Rationale for vertically integrated LCPs

Description

Under the proposed commercial marihuana production regulatory framework, Licensed Commercial Producers (LCPs) will be the sole suppliers of seeds/clones and dried marihuana. LCPs who choose to only produce seeds/clones only must meet all relevant requirements under the new regulations including requirements for security and record-keeping.

Vertical integration refers to a business model in which a firm has ownership control over more than one stage of the supply chain, from the supply of inputs to the sale of finished products to the consumer. A firm can be forward integrated (e.g. manufacturer/distributor) or backward integrated (e.g. processor/grower). A firm can also be integrated along the entire supply chain for a product (see annex).

It is proposed that under the new regulatory framework, LCPs be required to be fully integrated. That is, licence holders must control both the supply of raw material (i.e how much unprocessed marihuana is produced) and finished products (how much dried marihuana is distributed/sold).

Rationale

The objective of the marihuana medical access regulatory reform is to minimize criminal involvement in the supply of marihuana for medical purposes, protect public health, safety and security and to improve the way seriously ill Canadians obtain dried marihuana for their medical needs. The reform is guided by the principle to treat marihuana for medical purposes as much as possible, like any other "medication".

In the case of controlled drugs, HC licensing and the established pharmaceutical distribution system serves as an effective control to limit unlawful access to raw material or finished product. As well, most other narcotic drugs obtained from plant origin are not grown locally and thus do not present the same potential for diversion and abuse. On the contrary, marihuana is widely grown and available illegally and a failure to establish controls for the legal growing, processing or distribution under the new framework could exacerbate illegal activity. As well, to the extent that the new framework is seeking to establish a "new" legal marihuana market supported by new businesses and consumers, the legal pharmaceutical or consumer products market is not an appropriate comparator for business models. Under the proposal, marihuana will be widely produced domestically by LCPs and existing regulatory limitations dictate that dried marihuana cannot be immediately distributed through the established system for pharmaceutical drugs. By requiring that LCPs grower, process and distribute their products, the potential for diversions along the supply chain due to many intermediary transactions taking place in the market is minimized.

Secondly, licensing LCPs to undertake each activity separately will create multiple market entry points in the new industry that will make it nearly impossible to accurately track and monitor without significant resource costs. As a signatory

to UN Single Convention on Narcotic Drugs, Canada must maintain its ability to meet its treaty obligations to monitor and report the production and use of marihuana, even in a legal marketplace.
From an administrative perspective, multiple businesses along the supply chain will have significant implications for Health Canada's ability to licence, inspect and monitor compliance under the new framework. If the department is unable to carry out these activities in a timely manner due to capacity constraints, the viability of the proposed market could be compromised.
Finally, vertical integration improves business efficiency and the chances of success of the regulated market. From a cost control perspective, it may force business to consolidate all operations and minimize duplicative set-up costs such as for security. As well, the business' control over growing and distribution means better inventory control and the elimination of potential raw material (and dried marihuana) shortages or surpluses. (Further advantages of vertical integration as applied to LCPs is presented in the appendix)
Vertical integration in the marihuana for medical purposes market is not without precedent. In the state of Colorado, Optional Growing Premises licence is granted only to businesses already licensed by the State as a Medical Marihuana Centre to process and distribute marihuana. However, Medical Marihuana Centre licence holders cannot source more than 30% of their annual inventory from other Centres. Thus effectively, licencees are required to maintain control not only over the sale of finished products but also over the supply of raw marihuana.

Imposing vertical integration by regulations however has limitations including increasing set up costs, reducing or limiting business choice and potentially reducing competition between suppliers. However, under the particular circumstances posed by the controlled commercialization of marihuana, where control over the entire supply chain is necessary objective, it (VI) offers a way to achieve this goal without jeopardizing the chances for market success.

Licensing Implications
Consistent with existing frameworks, licensing of LCP activities will be tied to the premises specified in the application. Under the MMAR, however, PUPLs and DPPLs are allowed to indicate as part of their application for licence, a location for keeping dried marihuana that can be different from the site where growing takes place. Though it is feasible and financially more attractive to confine growing, processing and distribution of dried marihuana to a single location, an LCP may conceivably choose to carry out the different activities at different locations for business or convenience reasons. In this case, it may be necessary to allow the applicant to declare more than one premises to which the licence would apply. This additional location(s) must be an integral part of the applicants business. As well, all sites in a licence application must meet the regulatory requirements for security for the licence to be issued. Since LCPs will not be licensed by activity, growing, processing/manufacturing, distribution or sites for other similar activity cannot be independently licensed.

Recommendation

It is recommended, therefore that given the objectives of the reform, that LCPs be licensed to grow, process and distribute their products in order to minimize the potential for diversion and the chances of success of the new regulated market. An LCP will be licensed only as a vertically integrated firm with full control over the growing, processing and distribution aspects of their final products, whether seeds, dried marihuana or both. The licence will allow LCPs to undertake all activities along the dried marihuana supply chain. LCPs will not be licensed to undertake only individual activities (e.g. grow or distribute only) but can indicate more than one premises to which they intend to apply for the licence. With respect to the LCP whose final product is seeds/clones only, all requirements for licensing must also be met as set out in the regulations. For greater control and accountability, LCPs must maintain control over all activities along the supply chain involving the handling of the product. With respect to testing, it is recommended that provision be made in the regulations to allow accredited laboratories (or those already authorized to possess and test cannabis for THC) to possess test samples without becoming licensed as LCPs.

APPENDIX

Advantages of the Vertically Integrated Model for Licensed Commercial Producers (LCPs): Prepared by Delsys Research March 23 2012

One of the interesting and potentially very attractive features of the regulatory proposal for improving the MMAR is the establishment of vertically integrated licensed commercial producers (LCPs). The LCPs will produce and distribute legal medical marihuana (MM) and will have the responsibility for the final sale and shipment to the patients/users of legal MM. This would be consistent with the increasingly popular mail order model for direct sale from the factory to the final consumer (called in the literature buying factory direct), which in recent years has been facilitated and expanded through E-commerce/sales on the Internet – whereby the same company is responsible for production, distribution and direct sale to the final consumer.[1]

This vertical integration model for LCPs has a number of advantages that over time should result in lower production, distribution and selling costs, lower information and transactions costs, and lower quality adjusted prices to patients. LCPs will not need to incur the additional costs and risks of establishing contractual and other relationships with legal MM distributors and retailers, including compassion clubs and medical cannabis dispensaries now operating in the illegal market.

Alternatively, under the regulatory proposal, LCPs will not need to incur the additional costs and risks of establishing their own store-fronts and retail chains. Under both alternatives, vertical integration reduces the costs of LCP entry, makes entry by SMEs much easier, and increases the probability that the new regulatory regime will result in a reasonably competitive industry with producers of different sizes.

Vertical regulation also removes the problems and inefficiencies with double marginalization/markups, which are associated with markups by separate companies at different stages of the supply chain. Removing double marginalization is one of the efficiency benefits of vertical mergers when these are reviewed under competition law.

This can be demonstrated with some simple arithmetic. If the factory gate price (cost of production including fixed and variable costs) before markup is $1.00 and there are separate markups of 25% by the manufacturer, distributor and retailer, the final consumer price is 1.00*1.25*1.25*1.25=1.95.

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[1] Manufacturers that sell directly to consumers is reportedly the fastest growing online retail category – see e.g. GetElastic (2009) "Manufacturer Advantages in Direct-to-Consumer Selling" August 19th 2009
http://www.getelastic.com/manufacturer-advantages-in-direct-to-consumer-selling/

Vertical integration of LCPs also has attributes that are similar to the highly successfully IKEA business model, whereby the same company produces, distributes and sells to the final consumer – except that the LCP model does not include the additional cost of establishing retail stores and a retail chain.

The vertically integrated firm selling directly to the final consumer may still have a markup of 75%, but the final consumer price would be only $1.75 or 10% below the price when the supply chain includes separate distributors and retailers. Of course, whether this and other efficiencies of vertical integration are passed on to the final consumer (patents/user of legal MM) in the form of lower quality adjusted prices depends on the extent of competition in the product market.[2]

Under the vertical integration business model for LCPs, LCPs will have direct contact with their customers through the latter's telephone and Internet orders. This information will help them to plan their production for the next year, while current patients who reorder or fail to reorder from the same LCP will provide important information to the LCP on whether product quality and customer service are meeting the needs of their customers.

Therefore, buying directly from the LCP should reduce the information and transactions costs and the risks of information failures of both LCPs and their customers and will provide important signals to LCPs on whether their prices, quality, and service are competitive with other LCPs. This information is especially important because, under the regulatory proposal, LCPs will not be able to advertise and market directly to current and potential future patients and to the general public.

Finally, supply chains that involve fewer stages and companies should reduce the risk of diversion to the illegal market and related abuses of the new regulatory regime.

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[2] See e.g. Church, Jeffrey and Roger Ware Industrial Organization: A Strategic Approach, Boston: Irwin McGraw-Hill 2000 Chapter 22 pp. 684-688.

Health Canada Meeting with Potential Licensed Commercial Producers
February 15, 2012
Victoria Executive Centre
Notes by Chris Fay

9:00 am

HC Head Table, Deidre, Ingrid, Courtney, Jeannine, Chantz, Jacqueline, David
- work with Medical Marijuana Regulatory Reform team, HC in Ottawa

Participants
Table 1 – Ruth, Vic, Nick, Ian K, Hilary Black, Phillipe Lucas, Fonda, Kirk Tousaw, Chris M.
Table 2 – Ron Bell, Don F, Ian L, Dave C, Todd J, Christina S (HC), Ken C, Liana (?), James, Eric Nash, Donovan (?), Shadrick,
Table 3 – Casey, Jason Yip, Bob Kay, Bob Marsh, Bob Beck, Chris Fay (HC), John Carol, Gavin R, Helen Reid, Coral Saunders

Jeannine – Opening Remarks
- clear from start, talking about requirements for LCPs
- not about GoC's overall proposal
- moving into technical regulatory drafting stage based on input during consultations
- technical details required for licensed commercial production
- want to talk about recordkeeping, quality, security
- not in GoC's interest to set regulatory bar so high that none of the people in the room have capacity to become LCP
- later in afternoon we have opportunity for Q&A
- Q (all questions that follow are from participants): Will you be distributing minutes of meeting?
- A (all answers that follow are provided by Jeannine Ritchot): Yes, will not be attributing comments, will pass minutes on to all participants
- Next item on agenda is update on reform
    - Consultation wrapped up end of November
    - Summary document going through approvals now and will be posted on HC website soon
    - Consultations very helpful for design of regulatory framework
    - This session is the next step, technical info, also meeting with physicians to get better understanding of what they need for framework
    - No longer undertaking public consultations
    - Goal is to pre-publish regulations in Canada Gazette 1 by end of year
    - At that time, another opportunity to comment, usual timeframe allows around 60 days to provide comments to HC
    - Based on those consultations, we refine regulations, publish to CG2, hopefully in spring 2013
    - Then transition period, ramp up production for newly licensed establishments, hope that there will be enough LCPs to supply market
    - We need to get understanding today of how long it would take to transition
    - This is very first in round of tech meetings

