THE MMPR]

The proposed *Marihuana for Medical Purposes Regulations* would authorize the following key activities:

- the possession of dried marihuana by individuals who have the support of an authorized health care practitioner to use marihuana for medical purposes;
- the production of dried marihuana by licensed producers only; and
- the direct sale and distribution of dried marihuana by specific regulated parties to individuals who are eligible to possess it.

**The current MMPR regulations forbid a personal growing licence, however a 2014 Canadian Federal Court ruling has continued allowing for personal production of up to six plants by licensed growers under the old MMAR system.**

**Production of dried marihuana by licensed producers**

The proposed MMPR set out a licensing scheme that is intended to allow for larger-scale production, comparable to that for other narcotics used for medical purposes. This would permit commercial production while regulating the quality and security of dried marihuana, thus reducing public health, safety and security risks.

Production sites would only be located indoors, and not in a private dwelling. This would reduce the risks of diversion posed by outdoor production and the health and safety risks associated with producing marihuana in a private dwelling. Indoor production also addresses the risk of cross-contamination with other nearby crops, particularly industrial hemp.

**Licensing**

Either an individual or a corporation would be eligible to become a licensed producer. In their application, applicants would have to describe the activities they wish to conduct with marihuana and the purpose for conducting those activities. Licensed producers could also become licensed to conduct certain activities with standardized samples of chemicals that occur naturally in the marihuana plant in order to conduct analytical testing of dried marihuana. For example, they would need to possess pure samples of THC and cannabidiol in order to determine the percentage of THC and cannabidiol in marihuana.

A number of conditions would have to be met before the issuance of a licence. The licensed producer would have to designate key personnel under their licence. The senior person in charge (SPIC) would have overall responsibility for management of the activities carried out at the licensed site, while the responsible person in charge (RPIC), and alternate RPICs if applicable, would supervise all activities being carried out with marihuana and cannabis other than marihuana (i.e. pure samples of THC and cannabidiol). Key personnel, along with directors and officers in the case of a corporation, would have to hold a valid security clearance, issued by the Minister of Health (see “Security” section for further detail).
The applicant for a production licence would also have to provide a written notification of their application to the local police force, local fire authority, and local government. The notice would have to specify the activities for which the licence would be sought, and the address of the site at which activities would be conducted.

The applicant would have to provide information that allows Health Canada to assess whether the applicant has certain key measures in place. The applicant would have to provide the following:

- a detailed description of the physical security measures that would be put in place at the site;
- a detailed description of how the licensed producer would keep records of their activities with marihuana and cannabis other than marihuana;
- a quality assurance report that shows that the buildings, equipment, and proposed sanitation program to be used meet the good production practices (see “Good production practices” section) requirements;
- a copy of the notices provided to the local police force, local fire authority, and local government;
- the maximum quantity of dried marihuana to be produced and sold or provided under licence (if applicable); and
- floor plans of the site.

The MMPR also outlines a number of reasons for which the Minister of Health (the Minister) would be required to refuse to issue, renew or amend a licence. These include

- grounds to believe that false or misleading information has been provided with the application;
- information received from a peace officer or other authority gives the Minister reasonable grounds to believe that the applicant has been involved in diversion of a controlled substance;
- the issuance or continuation of the licence would likely create a risk to public health, safety or security, including diversion; and
- key personnel do not hold a valid security clearance.

Once issued, a licence would be valid for up to three years, and could be renewed. The proposed MMPR also set out a process for amendments to any information on the licence (e.g. the licensed producer wishes to increase its production yield or change sites).

Before selling dried marihuana to an individual, a licensed producer would have to register the individual as a client. In the process of registering a client, licensed producers would have to verify that the supporting authorized health care practitioner is entitled to practice their profession in the province in which they were consulted by the prospective client and that they have not been prohibited from prescribing narcotics. These tasks are similar to those conducted by a pharmacist when filling out a prescription. The licensed producer would also have to confirm with the office of the authorized health care practitioner that the information in the medical document, including the daily quantity, is correct and complete.
**Shipping**

Dried marihuana would have to be shipped directly to a registered client using a shipping service that includes a means of tracking the package during transit. It would have to be sent in only one shipment per order. Finally, dried marihuana would have to be securely packed and shipped in a container that would not allow the contents to be identified visually or by odour.

**Access Points: Dispensing dried marihuana through pharmacists & dispensaries**

The current MMAR allows for pharmacists & dispensaries to dispense marihuana that has been produced by a licensed dealer under contract with Her Majesty in right of Canada to the holder of an authorization to possess. This provision was added in 2005 when some provinces and territories expressed an interest in allowing pharmacists to undertake this activity. While it is permitted under the current MMAR, dispensing of marihuana for medical purposes by pharmacists has never been done to date.