- Q: Will pre-publishing include regulations around production?
- A: Yes, entire regulatory package
- Q: How long until you'll be ready to accept LCP applications?
- A: We don't think we'll be ready immediately after CG2 process, need to get better understanding of how long it will take LCPs to set up. Day after regulations go into CG2 they become law.
- Q: Will there be a cap on number of LCPs?
- A: If you can apply and meet regulatory requirements we are not expecting cap. Interest is in meeting market supply. Depends on how much LCPs think they can produce.
- Q: Does government have numbers on what we think market for medical marijuana is?
- A: No, but there are 13,288 with license to possess right now. Don't have answer to what marked would be right now, but we have to do cost-benefit analysis for regulations. Challenge is that we only have numbers for people who are licensed through program, not outside of it.
- Q: Have you spoken with dispensaries to get a sense of market?
- A: Yes, we have.
- Q: What's average daily consumption volume?
- A: In program, average daily consumption is 6.2 grams.
- Q: Will you release stats on average daily purchase? This information could really sway numbers in terms of what we need to provide.
- A: Don't know if we can. Generally speaking, people who purchase from PPS consume what their doctors approve.
- Q: How much of a change will the new program be in terms of people getting permits? Far many more out there who would like permits than who actually have them, but people face difficulty with doctors, etc, holding back.
- A: Difference between status quo and new framework is that individuals are no longer licensed to produce themselves and won't have to come to HC anymore for approval. Next meeting with physicians to figure out what their needs are to make them more comfortable with new framework.
- Q: Of 6.2 grams in daily consumption and 13000 people, what's projected growth rate say 1, 2, 5 years down the road?
- A: Don't have stats off top of head, but can provide them. Program has done projections. Since March 2010, grown from 4500 to 13000. Expected to continue to grow.
- Q: Can we have list of sympathetic doctors? We don't know who's going to prescribe right now.
- A: Can't do so now or in future.
- Q: Mentioned in summer consultation that PPS contract is not gold standard. Are PPS model and its requirements going to be integrated into new framework?
- A: PPS only system we know right now that's endorsed by HC. But it's a contract with Crown, which is very different thing than LCPs, which won't be under contract with Crown. But it's not a baseline.
- Q: Are physicians representing themselves or are you speaking with the Canadian Medical Association? Medical marijuana can expect a huge influx of people once

doctors are no longer uncomfortable. Also, are we deciding that producers are going to be distributors in this meeting?

- A: We've spoken with CMA and colleges, as well as College of Family Physicians. Second question: today is not to discuss distribution. I know it's a burning question. The govt's proposal remains no storefronts or intermediaries, but not to discuss today. Next big issue is production requirements. I know there's strong opinion that there should be intermediaries and we're looking at the question.
- Q: How are people going to pay for medicine? Don't have money because they're sick and there's no government coverage.
- A: Don't really have good answer. But there are other therapeutic programs/devices/drugs that governments don't pay for.
- Q: Is HC going to put price cap on marijuana?
- A: Something we're looking at to address cost question. Haven't done full analysis yet.
- Q: Any info on dispensaries, how much product they're selling?
- A: Only if they provide it. We have stats on everyone in program.
- Q: Are you considering any other forms of cannabis?
- A: Govt's proposal is dried only, but we've heard lots of response on other products so we're taking closer look at that element of proposal.
- Q: Written in stone that people can't produce for themselves?
- A: Govt's proposal is that no classes under current program will exist under new form. Will brief Minister of what we've heard.
- Q: There's talk of grandfathering in existing MMAR licenses. Does this option still exist?
- A: Still talking about this within department.
- Question posed by Jeannine: How many consider non-dried forms of cannabis important in medical marijuana industry?
- RESPONSE: All hands raised in room.
- Q: Are you going to look at zoning issues as part of growing?
- A: Encourage you to bring them up. We need to know things like if regulations should say no residential. Should we ask for municipality checklist as part of application process?
- Q: Big thing right now is wet cannabis. Should we be discussing that today as well? What is dried cannabis?
- A: Today is for figuring that out in part. Encourage you to raise it in discussion.

- Jeannine: Want to go over three high-level frameworks
  - Jeannine reviewed the LCP Life Cycle diagram; we've mirrored concepts as much as possible to other HC reg frameworks (eg Narcotics control regs, natural health products framework and regs, food and drugs regs)
  - Step 1: Apply to become LCP
    - Eligibility criteria: Canadian address, corporation/government/university/individual, over 18, criminal record verification (this is up for discussion in security framework)
    - Application content: proposed scale of production, proposed activities, checklist from municipal govt (also up for discussion today)

- Step 2: Obtain starting materials: Sources of production: seeds, Crown stock (PPS, RCMP seizures), existing licenses (PUPLs, DDPLs)
- Step 3: Cultivation:
  - Regs don't set max amount, but you'd have to tell HC how much you're growing
  - Location: know govt proposal said no outdoors, but want to talk about it today. It would likely cost more money to secure, but we want to talk about it to determine if there's real interest.
  - Personnel: Don't think we would require anything special, but people would have to sign declaration that they understand responsibility under regulations
- Step 4: Processing/Manufacturing
  - Regs would not prescribe what part of plant is harvested, up to LCPs
  - Would permit mixing strains, producers responsible for truthfully describing products on labels (eg THC content)
  - Regs would require equipment be cleaned and stored, but won't dictate how (comparable to industrial hemp)
  - Define disposal in regs, would stipulate that weight of disposal must be reported
  - Processing: could package in bulk before distribution
- Step 5: Security packaging
  - Tamper evident, childproof, thinking of imposing size limit
- Step 6: Labelling
  - Product label: brand, brand name, lot number , expiry date, producer name, general statement (keep out of reach of children), narcotic symbol
  - Proof of possession is label with name of patient, producer, dose, period of use, date shipped, narcotic symbol; LCPs would replicate as receipt so they don't have to carry around package
  - Also risk info sheet with standard use/risks
  - Comment from participant: All this info is available on BC pharmanet; Jeannine: very similar to what's already required in fed regs
- Step 7: Storage
- Step 8: Distribution
  - Producers required to verify status of physician, patient's address, Canadian shipping address, no quantity/frequency exceeding what physician says, affix label to packages
  - Shipping: does not permit contents to be identified, tamper evident, allows package to be tracked
- Questions about LCP life cycle diagram
  - Q: Considering minimum potential size of orders?
  - A: Haven't considered, but would like to know peoples' views.
    - Comment: clients will figure out how much it makes sense to order given shipping costs
  - Q: Does govt or HC have concerns about rising cost in prescription medicine for clients? What we're talking about now in terms of distribution requirements is raising concern about costs.

- A: It's real concern. Federal govt doesn't cover price of meds, but we're meeting with provinces to discuss. Don't want to comment on provincial issues.
- Q: Will we be able to ship to doctors?
- A: Problem with MARR is that they don't allow caregivers to possess for clients. We want to fix that as long as caregiver can sign for it.
- Q: What about importing for new genetic strains?
- A: Thinking about this in regs.
- Q: Such things as plant breeders' rights. If I come up with strain of plant I own right to it. How does this fit into regs?
- A: We're talking to Agriculture Canada colleagues about these issues and looking at global agriculture practices. If you have opinion on how we should recognize this I welcome discussion.
- Q: So you're not considering capping number of LCPs?
- A: We didn't think it was prudent.
    - Followup comment from participant: Everyone agrees there will be fierce competition, rather see cooperation instead of undercutting.
    - Response from Jeannine: We say LCPs but don't mean just commercial; refers to non-individual users. Co-ops are another option. But not everyone who wants license will get license. Security requirements may be very high. We expect a lot of applications but not everyone will get license. Today about sweet spot for setting bar to make sure we get enough licenses.
- Q: Speaking to RCMP in consultations?
- A: Absolutely, spoken to RCMP, police association, munic govts, etc.
- Q: Are there going to be fees for LCPs?
- A: Huge process for fed govt to set up user fees. Don't expect it right away, maybe down the line. Would take years.
- Q: We think large scale when we hear commercial. But some may want to start small and expand.
- A: Part of regs will be renewal of license. If you're planning to grow, in the renewal process you'll have to say to HC what your new security, personnel, etc will be. Allows for growth.
- Q: Would you have problem with multiple sites? NHP regs allow it.
- A: In theory, no, we wouldn't object to that.
- Q: Current uptake of PPS suggests patients aren't keen on getting product through mail. Consideration been given to that?
- A: We're talking with provinces about options for dispensing. Pharmacies, for example.
    - Followup Q: Would provinces be interested in regulating community-based access?
    - A: We're considering asking them. But we don't regulate retail at the fed level. We'd have to talk to provinces. No secret that every stakeholder group loves ideas of pharmacies. We talked to Netherlands about pharmacy distribution, but they don't have provinces like we do so no jurisdiction issues.

        - Q: Any regionalism considered? Could I send anywhere in Canada?
        - A: Part of proposal is mail-distribution, so you'd be able to send anywhere in country. Challenge is patients might not live where there's storefront so mail has to be option.
        - Q: In terms of zoning, is HC going to stipulate zoning requirements in policy or leave it to municipalities to figure out?
        - A: Spoke with Federation of Canadian Municipalities, bureaucrats, not mayors. Big concerns are they want to know where production sites are and don't want them in residential areas. Feds have no jurisdiction over zoning. Regs could say no LCPs in residential areas. Could ask for signed declaration that municipality is supportive. Another challenge is different licensing/zoning requirements in municipalities across country. Can't put that all together in regs.
            - Comment: Regs could suggest that LCPs grow in light industrial only.
            - Comment: Concern with municipal signatures is that municipalities are already saying no to any medicinal marijuana in their boundaries.
            - Comment: You need building permit, business license and approvals from local municipality.
            - Comment: Not necessarily productive to discuss cost, zoning in this session because HC has no jurisdictional authority.
- First Break at 10:30 am
- First breakout session at 10:45 am
- Lunch at 12:00 pm
- Second breakout session at 1:10 pm
- Third breakout session at 2:45 pm
- Final discussion started at 3:35 pm
- Jeannine: Final Discussion
    - Question from Jeannine: Did that format work? Did you like setup? Could you pass on appropriate info?
        - **RESPONSE:** Yes, it worked, but suggest additional time.
        - Comment from one participant: Also would like recap from facilitators so each group knows what the other said.
    - **[Follow-up Required]** Jeannine: We'll provide notes that were taken in each group. Also, please pass on any additional comments you have to the consultations email address.
    - Q from Jeannine: What if we asked producers to produce both dry product and resin? [
        - **RESPONSE:** Applause from crowd, with some standing ovation
            - Jeannine: Caveat is that you couldn't produce products like creams, salves, etc, would allow you to produce resin form.
        - Q from participant: What's rationale to not allowing people to produce alternative forms of ingestion? It's something not everyone can produce at home.

        - Follow-up Q from participant: If producing non-hash based resin, eg salve, I've made alternative products. This is exactly what people are already trying to do this with purchased medical marijuana.
        - Jeannine A: There are other reg regimes that HC has in place that say when you want to make health claim about product/drug you have to demonstrate from evidence point of view why product is good.
            - For example, Sativex, went through procedure in order to market spray.
            - Can't circumvent this route that we've already forced others into. Allowing resins would provide compromise this already existing reg regime.
            - If patients buy marijuana from LCP and make resins (eg bake), HC doesn't care because regime is not set up to police what individuals do with medical marijuana in terms of consumption.
        - Comment from participant: Delivery mechanism is extremely important because it allows patients to vary their intake and how it's ingested
        - Comment: Patients want this desperately
        - Comment: For elderly, skin patch is great idea, standardized dose in liquid form, allows people who have never smoked in their life to get benefits
        - Q: on topic of making claims for products, what if salve was offered without making claims at all?
        - A: This is something we could consider.
        - Comment: If patient chooses to make batch of cookies, is RCMP going to get involved if patient shares a cookie with a friend, that's not trafficking, even though they both have legal possession, don't want to contravene Criminal Code
        - Comment: NHP regs contemplate making of different forms of health products.
            - Most producers considering alternative means of consumption do it with leaf matter that has no value otherwise
            - If you're able to sell product you'd be able to produce at much lower cost
            - Much less chance of diversion to black market with products like salves as opposed to medical marijuana
            - Follow-up comment: not cool to put some butter in your mouth or rub some salve on your hand, unlike smoking weed.
- Jeannine: model we're selling today is vertical integration, how realistic is it to expect producers to do everything from A to Z?
    - Whole room: very realistic.
    - Comment: It's about integrating existing system into legal system.
        - Comment: challenge of expecting producers to do a number of things that aren't manageable, such as patient relationships
        - Comment: We ask that when you're drafting regs, you don't preclude dispensaries from distribution [received applause]
    - Comment: direct distribution to patients still desirable, depends how we do it

        - Comment: Look at methadone model. Distributed to individuals but also through community clinics. Want product to get to patients with information to ensure best possible outcomes
    - Q from participant: what's HC model for vertical integration?
    - A from Jeannine: Everything from startup, growing, product, distribution, etc. Question is can we get enough LCPs with this expectation?
        - Comment: competitive environment will require production and distribution to merge at some point regardless.
        - Comment from participant: I'm here for just two consumers, but don't want to be biggest guy on block, so don't make it requirement that we have to distribute; I have no idea how to handle 500 people or 5000. This is very exciting time, hoping there's some form of cooperation rather than competition in industry.
        - Comment: Distribution model is vastly different, don't know until you see 500 patients which strain appeals to which patients; distributor knows all about these sorts of things; producers can tell you about nutrient value, THC, etc, but distributor required to understand how to move product to people.
        - Comment: would like to see distribution and LCP to have ability to be separated.
        - Jeannine: heard loud and clear through consultations that this is preferred route, but need to know this can work if we can't separate producer and distributor roles.
        - WHOLE ROOM: Yes, it can.
        - Comment: It's all about patient care, need to have someone for patient to talk to so they can find out info, what makes sense for them.
        - Jeannine: Everyone in this room prefers face-to-face interaction, but is there anything in LCP model that prevents interaction given that there's no storefront?
            - Comment: could have some sort of info centre that provides all info that client needs
            - Q: Is it right that we can't openly market strain or genetics?
            - Jeannine A: Prohibition on marketing narcotics openly. We have to figure this out. Allowing LCPs to produce different strains and info has to get to consumers, but we don't know how this will work yet.
        - Comment: If I'm treating 65-year old woman with cancer I wouldn't be able to show her how to role joint, teach her about different varieties/strains, etc. Tremendous amount of patient info you can only do face-to-face. Challenge with excluding edibles from regs because dosing windows so much larger, can actually cause a lot of harm with consumption as opposed to dried product. Really good patient education required especially in case of elderly patients because these people may get hurt trying to figure out edibles on their own.
- Jeannine: don't have time to talk about issues we've left in parking lot on white board, but want people to know that issues won't get lost

Turn over to general question and answer for last half hour (CF note: Q&A addressed all the issues that were in parking lot on white board)

- Comment: Genetics is important to talk about to determine how we're going to make high quality product available in new system
- Comment: Ability to share within LCPs is extremely important to show HC that strains were sent between producers and to know where strains are.
- Comment: Problem is the initial strain (zero seed); under current GNP regs you need to be able to trace back to original strain; how do you legitimize other strains to bring into production?
    - Jeannine: Should HC care about this or are they just business decisions?
    - Response from WHOLE ROOM: Leave this out of regs, these are business decisions
    - Jeannine: earlier today I said the options we were considering for 4 available sources: Crown (PPS), seized materials, import, existing PUPD/DPPL
    - Licensees selling to each other is not trafficking because they're licensed
        - CFIA doesn't have any problems with these 4 options
    - As transition measure, we'd consider that people with licenses under current program would be allowed to provide/sell seeds
    - If LCPs want to do that and get mad later for not having quality product and HC inspectors nab them for poor product, that's their business decision, not HC regs' fault
    - As long as it's produced legally, don't care how it got there
    - Comment: Group thinks it'll take at least two years for LCPs to get on stream given need to meet certain regulatory requirements, means that existing program will need to run until 2015 given that LCP regs will come in spring 2013; Q: can you give us info to get a head start on LCP role and production?
        - Jeannine A: We have options for this: blow our timeline past 2013 and allow current program to go until 2015; or find mech to allow certain activities to start immediately to allow transition. Expected answer from groups to be 12-24 months for getting up and running. Need to look at options, make absolutely no guarantee that anything will be allowed to start early. I'll be briefing the Minister about the 12-24 months to start up an LCP issue.
- Q: Can we discuss multiple facilities? If we wanted to do number of smaller scale facilities can we streamline licensing process?
- A: only way to streamline is if we had info about all facilities at same time. Can process application if LCP provides all info required by regs. If that's your business plan and you want to have multiple facilities than you need to provide all info at once.
- Jeannine comment: Don't know how long it'll take HC to license once we get applications, but requirement for regulatory process is producing service standards. HC must make service standards public and live up to them. Don't know what they are yet, but have to deliver them so people know.
- Q: Will HC help with marketing facilities on website?
- A: We're looking at that option. Can we publish list on website along with strains LCPs have? Do people like that option?

  - RESPONSE: Yes, it should be done. We should also be able to have our own websites so people can track us down.
- Q: Can we provide doctors with samples so they can market products?
- A: We're struggling with that. Obviously pharmaceutical companies do it with doctors. We're asking doctors in our consultation process. Do you want that?
  - ALL: yes, this would be great.
  - Comment: reason that comes up is because doctor has no medical knowledge of marijuana use, we need to educate them on this.
  - Q: On pharmaceutical websites for Sativex I can see all side effects, benefits, etc. If you have link to LCP sites on HC website can we do that?
  - A from Jacqueline (HC): Not allowed to access/advertise any info on drugs on websites.
  - Q: So our sites could provide contact info and we can follow up with this detailed info on product, side effects, etc?
  - A from Jeannine: difference between these products and med marijuana is that pharmaceutical product has undergone extensive clinical trials, that's where info comes from.
  - Q: Can I list different strains and product on website or is that considered advertising?
  - A: We don't know. We have questions in with legal counsel about exactly this.
- Q: Have you spoken with big pharmacy chains about distributing product?
- A: Not chains, but have spoken with Canadian Pharmacy Association. They're lukewarm. Trained in pharmaceuticals and to understand what products are used for. They don't know what different medical marijuana strains are used for.
  - Followup comment: You can train pharmacies to know this.
  - Jeannine: But that's not HC's role. Proposal is that this is LCP role.
- Q: But can we have storefronts?
- A: No, not under proposal.
- Q: If you're writing regs to allow for integration, what's so far-fetched to allow for production and storefronts?
- A: That's not government's proposal.
- Q: Any thought at HC when med marijuana will get DIN?
- A: To get a DIN you need to conduct clinical trials. There's nothing in existing regs that precludes anyone here from conducting clinical trials. To date, medical marijuana has not successfully met tests under FDR. This is not a natural health product. If it has a DIN and is a recognized drug in Canada that's put on formularies this is no longer an issue.
  - Mechanisms exist under NCR and CDA to apply to HC for research license (S. 67 of NCR).
  - This regulatory reform exercise is not the mechanism to get marijuana a DIN.
- Q: Concern about waste of products in growing process. What will HC require?
- A: Not going to require incinerator on site, but will require disposal and will issue guidelines for disposal.
- Q: But will you exclude root balls from disposal requirements?
- A: Yes, heard a lot about this today.
- Q: How long will renewal process be? The amount of time allowed for a license has a significant impact on the viability of the business model.

- A: All narcotic licenses in HC are 1 year. But don't want to create burdensome system on brand new industry. Still have to do analysis. What's reasonable in your mind?
    - WHOLE ROOM: 3 to 5 years.
    - Comment: Less time allowed means more capital required at your disposal to keep operation running.
    - Jeannine: When I say 5 years to cops they will say get out, absolutely not.
    - WHOLE ROOM: Supportive of 3 years.
    - Q: What if I want to change license? Would I have to wait until renewal time is up?
    - A: Don't think you'd have to wait, but you'd have to provide information to HC before allowed to proceed with changes to operation.
- Q: Liability, what happens if someone dies or is injured off product? What about liability through mail system: you're not able to get any insurance on mail over $100.
- A: This is an unpopular response: you're entering business with risks, HC not interested in assuming liability. If you want to market/distribute product with no tests, shouldn't you be assuming liability?
    - WHOLE ROOM: Generally supportive of this point. It's up to businesses to assume risk.
- Q: If license is only 3 years, and I assume you're doing unannounced audits, will police really have problem with longer licenses?
- A: Yes, they will. They've already said so.
- Q: Can you help us with other government departments? For example, Farm Credit Canada won't provide money for this.
- A: I have intergovt group that meets every 3 months, but I have no sway on their decisions after that.
- Q: Have other groups like police said what they think appropriate license should be?
- A: Yes, one year.
- Q: What's liability in PPS contract?
- A: It's in there, but we don't know what it is off the top of our heads.
    - Jeannine: Have to be willing to assume liability to operate any business. Trying to create market so principle is that it needs to operate the same way that other legal markets operate. Not popular answer, but true.
    - Comment: That's why god invented limited liability corporations. Though worth mentioning that as soon as product leaves door and enters mail system you can no longer control liability. Any suit may be filed against distributor, pharmacy, producer, etc.
    - Comment: You're misunderstanding the concern about liability. Point is whether HC will require onerous level of liability through new regs.
    - Jeannine: Don't see it as requirement in regs, but rather business decisions. PPS contract is unique because product belongs to Crown.
- Q: License renewal: do you have license renewed automatically if nothing's changed?
- Jeannine A: Very bureaucratic answer: we'll have service standard, we'll try to process renewals within certain standard. Don't know yet if we'll require producers to submit entire package for renewal. Crux is that if you want renewed license you need to demonstrate that you continue to meet all the requirements for program.

Jeannine – Brief Discussion on Next Steps

- We're doing this next Wednesday in Ottawa with large group, similar numbers to this one
- We'll make same commitment to them about sharing notes from sessions
- Already touched on next steps this morning when talking about timelines
- Talking with physicians, provinces next, then regulatory development based on public consultations and tech details
- Have to do cost-benefit analysis, regulatory impact statement, these consultations form all of that
- Don't know if we'll have another opportunity to speak face-to-face but you can comment at CG1; can also email at any time through consultation email address; Not shutting down contact at this time
- Q: Are you just meeting with the groups in Ottawa and BC right now? Can others get involved?
- A: Please share the questions with other people and ask for their input. The more people we hear from the better. You know the community better than we do.
- Q: Can we have copy of what you were reading this morning?
- [**Follow-up Required**]A: You'll get that with notes.
- Comment: The food was great ☺

This is **Exhibit "Z"** referred to in the
Affidavit of **JEANNINE RITCHOT**
Affirmed before me at the City of Ottawa,
in the Province of Ontario,
this 15th day of January 2015.