Under the proposed MMPR, pharmacists would have the ability to order dried marihuana from licensed producers and to dispense it for medical purposes in accordance with the NCR (Narcotic Control Regulations), provided that P/T regulations governing the practice of pharmacy permit them to do so. In P/Ts where pharmacists are authorized to dispense dried marihuana for medical purposes, individuals would be able to go to a pharmacy with their medical document to receive dried marihuana (it is not clear that this made it into the actual regulations). Stakeholders, including some P/T health authorities, felt that this would bring the distribution of marihuana more in line with the distribution of narcotic medications.

**Security**

The proposed MMPR also set out physical security requirements for the entire site, as well as for restricted-access areas. Restricted-access areas would include all areas where a licensed activity is conducted with marihuana and cannabis other than marihuana (i.e. a lab, the production room, the area where dried marihuana is packaged and labelled). Access to these areas would have to be restricted only to individuals whose presence is required because of their work responsibilities. Licensed producers would have to put systems in place to ensure that access is controlled at all times, as well as 24-7 visual monitoring systems to detect unlawful conduct. The restricted areas would also have to be secured by an intrusion detection system that would detect attempted or actual unauthorized access to the area. The same principles of visual monitoring and intrusion detection would apply to the perimeter of the entire site. Licensed producers would also have to ensure the site and its restricted areas are designed in a manner that prevents unauthorized entry. Should an applicant for a licence fail to demonstrate that they have put in place appropriate physical security measures as outlined in the proposed MMPR, the production licence would be refused.
The proposed MMPR also include requirements that the holder of the production licence, directors and officers (in the case of a corporation) and all key personnel must hold enhanced security clearances prior to the issuance of a producer’s licence. To obtain an enhanced security clearance, these individuals would be required to submit an application with personal information and documents to Health Canada, so that checks and verifications of relevant files of law enforcement agencies could be conducted. As well as criminal record checks, these clearances would involve a global evaluation of the applicant’s potential associations with criminal or violent organizations, associations with individuals linked to such organizations, and the risk of whether the applicant might be induced to assist, abet or commit any acts that would pose a risk to the control of the production and distribution of cannabis. Should the applicant not successfully obtain a security clearance, the production licence would be refused.

**Information sharing**

The proposed MMPR include provisions that would require licensed producers to share information with appropriate authorities in certain circumstances. For example, as with the current MMAR, law enforcement needs a way to verify whether a named individual is a registered client of the producer. If a member of a Canadian police force requires information in the course of an investigation, a licensed producer would be required to confirm as soon as practicable whether the individual is a registered client or an individual who is responsible for a registered client and the daily quantity of dried marihuana specified in the medical document.

**Record keeping**

As described under the proposed MMPR, licensed producers would have to keep records of their activities with cannabis, including all transactions (sale, exportation, importation), all dried marihuana returned from clients, and an inventory of cannabis (e.g. seeds, fresh harvested marihuana, dried marihuana and packaged marihuana). All records would have to be kept for a period of at least two years, in a format that would be easily auditable, and would have to be made available to Health Canada upon request.

**Direct sale and distribution of dried marihuana to individuals authorized to possess it**

Individuals who require marihuana for medical purposes have several avenues to obtain it under the proposed MMPR. Dried marihuana could be sold or provided directly to registered clients by the licensed producer through secure shipping only. It could also be sold or provided by pharmacists, authorized health care practitioners, and hospitals, who could purchase it directly from licensed producers.

**Distribution through licensed producers**

The primary means of distribution of dried marihuana would be directly from the licensed producer to the registered client using secure shipping methods, as the proposed MMPR do not allow for store-front or retail distribution centres.
[Market Analysis]

**Producer surplus gains**

The proposed MMPR would establish a regulated commercial market for the production and sale of marihuana for medical purposes. Private industry participation in the proposed regime is expected to yield benefits to society. Under the status quo, marihuana is either produced through private arrangements or at a cost to the taxpayer. There were no benefits to society at large beyond the benefits to the individuals involved. Under the proposed MMPR, there would be beneficial impacts for the industry, over and above the benefits to the individuals involved in the market. The analysis measured this change in welfare by estimating a change in producer surplus gains under the proposed policy. No producer surplus is derived in the status quo. The CBA found that the new regulated market would generate an overall producer surplus of $2.64 million in the first year of implementation (2014–15), rising to about $110 million in 2024 as the market expands. The present value of producer surplus gains over the policy horizon (2014–24) was estimated at $339.85 million or about $50.65 million (annualized average) per year for 10 years.