A Commissioner for Taking Affidavits

Issue Analysis Summary

Physical Security

ISSUE

Under a reformed Marihuana Medical Access Program, licensed commercial producers who cultivate and supply marihuana to patients for medical purposes must ensure control of a narcotic and that diversion risks are minimized. Health Canada will need to determine realistic minimum physical security requirements for licensed commercial producers.

CONTEXT

The safeguarding of controlled drugs and substances is an issue that confronts all manufactures, distributors, pharmacies, law enforcement and government. Health Canada limits the handling of these drugs and substances through policies, guidelines and legislation such as the *Controlled Drugs and Substances Act* (CDSA) and the *Narcotic Control Regulations* (NCR). Those wishing to engage in lawful activities with narcotics must be properly licensed in order to ensure that they are adequately secured and safeguarded at all times to ensure public safety and minimize risks of diversion.

In Canada, any person wishing to engage in lawful activities with a narcotic which involves producing, making, assembling, importing, exporting, selling, providing, transporting, sending or delivering is subject to the requirements outlined in NCR and must be a licensed dealer. These requirements range from eligibility, personnel, security and record-keeping for licensed dealers.

To be eligible for a dealer's licence under Section 8 of the NCR, a person must be:

- an individual who ordinarily resides in Canada;
- a corporation that has its head office in Canada or operates a branch in Canada; or holder of a position that includes responsibility for narcotics on behalf of a department of the Government of Canada, or a government of a province, a police force, a hospital or a university in Canada;

Some general NCR personnel and security requirements include that a licensed dealer:

- shall designate one qualified person in charge (QPIC), who may also be the licensed dealer, who must work at the premises, have responsibility for supervising activities with respect to narcotics specified in the license and for ensuring that those activities comply with Regulations;
- may designate an alternate qualified person in charge (A/QPIC) who must work at the premises and has the authority to replace the QPIC when absent;
- the QPIC and A/QPIC shall be familiar with the Act and regulations that apply to the licence of the licensed dealer, have a knowledge of chemistry and pharmacology and experience in the fields to properly carry out their duties;
- the individual in charge of the premises, QPIC and A/QPIC shall not have been convicted, as an adult, within the preceding 10 years of a designated drug, a

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designated criminal offence or an offence committed outside of Canada and must provide a CRC issued by a Canadian police force;

- the person in charge of the premises, QPIC and A/QPIC shall not have been convicted of an offence committed outside of Canada;
- the QPIC and A/QPIC must provide a detailed description of the security measures at the premises, determined in accordance with the *Directive on Physical Security Requirements for Controlled Substances*, 1999;
- Will be subject to pre-inspection and subsequent inspections of the premises at the discretion of the Minister;
- A dealer's licence expires 3 years after its effective date.

In 1985, Health Canada published the *Directive on Physical Security Requirements for Controlled Substances.* This Directive was subsequently amended in July 1999. The primary purpose of the Security Directive is to establish realistic minimum security standards for the storage of controlled substances and drugs and to assist licensed dealers, manufacturers or distributors as well as for research scientists and analytic laboratories in security design.

The Security Directive outlines security requirements based on levels, which range from 1 through 11, with level 1 requiring the least amount of security since level 1 only allows you to possess a maximum value of $500 of controlled substances or drug on your premises at any given time whereas level 11 is valued at $150 million and up. In order to determine which of these levels apply, the Directive describes three factors that must be taken into account: (1) the geographical location of the premises, (2) the illicit value of the controlled substance or drug and (3) the amount. According to the Directive, geographical locations are split into three regions, with region I having the largest number of reported break and entries, armed robberies, pilferage (e.g. small bottle that can be easily slipped into a pocket and taken outside the building during breaks or at quitting time), loss in transit and unexplained losses of controlled substances. Locations that meet these criteria include Toronto, Montreal, Vancouver, Edmonton and any location within 100 km radius of these cities. Locations falling under region II have shown significant numbers of illegal activities and include Halifax, Quebec City, Ottawa-Hull, London, Winnipeg, Calgary, Windsor and any location within 50 km radius of these cities. Finally, region III includes any locations in Canada which are not in regions I or II. The Security Directive also provides prices to be utilized in determining the illicit value of controlled substances. The prices are calculated using a combination of the illicit market price for a finished product as well as for the raw material. *Cannabis Sativa*, its preparations, derivatives and similar synthetic preparations except Nabilone are valued at $10 per gram.

Some of the major gaps identified within the current Directive are with respect to

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cultivation of marihuana for medical purposes and include determining which factors will set the levels of security, for example, the illicit market price of the plant at each stage of growth or perhaps the risk of theft, i.e. it is more difficult to steal a plant than it is to steal packages of dried marihuana. Furthermore, the Directive does not take into account securing a cultivation which could occur outdoor or indoor (in a greenhouse), variations in plant yield per plant and concentrations of THC, cultivation requiring appropriate lighting and ventilation which may not be achieved in a vault. These gaps would require further analysis.

Current Status:

Under the MMAR, holders of a valid authorization to possess (ATP) have access to three supply options for marihuana for medical purposes: they can grow for themselves under a personal-use production licence (PUPL), they can designate someone to grow on their behalf under a designated person production licence (DPPL) or they can receive a Health Canada supply which is contracted by the Crown to Prairie Plant Systems Inc., (PPS).

Currently, PUPLs and DPPLs, may choose to have an outdoor or indoor cultivation site whereas PPS must cultivate indoors only. With respect to PUPLs and DPPLs with an outdoor cultivation site, under Section 28 (1) (g) of the MMAR, these sites must not be adjacent to any public property that is mainly frequented by persons 18 years of age or younger, such as a public playground, school or a day care:

28. (1) The declaration of the applicant under paragraph
(*e*) the full address of the site where the proposed production of marihuana is to be conducted;
(*f*) the proposed production area;
(*g*) if the proposed production area involves outdoor production entirely or partly indoor and partly outdoor production, that the production site is not adjacent to a school, public playground, day care facility or other public place frequented mainly by persons under 18 years of age;
(*h*) that the dried marihuana will be kept indoors and indicating whether it is proposed to keep it at (i) the proposed production site, or (ii) the ordinary place of residence of the applicant, if different; and (*i*) a description of the security measures that will be implemented at the proposed production site and the proposed site where dried marihuana will be kept.

This requirement also mirrors Section 36 of the *Industrial Hemp Regulations* (IHR) with respect to outdoor cultivation requirements:

36. No person who holds a licence to cultivate industrial hemp shall cultivate it within one kilometre of any school grounds or any other public place usually frequented by persons under the age of 18 years.

In addition to the above, DPPL's are also subject to additional requirements under Sections 34 (1) and 34 (1.1) to ensure that they are only supplying marihuana for medical purposes to holders of a valid ATP, that they are not exceeding their maximum

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possession amounts and transport and distribution requirements:

34. (1) The holder of a designated-person production licence is authorized, in accordance with the licence,
(*a*) to produce marihuana for the medical purpose of the person who applied for the licence;
(*b*) to possess and keep, for the purpose mentioned in paragraph (*a*), a quantity of dried marihuana not exceeding the maximum quantity specified in the licence;
(*c*) if the production site specified in the licence is different from the site where dried marihuana may be kept, to transport directly from the first to the second site a quantity of dried marihuana not exceeding the maximum quantity that may be kept under the licence;
(*d*) subject to subsection (1.1), if the site specified in the licence where dried marihuana may be kept is different from the place where the person who applied for the licence ordinarily resides, to send or transport directly from that site to the place of residence a quantity of dried marihuana not exceeding the maximum quantity specified in the authorization to possess on the basis of which the licence was issued; and
(*e*) to provide or deliver to the person who applied for the licence a quantity of dried marihuana not exceeding the maximum quantity specified in the authorization to possess on the basis of which the licence was issued.

(1.1) A holder of a designated-person production licence sending dried marihuana under paragraph (1)(*d*) shall
(*a*) securely pack the marihuana in a package that
(i) will not open or permit the escape of its contents during handling and transportation,
(ii) is sealed so that the package cannot be opened without the seal being broken,
(iii) prevents the escape of odour associated with the marihuana, and
(iv) prevents the contents from being identified without the package being opened; and
(*b*) use a method of sending that involves
(i) a means of tracking the package during transit,
(ii) obtaining a signed acknowledgment of receipt, and
(iii) safekeeping of the package during transit.

In contrast to PUPL and DPPL requirements, PPS, the HC supplier of marihuana for medical purposes uses an indoor cultivation facility which is subject to security requirements imposed by a contract with the Minister. Requirements under this contract include that PPS become a licensed dealer as defined in Section 2 of the NCR and that they comply with all applicable requirements under the CDSA and its regulations. The contract also requires that at all times PPS meet the security requirements for storage of the *Directive on Physical Security Requirements for Controlled Substances,* 1999.

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Based on a analysis on behalf of the CACP by the RCMP in November 2010, *An Analysis of National Cases Related to the Marihuana Medical Access Regulations,* found that current MMAR's security requirements are ineffective as there has been and continues to be increases in criminal activities such as theft of marihuana plants, grow operations and marihuana being produced in excess of licence requirements and being diverted to the illicit drug market.

Proposed Changes:

For context on the proposed changes to the MMAP, please refer to Health Canada's consultation document entitled *Proposed Improvements to Health Canada's Marihuana Medical Access Program.*

Current PUPL and DPPL's are not required to meet security requirements above and beyond what is currently described in the MMAR. These requirements have proven to be ineffective thus far and therefore we are proposing to continue to include those elements from the MMAR, however to include additional requirements such as those set out for narcotic licensed dealer's under the NCR and storage requirements as described in the *Directive on Physical Security Requirements for Controlled Substances,* 1999. Please note that the current directive does not cover securing live plant material.

CONSULTATIONS

Potential LCPs expressed that the value of their assets should be assigned based on quality of the final product rather then the specific medium in which it was grown. Participants also stated that dried marihuana produced by outdoor cultivation tends to sell for approximately half of indoor, as it is often viewed as being lower quality due to exposure to many factors (ie. weather and pests). Participants also highlighted that the final product (dried marihuana) is more valuable than the starting materials (seeds, plants), due to the relative ease of diverting dried product. Participants suggested security should be more advanced (vault, safe, restricted area) for finished product.

With respect to criminal record checks (CRC), potential LCPs were comfortable with them for their employees. They are interested in knowing if their employees have been convicted of theft, fraud or any violent crimes. Beyond those requirements there was concern about CRCs checking for past marihuana drug offences (i.e. production) as it is likely that the best employees/LCPs would be those who have prior experience in the production and distribution of marihuana. Some agreed that CRCs should be required by regulations for the owner(s) and supervisors. Employees' record checks should be left to the discretion of management.

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Stakeholders are comfortable with municipal services knowing the location of their facility for safety and security reasons but they do have reservations. LCPs see municipal knowledge as unavoidable due to the need for permits, licences, fire inspection etc. Participants are concerned that municipalities will not want LCPs operating in their area, and by letting them know of their intentions they are giving municipalities a chance to deny a licence. They are also concerned that once a municipal licence is issued the information becomes public record which may leave their location vulnerable to security threats.

Overall stakeholders felt that as long as security is sound, a facility's proximity to police services is secondary. Police presence and proximity is one risk management

IDENTIFICATION AND ANALYSIS OF OPTIONS

1. Existing Physical Security Directive Only

Under this option, Health Canada would require that LCP's meet at minimum the current physical security directive: *Directive on Physical Security Requirements for Controlled Substances* for storage of marihuana for medical purposes, including seeds and live plants.

PROS

- Consistent with NCR for the physical security of other narcotics;
- Current Crown supplier was required to use this directive only to secure the storage premises;
- Minimal burden on HC as we would have LCPs use a document that already exists;
- HC inspectors are familiar with the requirements found in the existing security directive;

CONS

- Current Crown supplier used this directive only, however had to perform a time consuming and burdensome threat risk assessment;
- Existing security directive has major gaps such as defining cultivation security.
- Some of the existing security directive would not apply to LCPs and this could lead to confusion;
- HC inspectors would be using a security directive to compare compliance against that is not suitable for the marihuana cultivation scenario – leaves it open for judgment calls which inspectors may be uncomfortable with given the stigma and sensitivity surrounding marihuana for medical purposes.

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2. A new Physical Security Directive for LCPs that incorporates the existing Security Directive for storage and new guidelines for cultivation.

Under this option, Health Canada would require that LCP's use a new Physical Security Directive document that would essentially be the current existing directive on physical security (1999) in addition to requirements for securing cultivation.

PROS

- Additional document would address major gaps such as securing cultivation.
- HC inspectors are familiar with the requirements found in the existing security directive, and would be given clear instructions with respect to cultivation.

CONS

- Burden on HC as we would to develop an additional cultivation document but less of a burden then developing an entire new physical security directive altogether;
- Existing security directive has major gaps such as defining cultivation security.

CONSIDERATIONS

- A Threat Risk Assessment would not be conducted by potential LCPs as we do not require them for other licensed dealer's under the NCR. In addition, it is likely that HC will not be allowing outdoor cultivation and therefore there is a decreased threat risk as the marihuana crops will not be visible to members of the public;
- Security requirements must not be overly burdensome as to drive potential LCPs to no longer be interested in applying;
- Security level of seeds versus live plants versus dried plants versus packaged material versus waste is based on their threat of being stolen rather than one illicit market value for all. Plants are harder to steal however it is the final product that is considered the most valuable asset.

RECOMMENDATION

Option 2 is recommended because the current physical security directive alone does not provide sufficient guidance and requirements for securing plant cultivation. HC will develop an additional guideline which would be tailored to this program and would

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address what is necessary for securing cultivation in order to minimize risk to public health and safety.

NEXT STEPS

Consultation with the RCMP and other individuals with appropriate expertise will be engaged in the development of requirements.

This is **Exhibit "AA"** referred to in the
Affidavit of **JEANNINE RITCHOT**
Affirmed before me at the City of Ottawa,
in the Province of Ontario,
this 15th day of January 2015.

A Commissioner for Taking Affidavits

Issue Analysis Summary

DRAFT (Protected B)

Price Regulation – Issue Analysis Summary

Issue:

Under the proposed changes to the Marihuana Medical Access Program (MMAP) announced by the Minister of Health, should the price of marihuana be regulated?

Analysis:

Generally speaking, governments can enact legislation to limit or control any aspect of economic or industry activity in any manner deemed necessary by the government in order to attain a particular policy goal. However, in a free market economy, such interventions are generally restricted to instances where regulations will be beneficial to the public interest and where the forces of demand, supply and competition are likely to produce results and outcomes that are socially desirable. As a general rule, economic activity in free markets is guided by market forces and is seldom subject to government intervention. There are several ways in which the federal government can regulate an industry in the economy. In theory, depending on the policy goal laws can be made to control various activities in the market such as who is allowed to produce a product, how much they can produce, the price at which the product can be sold or who is allowed to legally use/buy the product. Practically, though, industry regulation is usually limited to production activities such as packaging, labelling, advertising and promotion, hiring, distribution, transportation, storage, import and exports of goods and others that are deemed necessary in order to protect health and safety of citizens and to ensure consumers have the information they need to make choices in the market place.

The question of whether or not to regulate an activity in an industry depends on the government's policy objective. For the purposes of this analysis, the question to be answered is whether or not to include specific provisions to control price in the proposed regulations to establish a regulated commercial market for the production and sale of marihuana for medical purposes. (Note: rationale for regulating other activities is the subject of separate issue analyses). To answer this, first, it is important to establish whether a justifiable reason exists to support government intervention in the proposed marihuana market; and if so, what the options are for imposing such controls. As indicated above, price regulation only makes sense in a free and competitive market if there are reasons to suggest that without such an intervention, the market will fail to produce socially desirable outcomes. In other words, without price regulation, would marihuana prices be set too low so as to discourage suppliers from entering the market and thus defeating the purposes of the reform or too high so that it is unaffordable to those who depend on it for maintaining or improving their quality of life? Since licensed producers (LP) would be the setting the price in the proposed market, it is unlikely that the former situation will apply. It is however possible that LPs could charge prices way in excess of their cost of production and thus

place consumers at a disadvantage though as explained below, this behaviour is highly unlikely in a free and competitive market.

Under the current Marihuana Medical Access Regulations (MMAR), authorized users can legally obtain their supplies from one of 3 sources: personal production under a Personal Use Production License (PUPL), from a designated grower with a Designated Person Production License (DPPL) and Health Canada. Currently, 13% access Health Canada's supply of dried marihuana; 64% produce under a PUPL, and 16% produce under a DPPL 1. The remaining 7% indicate in their application that they will buy from Health Canada, but ultimately do not. Health Canada does not have access to information regarding where these program participants obtain their supply of marihuana for medical purposes.

Health Canada currently provides dried marihuana to authorized users who prefer to obtain their supplies from the Government of Canada at a cost of $5/g. Elsewhere, on the street, the RCMP and other literature sources cite the going rate to be between $ 10 and $15 per gram, depending on the grade. For authorized users who produce for themselves or obtain from a designated grower, the price paid is likely to be below $5/g. It is difficult to know the exact price current authorized users pay to their designated growers under private contracts or accurately assess the per unit cost of production. No indisputable information exists. However, estimates for personal production costs range to as low as $1 or $2 a gram.

The price of marihuana to be produced by LPs under the proposed new framework would likely cost more than the amount authorized users currently pay for the product. Regulatory requirements necessary for the orderly operation of a legally regulated market will impose certain new overhead (e.g. investment, licencing, security) and operational costs (e.g. testing, packaging, shipping, reporting) on producers which, along with LP profit margins, will be wholly or partially passed on to the consumer in the form of higher prices. As well, LP revenues will need to cover other business-related expenses such as the return on borrowed capital, cost of advertising and promotion activities (if permitted) and customer / after sales support services. For the regulated market to be viable and attractive to potential producers, it must offer a business the opportunity to earn a profit from entering the market. This ability to earn a profit is closely tied in to the price LP would be able to get for their products and whether this price will be limited in some way. It is impossible to determine in advance the price range at which marihuana will be sold under the regulated market. But since LPs as a group will most likely still be competing against black market prices, prices in the regulated market will in all likelihood be lower and perhaps unlikely to ever exceed those prevailing in the underground market. Assuming LPs will be able to offer a product variety similar to those available from "compassion clubs" and other illicit sources, the maximum price they could charge, based on today's estimates, would not exceed $10 to $15/g, depending on type of product. At this price range, 90% of current authorized users will need to spend more than they currently do to get their supply and will be economically worse-off. For personal producers, such a price could represent up to a 10-15 fold increase in cost of obtaining their medication under the current system while the increase will be less dramatic for current

1 August 2012 data.

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Health Canada clients, representing 2-3 times the price per gram that they currently pay.

Is a potential $10-$15/g price for dried marihuana for medical purposes in the LP supply system too high and unaffordable to current and potential users? Considering the fact that this is how much marihuana currently retails for outside the subsidized federally mandated supply system, this price can be seen as the fair market value of the drug and cannot therefore be said to be too high. As well, this price range compares fairly well with the cost of daily dosage of comparable THC based pharmaceutical preparations such as Sativex, Marinol and Cesamet. The current supply system is based on an unsustainable system of subsidies (for Health Canada clients) or cheap at-home production (using production facilities not designed for this purpose and excluded from the application of general safety and security requirements and regulatory oversight). This system supports artificial prices that do not reflect true cost of making marihuana available in the form and manner required for other therapeutic products or substitutes. Replacing the supply options under the MMAR with the regulated commercial market proposed under the reform will bring the price of the drug closer to the true cost of making it available under conditions similar to medications and health products. For producers, it will ensure an incentive to produce for a chance to earn returns. For individuals, it guarantees availability of their marihuana in the quality, form and manner comparable to the way medications, health and food products are made available to the consumer – in a commercial market with regulatory safeguards and quality guarantees. There is no reason to expect that in an open, free and competitive market, such as is being proposed for the new supply system, that LPs will be free to charge consumers unfair prices for their products. In a market where there are likely to be little barriers to entry and exit, and consumers are free to purchase from the supplier of their choice, it is reasonable to expect that the forces of demand and supply can be relied upon to produce the price ranges that reflect a fair market value for the product. In the long run, it is expected that the forces of competition will result in lower prices, better quality and improved product choice for Canadians who use marihuana for medical purposes just as it does in medication, health and food product industries. If however, the proposed regulations end up unfairly restricting the market or creating unfair advantages that smother competition, or that the market structure that evolves under the regulations somehow ends up becoming something other than free and competitive, then government intervention may become necessary to either ensure market viability or to protect the consumer from potentially high prices.

The question of affordability is difficult to answer objectively as affordability is a very relative concept. The fact that the prevailing market price in the regulated market would likely not be too high and reflective of the fair value of the drug in no way suggest that users currently obtaining marihuana at much lower prices would not be negatively affected by the switch to LP supply. In fact many will. It is possible that even at the fair market price of the drug, a large segment of current consumers who could only afford the medication at the subsidized rates will no longer be able to count on the supplies they need to maintain or improve their quality of life. In particular, individuals who require larger quantities of the product to use in ways other than smoking (e.g. cooking, baking) will be mostly adversely affected. Similarly, those on low incomes (pensioners, disability and social assistance claimant) who could constitute not an insignificant proportion of current users may even have difficulty continuing to use marihuana for medical purposes if it can

only be obtained legally at retail prices from the open market. The size of this group and the extent of this impact are difficult to estimate.