**Loss of consumer surplus**

Consumer surplus was estimated as the area under the demand curve and above the price consumers would potentially pay for marihuana under the proposed MMPR. Under the proposed MMPR, the analysis projected a reduction in the number of legal marihuana users vis-à-vis the status quo, and a reduction in the quantity consumed due to a potential increase in the price of marihuana in the regulated market. Under this scenario, the CBA predicted a significant loss of consumer surplus from this policy change. The analysis assumes a price change from about $7.60 per gram to about $8.80 per gram over the 10-year period. This assumption reflects the potentially higher cost of producing marihuana in the new commercial market, compared to personal or designated production under the current MMAR. The higher price also reflects the potentially higher product quality due to quality control measures to limit contaminants and toxic substances and to ensure a product of consistent quality over time. The analysis assumes that this projected price change would lead to a decrease in the relative number of legal users by about 30% over the next 10 years compared to the status quo. The total quantity of marihuana consumed was also estimated to decrease. On average, the loss in consumer surplus (representing the total social costs of the proposed MMPR) was estimated to be about –$166 million per year. The present value over 10 years was estimated to be about $1.115 billion. (The study did not estimate consumer surplus for any consumption derived from illicit supply sources).

**Business compliance costs**

Business compliance costs were estimated as 10% of overall supply cost. Based on this, the CBA estimated that business compliance costs would be about double under the proposed MMPR. As business compliance costs are incorporated in the supply cost for both the status quo and policy cases, they do not form part of the CBA. The business compliance costs mostly fall on medium and large businesses (as opposed to smaller businesses) as the scale of licensed producer activity (in terms of employees and sales revenue) is expected to grow beyond that of a small business after two years.
**Small business lens**

The proposed MMPR would enable an entirely new industry to be created in Canada. There are therefore no incumbent firms directly affected by the regulatory change.

Achieving the benefits contemplated by the proposed MMPR is highly dependent on establishing a viable marihuana for medical purposes industry, with licensed producers that produce as the anticipated demand for the product increases. Based on consultations to date, it appears that all entities contemplating entry into the new market would currently qualify as small businesses. Small businesses typically have less capacity to make the investments required to comply with regulatory requirements; therefore, their viability could be disproportionately affected. The proposed MMPR, therefore, have been designed to minimize compliance and administrative burden to the greatest extent possible, based on the feedback received from potential licence applicants. The MMPR account for the need to maintain reasonable safeguards against the risks of illegal diversion of the product, entry into the market by criminal elements, and the ability of the Government to detect potential misuse of the system by users.

The impact of the regulatory burden on small businesses, however, is expected to be transitory. Projections indicate that, due to the significant size of the potential legal market, within two years of implementation, competent licensed producers could earn returns that can compensate for the initial outlay on regulatory-related and other start-up costs, and could also potentially have experienced growth in their businesses to no longer be designated small businesses.

**Regulatory flexibility analysis statement**

According to Health Canada’s analysis using the Regulatory Cost Calculator, the two most significant cost drivers for businesses under the proposed MMPR are “equipment” (included in compliance cost) and “record keeping” (administrative costs). Equipment costs include security-related expenditures required by the proposed MMPR.

Security-related costs were the most important equipment-related costs contributing to the business compliance burden. These costs include securing production facilities from external threats, installation and operation of surveillance systems, personnel access control and ongoing site monitoring to prevent unlawful access.

In general, the security of the entire regulated supply system from infiltration by criminals or from abuse and exploitation was considered by far the greatest risk faced by the new regime. Thus, the initial option considered proposed stringent, prescriptive requirements and controls around production, sale and distribution of marihuana as the way to mitigate these risks. However, these requirements were eventually rejected in favour of greater supply flexibility and a performance-based production security standard which achieves the same objectives but minimizes the compliance burden on potential businesses. The original option estimated compliance costs based on the prescriptive requirements. The flexible option assumes that small businesses would tailor their compliance costs in a more efficient way to meet the performance standards outlined in the proposed MMPR.
Similarly, costs associated with maintaining and reporting activities with marihuana were the most significant administrative cost identified in the Department’s analysis. As part of the options considered for LPs to track and maintain a record of their activities, the initial option considered requiring a centralized reporting and patient tracking database system to further mitigate the risks of diversion and abuse. This would have entailed a corresponding investment in IT infrastructure and high maintenance and operational costs to be incurred by all LPs. The initial option cost estimate is higher partly because of the higher administrative burden imposed by this requirement. The proposed MMPR, conversely, include record-keeping costs associated only with patient registration and the supply of orders. This does not include any capital, maintenance or other operational expenditures related to record-keeping or other tracking systems since none is specifically imposed by the proposed MMPR. The flexible option, therefore, has lower business administrative costs.

Another provision made to ensure regulatory flexibility for businesses is the requirement under the flexible option for LP licences to be renewed up to every three years as opposed to annually, as considered under the initial option.

Finally, the above consideration notwithstanding, the recommended flexible option may still appear to be imposing heavy compliance and administrative burdens on potential small business LP, upon closer examination. However, it should be noted that the requirements included in the proposed MMPR are considered necessary to achieving the goal of reducing the potential for abuse and exploitation of the proposed system and reducing the risks to public safety and security, while still maintaining access to marihuana for medical purposes for Canadians with medical need.