In response to the original question therefore, though it is clear that LPs will charge higher for their products under the proposed framework, the expected price increase is unlikely to significantly exceed the true cost of making marihuana available to users in a form and manner similar to other products. Since the illicit market will continue to exist, there is little evidence to suggest that LPs will set a price higher than the price at which marihuana is currently being sold in the illicit market. On the contrary, it is possible that market forces could act to drive prices lower in the long term as the market establishes and the industry takes shape. There is therefore no clear rationale or policy justification to control pricein the proposed market. That said, the potential price increase under the LP system could impose serious hardships on current users the greater the price differential between the amount they currently pay and the market price under the new supply system. It is impossible to know how many potential users fall into a low income category for which the price rise will create access issues. Support systems however exist for this group in various forms and price controls is not the right tool to alleviate these concerns. Should the price range under the LP system in fact end up being higher than as expected (i.e. greater than black market prices), then further investigation and potential remedial action would be warranted but this is impossible to predict until more is known about the nature and structure of the proposed market.

Proposed Approach:

Currently, the pharmaceutical drugs market in Canada is open and competitive with limited government control on suppliers' ability to fairly price their products. The *Patented Medicine Prices Review Act* (PMPRA) and regulations are the only federal rules governing the pricing of patented pharmaceutical products in Canada. The Patented Medicine Prices Review Board is the health portfolio organization that administers the PMPRA and regulations. PMPRB is a quasi-judicial body, operating at arms-length to the minister of health and is mandated to regulate "factory-gate" prices of patented drugs. The Board ensures that the price patent holders charge wholesalers, hospitals and pharmacies are not excessive. It issues pricing guidelines to patentees that compare the price of patented drugs to the price of existing treatments for that condition(s) and the producer prices for the drug if it is already available in markets outside Canada. Marihuana for medical purposes is not a patented drug and therefore cannot be regulated under this law even if price regulation was the preferred approach. As well, the PMPRB's mandate is restricted to producer price regulation and does not extend to wholesale or retail price of any drug sold in Canada. The retail price of both prescription and non-prescription medications sold in Canada are set by the market. Consistent with this and the overall federal role in the drugs industry, Health Canada does not intend to interfere with the market's ability to set the price for marihuana for medical purposes. Under the proposal, LPs will have the freedom to determine what strains to produce, how much to produce and what to charge for their products. Consumers will be free to choose their strains, supplier and levels of quantities of marihuana they would like to use and to adjust this level based on how much they can afford. Health Canada does not

determine nor control the price of any other non- patented drug on the market. This proposed approach is consistent with the principle of treating marihuana as much as possible like a medication. In a free market economy such as Canada, prices of goods and services are determined by market forces and subjected to government control only under exceptional circumstances, in particular types of industries and in very specific ways. A marihuana for medical purposes industry does not fit the criteria for intervention.

Consultations:

During consultations, patients and their advocates (e.g. compassion clubs) strongly opposed the proposed elimination of personal production in part because it will force them to buy their marihuana from the regulated market at prices far above what they currently pay. There was great concern among this stakeholder group that marihuana will no longer be affordable or of desirable quality under the new framework unless the regulations imposed some restriction on the prices suppliers are allowed to charge. While compassion clubs did not endorse a price cap policy, they strongly advocated for public insurance coverage for the drug. In their view, marihuana for medical purposes is sometimes used by individuals as a substitute for prescription narcotics and therefore saves society money by providing similar relief at a fraction of the costs. P/T ministries of health representatives expressed concern over the implication of higher prices for marihuana in a regulated market and the potential impact this could have on already stretched P/T drug benefits plans. P/T health experts believed that prices of the drug will escalate in the absence of regulatory control and this will lead to adverse health outcomes for individuals currently dependent on it for relief on treatment of their symptoms. Further they believed this will add to already high pressure on P/T governments to cover these costs without commensurate compensation from the federal government. In their view, P/Ts are unable to cover the cost of marihuana used for medical purpose without a Health Canada Notice of Compliance and/or Drug Identification Number signifying that it has been authorized for therapeutic purposes. In their opinion, consumers are the ones who will suffer if marihuana prices cannot be controlled under the framework and P/T drug benefit plans don't offer coverage.

Consideration:

The preferred course of action depends on the policy goal to be achieved. The recommendation below satisfies the general objective that the regulated market is viable and able to meet the markets' needs. Specifically, the recommended approach:

- respect the principle of the regulatory reform to treat marihuana like a medication;
- does not undermine the successful establishment of a regulated market for marihuana for medical purposes in Canada; and
- ensures marihuana for medical purposes continue to be accessible to current and potential users

Price regulation does not meet any of the above criteria. As a policy measure, it would be inconsistent with how HC treats medications. As well, depending on how it is implemented, it

could keep the market price of marihuana for medical purposes artificially low and provide a disincentive to potential suppliers to enter the market or to produce in sufficient quantities or quality to meet the needs of medical users. The absence of regulatory controls over LP pricing however does not mean other measures cannot be implemented to mitigate the potential impact of higher prices on the well-being of current users. But such measures should not be linked to the market. Price regulation changes market signals for everyone and undermines the efficiency of the free market to produce socially desirable outcomes.

Raising the Price of Health Canada Subsidized Marihuana:

This is a transition measure that will help establish the conditions necessary for a viable industry of licensed producers. By increasing the price of marihuana from $5 per gram to a price that is more consistent with the market price, the incentive for Health Canada clients to continue to purchase lower-cost, subsidized marihuana will be removed. This may encourage Health Canada clients to begin purchasing from newly established licensed producers during the transition period, rather than waiting until the Health Canada program comes to an end in March 2014. By announcing this transition measure at the same time as the draft regulations are pre-published, Health Canada is being transparent with its clients and letting them know its intentions as soon as possible.

Recommendation:

A key objective of the new regulations is to treat marihuana like a medication, and the Government does not regulate the cost of other medications. It is recommended that marihuana price be not regulated under the proposal. This will enable LPs to be able to set and adjust the price of their products in response to demand in order to arrive at a market value that will make the market sustainable in the long run. It will ensure suppliers are able to meet the growing demand of marihuana for medical purposes as the current subsidized supply system is phased out.

This is **Exhibit "BB"** referred to in the
Affidavit of **JEANNINE RITCHOT**
Affirmed before me at the City of Ottawa,
in the Province of Ontario,
this 15th day of January 2015.

A Commissioner for Taking Affidavits

Issue Analysis Summary
PRODUCTS

DRAFT (Protected B)

ISSUE

Health Canada (HC) will need to determine whether licensed producers (LPs) will be able to produce and distribute marihuana products as well as dried marihuana under a reformed Marihuana Medical Access Program (MMAP).

CONTEXT

Current Status:

Under the *Food and Drugs Act* (FDA), marihuana meets the definition of a drug. In order to be legally manufactured, sold and represented for medical purposes, a drug would normally have to go through an appropriate review and authorization process to obtain a Notice of Compliance (NOC) as a "new drug" and a Drug Identification Number (DIN). A NOC and DIN are obtained once a submission has been made to Health Canada by a manufacturer, demonstrating that the benefits of using said drug for medical purposes outweigh its risks and that the drug meets the safety, efficacy and quality requirements set out in the *Food and Drugs Regulations* (FDR) [1].

Marihuana has never been approved as a therapeutic drug under the FDA. Nonetheless, the Government has a constitutional obligation to provide individuals with reasonable access to a legal source of marihuana for medical purposes. The *Marihuana Medical Access Regulations* (MMAR) currently provides this framework, and individuals may obtain marihuana for their personal medical use in one of three ways: (1) by purchasing it from Prairie Plant Systems (PPS), a company under contract with Health Canada to produce and distribute marihuana for medical purposes; (2) by producing it for themselves under a personal use production licence (PUPL) issued by Health Canada; or (3) by designating another individual to produce it on their behalf under a designated person production licence (DPPL) issued by Health Canada. The *Marihuana Exemption (Food and Drugs Act) Regulations* (MER) exempt marihuana produced and sold by PPS or by holders of a DPPL from the provisions of the FDA and its regulations that would normally prohibit the sale of a drug that has not been approved for therapeutic purposes.

> Marihuana is exempt from the application of the *Food and Drugs Act* and the regulations made under it, other than these Regulations, if it is produced:
> (a) under contract with Her Majesty in right of Canada; or
> (b) under a designated-person production licence, as defined in subsection 1(1) of the *Marihuana Medical Access Regulations.*

A number of products containing cannabinoids have been authorized for therapeutic

1 See Annex A for details regarding the approval process for therapeutic products.

use in Canada:

- Sativex is a buccal spray containing extracts of cannabis with standardized concentrations of tetrahydrocannabinol (THC) and cannabidiol (CBD). It is authorized to treat certain symptoms associated with multiple sclerosis. It is also conditionally approved as for pain relief in adults with advanced cancer, in limited circumstances.
- Cesamet is a capsule containing nabilone, a synthetic cannabinoid. It is authorized for nausea and vomiting associated with cancer therapy.
- Marinol is a capsule containing synthetic THC. It was authorized for AIDS-related anorexia and nausea and vomiting due to cancer chemotherapy, but has been discontinued from the Canadian market by the manufacturer.

In all cases, the manufacturers were required to meet the requirements of the FDA and its regulations in order to sell the product in Canada.

There is also a limited amount of clinical data available on the use of cannabis for medical purposes. However, it relates to *dried* marihuana. In contrast, the risks and benefits of use of other unapproved marihuana products (e.g. salves, edible products, creams made with extracts) are unknown. For this reason, the current program is limited to the production and distribution of dried marihuana only. Individuals can make their own products at home if they wish to do so (e.g., by using dried marihuana in baking), but activities that extract the oils from the dried marihuana are prohibited, as they would constitute the production of another substance that is controlled under the *Controlled Drugs and Substances Act* (e.g. hash oil).

Proposed Changes:

Under the proposed changes, personal and designated production would be eliminated. LPs would be the only suppliers of marihuana for medical purposes, and would be authorized to produce and distribute dried marihuana only. Production and possession of all forms of products, whether made from dried marihuana or from its extracts, would be prohibited. Individuals or entities wishing to manufacture and sell such products for therapeutic purposes would be required to go through the appropriate FDA channels. For additional context on the proposed changes to the MMAP, please refer to Health Canada's consultation document entitled *Proposed Improvements to Health Canada's Marihuana Medical Access Program.*

CONSULTATIONS

During consultations, certain stakeholders, particularly "compassion clubs", emphasized that the program should permit a full range of available products. Many compassion clubs currently offer a variety of products manufactured either with dried marihuana or with extracts of dried marihuana.

In web consultations, some program participants indicated that the proposal should be revised to include products, focusing on edibles, topical products, and tinctures. Many indicated that they would like to see the new program permit participants to produce these products themselves, while others indicated a preference for the availability of such products from commercial producers.

Provincial/Territorial (P/T) officials, representatives of medical associations and individual physicians were generally not in favor of allowing marihuana products within the program, given the existing uncertainty regarding the efficacy of dried marihuana itself, and the lesser knowledge base regarding the use of products. Law enforcement was also not in favour of allowing for the production and sale of marihuana-based products, noting that it could be more difficult to control diversion if the marihuana were not in its raw or dried form.

IDENTIFICATION AND ANALYSIS OF OPTIONS

Criteria:

The recommended option should:

- be consistent with available knowledge about the therapeutic risks and benefits of using marihuana for medical purposes;
- not unduly impede access to marihuana for medical purposes;
- treat marihuana as much as possible like any other drug.

Options:

Please see Annex B for a list of known products by option.

OPTION 1: Dried marihuana only

LPs would produce any strain of marihuana, and they may blend strains as they wish. However, they could only distribute dried marihuana. Program participants would have

the option to smoke or vaporize their marihuana, or consume it with food (i.e. do their own baking).

PROS

- The limited clinical data available on the use of cannabis for medical purposes relates to either dried marihuana or to pure cannabinoids in formulated products.
- There is already an established knowledge base for this option, as dried marihuana for medical purposes has been available in Canada for over ten years.
- Treats marihuana as much as possible like any other drug in that all other products that make a health claim and that contain marihuana would have to go through the drug approval process. In turn, this option would not undermine the integrity of the FDA and its regulations by holding manufacturers of marihuana-based products to lesser regulatory standards.
- Need only regulate mode of production for dried marihuana, which means no ambiguity as to where a product falls in the regulatory scheme (i.e. no additional requirements to regulate food production).
- Other jurisdictions that allow edible products have reported significant challenges. For example, in San Francisco, the state is facing challenges in regulating food items that may be deemed inappropriate, such as rainbow coloured rice crispy squares that may appeal to children. (See Annex C for a detailed description of the discussion with the San Francisco Health Department)

CONS

- Does not address the concerns of many program participants and their advocates regarding access to marihuana-based products. This may in turn drive some individuals to an illicit market.
- A number of entities identified as having an interest in becoming a LP have also indicated that they wish to produce products. By limiting production and distribution to dried marihuana only, Health Canada may compromise the success of the market by limiting the number of potential LPs.
- Health Canada is aware of several situations where program participants have been injured while attempting to prepare marihuana extracts in their homes. Limiting the program to dried marihuana in products may perpetuate these activities.

OPTION 2: Dried marihuana on its own, and dried marihuana in products

LPs would be permitted to produce and sell dried marihuana on its own and in products, such as baked goods and capsules. Products would not, however, be

produced using extracts.

PROS

- Program participants would have access to a wider variety of marihuana products. They would be able to purchase dried marihuana, or products containing dried marihuana, including edibles and capsules.
- This may make the market more attractive to companies who have voiced an interest in producing products containing dried marihuana.

CONS

- More complex to administer than option 1, without significantly extending the range of dosage forms available to the program participant under option 1, i.e., food, smoking, vaporizing. For example:
  - quality requirements would likely be extended to cover manufacturing processes in addition to the drying process;
  - raw material controls would need to be considered;
  - raw material safety would need to be considered;
  - extended labeling requirements may need to be considered, e.g., ingredients, allergen warnings, instructions for use, etc.
- Food product quality may present unique issues both in terms of developing a quality framework and administering/enforcing the framework, e.g., food contaminants.
- Allowing for products that contain dried marihuana but not allowing those containing the by-product of extraction may be perceived as arbitrarily restrictive by some, e.g., marihuana butter versus marihuana brownie containing butter.
- Particularly in the case of food products containing dried marihuana, there may be issues ensuring the freshness of the product, given that distribution is proposed to be by mail-order only as opposed to by retail storefront. Consider a brownie that is received in the mail vs. a brownie that is purchased from a storefront location where it is freshly baked.
- HC is aware of several situations where program participants have been injured while attempting to prepare marihuana extracts in their homes. Limiting the program to dried marihuana may perpetuate these activities.

OPTION 3: Dried marihuana and any marihuana product produced from the plant, except products administered by injection.

This is loosely based on the NHP model, i.e., all products except those administered by injection. This would include topical products, sprays, capsules, suppositories, ophthalmic solutions, balms, soaps, food formats, and others. Production of extracts

and isolated cannabinoids would be permitted.

PROS

- Addresses program participant concerns by providing access to the widest possible range of marihuana products, which could be developed more quickly than if they went through the established approval channels.
- May make the market more attractive to companies who have voiced an interest in producing a wide variety of marihuana products.

CONS

- The limited clinical data available on the use of cannabis for medical purposes relates to either dried marihuana or to pure cannabinoids in formulated products. The risks and benefits associated with extracts, e.g., oil extracts, tinctures, or ointments, are not well established. (Note: Health Canada would need to determine whether the scope of this option is limited to crude botanical extracts, or if it would extend to purified or synthetic cannabinoids.)
- Could result in extracts or products with high concentrations of cannabinoids, potentially resulting in an increased risk of adverse health effects.
- Allowing such products will increase complexity of administering the program:
    - Increases the complexity of compliance activities.
    - HC would likely have to handle classification issues, i.e., determining where the product falls in the regulatory scheme, e.g., under the FDR or the proposed framework.
- Companies that hold NOCs for products containing cannabis may challenge this approach, as they have complied with the FDR in order to market these types of products.
- Inconsistent with practices for other drugs, i.e., every product must go through the approval process, which may in turn compromise the integrity of the drug approval process in Canada.
- Not supported by stakeholders other than program participants and compassion clubs.

CONSIDERATIONS

- The mandate of the program is based on court decisions that require the Government to provide reasonable access to a legal source of marihuana for

medical purposes. It could be argued that introducing a wide variety of products goes beyond that mandate.

- The issue of access to marihuana products is currently subject to litigation. The Crown's position in this litigation is that access should be restricted to dried marihuana only, particularly given that the risks and benefits associated with the use of extracts are not well established compared to the limited clinical data available on the use of dried marihuana for medical purposes.
- The key objective of reform is to reduce the risks of abuse and exploitation of the current program. The introduction of a variety of products does not help to further this goal.
- Review of products for quality, safety, and efficacy is not contemplated under the proposed changes.
- Explicitly defining what it is permitted under the new framework is an approach that ultimately offers greater control over the range of products on the market, which is an important consideration given that there is insufficient information about the therapeutic benefits of all forms of marihuana for medical purposes.
- In contrast, allowing for the production and distribution of any product that meets certain general criteria could result in a market containing a much broader range of products than initially expected, for which the risks and benefits are not sufficiently known. This would in turn significantly increase the complexity of administering the program.
- The distribution model may have an impact on uptake for various options, e.g., if distribution methods are limited to mail, the appeal of offering/purchasing food products might decrease.
- Officials from HPFB were consulted and felt that from a quality perspective, dried marihuana was preferable given the existing knowledge base on certain activities, particularly distribution, and also given the increased complexity of regulating products.
- It is unknown whether noxious by-products would result from baking or heating marihuana or marihuana extracts with other ingredients, whether prepared at home or in a commercial facility.
- For some dosage forms, e.g., edibles, it may be difficult for program participants to control/identify the required dose, as certain routes of administration could result in slower absorption than others.
- Regardless of option chosen, cross-border issues are not anticipated because allowing the production of marihuana at foreign sites is not being contemplated. Similarly, the export of products manufactured in Canada to other countries is not contemplated.

RECOMMENDATION

Option 1 is recommended. Although the Government has an obligation to provide access to marihuana for medical purposes, sufficient evidence has not been established regarding the safety, efficacy and quality of marihuana to have it approved as a therapeutic product under the FDA. Since the limited available clinical data relates almost exclusively to dried marihuana, and since there is no known knowledge of the risks and benefits of products containing marihuana extracts, it is recommended that the reformed program continue to authorize the production and distribution of dried marihuana only. Furthermore, the restriction of the framework to dried marihuana only will ease the administrative complexity that would be associated with the regulation of a variety of modes of production. Finally, the recommended option will protect the integrity of the drug approval process by continuing to require those who wish to make health claims about a marihuana-based product to follow the appropriate approval channels under the FDA.

NEXT STEPS

HC will consider what communication measures might be taken to emphasize that smoking marihuana is not recommended, and to provide clarity for program participants regarding what they can legally do with their dried marihuana.

Issue Analysis Summary
PRODUCTS

DRAFT (Protected B)

Annex A: Drug Approval Process under the *Food and Drugs Act* (FDA)

Persons or entities interested in making a health claim about a specific drug or product and subsequently manufacturing and selling it must go through certain steps in order to do so legally. They need to undertake clinical trials to generate evidence for the safety and efficacy of the product. This evidence, along with evidence of the product's quality, would be submitted to Health Canada for review. If Health Canada determines that there is sufficient evidence to support the safety and efficacy of the drug when used under defined conditions for a specific clinical indication, a Notice of Compliance would be issued under the *Food and Drug Regulations* (FDR), and the product would be assigned a DIN (see diagram below). Prior to selling the drug, fabricators, packagers, labelers, distributors, importers, wholesalers or testers of the drug are required to hold Establishment Licences (EL) under the FDR. In order to obtain an EL, a person must submit an application to Health Canada. Health Canada reviews the application, inspects the site, and issues a licence to conduct the relevant activities if appropriate.

When the drug is also a narcotic, a person or entity would also need to comply with the requirements of the *Controlled Drugs and Substances Act* (CDSA) and the *Narcotic Control Regulations* (NCR) or the MMAR to possess, produce, make, assemble, import, export, sell, provide, transport, send or deliver the drug. Should the person wish to conduct a clinical trial, they may require an exemption under section 56 of the *Controlled Drugs and Substances Act* to possess the drug and sell it to clinical trial subjects.

An overview of the regulatory process for therapeutic products can be found at:

http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/access-therapeutic_acces-therapeutique-eng.php

Issue Analysis Summary
PRODUCTS

DRAFT (Protected B)

Annex B: Known products by option

Option 1 Dried marihuana	Option 2 Dried marihuana in products	Option 3 NHP model
Dried marihuana (Program participants could make products themselves as described under option 2.)	Dried marihuana Flour product, for baking Baked goods, i.e., dried marihuana in a baked good Capsules containing plant material Cigarette Tea	Everything under option 2, plus: Tinctures Sprays Lotion/Salve Bath salts Massage cream resin 'Cosmetic' products (type and nature unknown) Capsules containing extract Baked goods, i.e., marihuana butter in a baked good Chocolate bars, i.e., marihuana extract in a chocolate bar Beverages

Issue Analysis Summary
PRODUCTS

DRAFT (Protected B)

Annex C – Email summary of discussion with San Francisco Health Department, July 11, 2012

From: Christine Leckie/HC-SC/GC/CA
To: Theresa Schopf/HC-SC/GC/CA@HWC
Cc: Carol Anne Chénard/HC-SC/GC/CA@HWC, Ken Moore/HC-SC/GC/CA@HWC, Jocelyn Kula/HC-SC/GC/CA@HWC
Date: 2012-07-11 05:17 PM
Subject: Teleconference with the San Francisco Health Department Regarding Medical Marihuana

Hello,

Today I had an hour long teleconference with Larry Kessler, Senior Environmental Health Specialist for the San Francisco Health Department's Medical Cannabis Inspection Program. I had prepared a list of standard items to ask when I contact each of the cities/states we discussed (San Francisco, Mendocino, Oregon and Colorado). It was a really interesting discussion. I have summarized what I thought would be the most relevant points below. Please share as you feel appropriate.

General:

The Federal US Government (eg. DEA and USFDA) and all applicable federal statutes (eg. CDSA and FDA) consider state laws enabling medicinal marihuana to be illegal
Recently the DEA is cracking down on cities in the State of California- the Mendocino County Medicinal Marihuana Program was just shut down and all registered growers were raided. Prior to being shut down, the Mendocino County Sherrif's Office was responsible for conducting inspections which they contracted out to third party individuals. The Sherrif would not speak with me for this reason. San Francisco is concerned that this could also happen to their program in the near future.

Regulations:

- California's Medical Cannabis Act
- The State enables the possession through the administration of the card issuance system to patients and each city regulates the distribution through their local County or City Ordinances
- The regulations came into effect in 2003 and the intent was NOT to allow store fronts, however this was legally challenged and in 2005 storefronts were allowed
- The San Francisco Department of Health conducts inspections against the local ordinances

Licences:

- Co-ops, dispensaries and compassion clubs are licensed through the issuance of a permit
- Permits are issued each year and cost $4000.00 (cost recovered program)
- They have approximately 30 co-ops/compassion clubs registered

Edible Products:

- They did not always allow edible products, but were challenged and started to allow this
- The biggest challenge is the sale of inappropriate food items. For example, rainbow coloured rice crispy squares that appeal to children
- Edible products are a challenge as they are subject to constantly changing trends
- Current trend is cannabis oil
- Because the USFDA considers this illegal, all edibles are made on site at co-ops/compassion clubs (eg. not manufactured at registered food companies)

Issue Analysis Summary
PRODUCTS

DRAFT (Protected B)

- Now that they have defined what edible food products are allowed and what the packaging, labelling, THC levels and dosage requirements are for edible products, the quality of these products have greatly increased

Inspections:

- Pre-licence inspections are conducted and are to approve the security and lighting plan submitted by the regulated party
- Routine inspections are also performed
- They mainly focus on the distribution- cultivation is usually done off premises (he thinks much of it is imported from BC)
- Only 4-5 dispensaries grow on site, they are limited to 99 plants (based on risk associated with federal trafficking charges)
- I attached their inspection checklist below:

Quality:

- On inspection they look at basic quality elements (eg. hand washing, use of tongs, gloves, etc.) however they cannot enforce these requirements- their local ordinances don't require it
- Quality of edible products is higher- dispensaries generally test for THC and moulds- however, there is no recognized testing methods and testing is done by underground labs

Security:

- On inspection they look at basic security requirements, however there is no standard to follow
- Security is assessed on a case by case basis and is often shaped by local community public hearings that raise concerns about establishments

Occupational Health and Safety Issues:

- use of unregistered pesticides, compressed gasses, moulds and spider mites is his main concern

Biggest Challenge:

- Disconnect between Federal, State and County laws- this causes enforcement issues and paranoia among regulated party

What Works:

- The industry is a passionate one and it is important to clearly communicate what is required. For edible products they did this and he feels that this has increased the compliance of the industry and quality of the products.

Lessons Learned:

- The industry wants to comply , but they need to be clearly told how to do this.

Please let me know if you have any questions.

Issue Analysis Summary
PRODUCTS

DRAFT (Protected B)

I am in the process of scheduling similar calls with Colorado and Oregon.

Christine Leckie
Manager, Controlled Substances Program
Ontario Region, Compliance and Enforcement
Tel: (416) 952-4521 Fax: (416) 952-0102
Website: www.hc-sc.gc.ca

Health Canada Santé Canada

This is **Exhibit "CC"** referred to in the
Affidavit of **JEANNINE RITCHOT**
Affirmed before me at the City of Ottawa,
in the Province of Ontario,
this 15th day of January 2015.

A Commissioner for Taking Affidavits

Issue Analysis Summary

FINAL (Protected B)

Product Distribution

Solicitor-Client Privilege/Protected

ISSUE

To determine the appropriate system for the distribution of marihuana for medical purposes from licensed producers (LPs) to eligible individuals under the reformed Marihuana Medical Access Program (MMAP).

CONTEXT

Current Status:

- Under the current program, about 10% of program participants order marihuana for medical purposes from Health Canada (HC). Dried marihuana is shipped by courier or, in remote locations, by Canada Post, to the authorized person, unless the authorized person has arranged for their medical practitioner to receive the dried marihuana on their behalf.
- A majority (80%) are licensed to produce for themselves or obtain their supply through a licensed designated producer. The source of supply for the remainder is unknown.
- Also under the current program, individuals who are designated to produce marihuana for an authorised person and who choose to send it to that person must use a method of sending that provides for a means of tracking the package, that obtains a signature upon receipt, and that provides for the safekeeping of the package during transit.
- Another distribution system exists for marihuana for medical purposes in the form of unregulated retail outlets ("compassion clubs") which, also allegedly supply marihuana (in person or by mail/courier delivery) to clients supported by a physician. These establishments are not licensed by Health Canada under the current program.

Proposed Changes:

LPs would be authorized to sell marihuana for medical purposes directly to individuals with a medical document form a health care practitioner via mail order. Clients' orders would be delivered through secured mail or bonded courier, with no intermediaries or storefront access.

For additional context on the proposed changes to the MMAP, please refer to Health Canada's consultation document entitled Proposed Improvements to Health Canada's Marihuana Medical Access Program.

CONSULTATIONS

- During consultations, certain stakeholders proposed other alternatives for distributing marihuana for medical purposes to individuals. Different stakeholder groups support different sale and distribution channels. There is no consensus on a common preferred approach.
- Sale through pharmacies is considered by many stakeholders (some P/T ministries of health, law enforcement, fire officials, municipalities, medical associations) to be the

preferred method of distribution because it offers the opportunity to take advantage of an established system of controlling and monitoring drugs and eliminates the need for a duplicative distribution system.

- The Canadian Pharmacists Association was consulted. Representatives noted that some pharmacists might be unwilling or unable to play a role in dispensing marihuana given a lack of knowledge about the risks and benefits of using marihuana for medical purposes. Some pharmacists also acknowledged concerns with respect to security issues associated with keeping a stock of dried marihuana on site.
- Absent a role for pharmacies, the proposed distribution of marihuana from the LP directly to the client via a secure form of mail is preferred by P/T ministries of public safety, law enforcement, municipalities and fire officials. It is seen as a safe alternative to minimize the potential of diversion and to strike an appropriate balance between individuals' need for access and communities' need for safety and security.
- Compassion clubs and patient advocates expressed the view that there should be an alternative that could allow individuals to purchase their supplies directly from a store (other than a pharmacy), licensed to distribute the product. Specifically, they recommend that cannabis dispensaries be licensed and regulated by HC to dispense marihuana to individuals. Under their proposed model, cannabis dispensaries would purchase marihuana in bulk quantities from a licensed producer, and they would then sell this at a reduced cost to registered clients. They also wish to be regulated to provide other products (e.g. foods and oils) and services, including education to clients regarding the use of marihuana. Other stakeholders, mainly law enforcement, municipalities and fire officials, are not supportive of distribution through compassion clubs as they believe that it would increase the risk of diversion and/or lack support from community members who do not wish to see such businesses established.
- Program participants expressed opposition to the elimination of personal and designated production and the subsequent replacement of this supply system with the establishment of a licensed commercial market. Opposition is based on two main factors: (1) belief that the ability to produce one's own supply of marihuana for medical purposes is a constitutional right; and (2) concerns that licensed production would increase the price of marihuana for individuals. Few program participants commented specifically on the Government's proposal to provide marihuana directly from a licensed producer to an individual.

IDENTIFICATION AND ANALYSIS OF OPTIONS

Criteria:

The distribution of marihuana for medical purposes from producer to registered client must contribute to the goals of reform. The preferred option to be imposed by regulations should:

- Not unduly impede reasonable access;
- Reduce the administrative burden for the program participant;
- Reduce Health Canada's role to that of regulator;

Issue Analysis Summary

FINAL (Protected B)

Product Distribution

Solicitor-Client Privilege/Protected

- Allow for communication between individuals and their provider to discuss issues and to address concerns;
- Mitigate potential risks to public safety and security from permissible use;
- Not inhibit the ability to control non-medical use as provided for under the CDSA and its regulations; and
- Be consistent with existing P/T Acts and regulations that are applicable.

Options:

1. **Direct LP Distribution**: The registered client buys their supply directly from the LP through mail order. The product is delivered by secured mail (e.g. bonded courier, chain of signatures).
    a. Pros:
        i. Direct to consumer sale and distribution minimize opportunities for diversion of large quantities of marihuana to the illicit market;
        ii. Secured mail distribution has proven to be an effective means of supplying marihuana to individuals for medical purposes since 2003 (fewer than 1% of annual orders filled by Prairie Plant Systems, the Government supplier under the current program, have been reported as "not received");
        iii. Canada Post and at least one private courier company in Canada have experience delivering marihuana for medical purposes securely via mail to individuals;
        iv. Does not require approval of other levels of government or professional health care bodies to become operational;
        v. Offers greatest potential for geographical reach/accessibility, regardless of geographic distribution of LPs
            - Remote locations could be serviced by Canada Post similar to the current arrangement with PPS;
            - Individuals in remote and isolated First Nations communities receive prescription medications (including controlled drugs) by secured mail shipments from retail pharmacies outside the communities;
        vi. Discreet and respectful of some clients' need for anonymity;
        vii. Likely to be favoured by the general public, LPs, law enforcement, fire officials, most municipalities and current program members as they are already familiar with the current HC mail delivery system; and
        viii. It would be clear for law enforcement that any storefronts or retail outlets that sell marihuana for medical purposes are doing so illegally.

    b. Cons
        i. Deliveries of marihuana could be delayed in the event of a transportation/ mail delivery system disruption;

ii. Does not treat marihuana as much as possible like a medication because it places it outside the traditional retail distribution model;
iii. Some individuals might maintain that they would not get all the perceived benefits of using marihuana for medical purposes in the absence of personal, face-to-face interaction with LP;
iv. Would be strongly opposed by compassion clubs and some individuals who have expressed concerns that purchasing directly from LPs and distribution through the mail would increase the price; and
v. Cost of secure shipping might significantly increase out-of-pocket expense for clients. For example, the chain of signature service offered by Purolator (firm used by PPS) includes a surcharge of $15 per piece for shipping of controlled drugs according to regulatory requirements. (For a typical participant using 150g/month, the surcharge is $0.10/g, which could be lower or higher depending on whether Health Canada would prescribe a limit on the amount of marihuana to be purchased and/or shipped at one time, as well as the price of product).

2. **Retail Pharmacy**: This follows the traditional retail pharmacy distribution of therapeutic medications containing controlled substances. The LP sells the product to a pharmacy, from where individuals buy their supply. LP does not directly sell to authorized users. Retail sales occur through pharmacies like prescription drugs.
   a. Pros:
      i. Individual could get education and medical counselling on use from pharmacist, provided that the pharmacist has the knowledge to provide such information;
      ii. Pharmacists are best placed to deal with "prescribing" health care practitioners on issues such as dosage, potential drug interactions, suspected abuse, than LPs or dispensaries;
      iii. Brings retail distribution of marihuana within the established prescription medication distribution system;
      iv. No need to establish new tracking and monitoring system;
      v. P/Ts, municipalities, law enforcement, health care practitioners and some individuals would likely favour;
      vi. Pharmacists have experience in handling and dispensing controlled substances so less potential for security breaches;
      vii. Accessibility and distribution of marihuana would be similar to other controlled substances; and
      viii. Consistent with overall government goal of improving access while minimizing criminal involvement.

   b. Cons
      i. Unproven as an effective method of retail distribution for marihuana for medical purposes;

ii. Pharmacists and their colleges might be unable or unwilling to play dispensing /advisory role (have expressed concerns similar to health care practitioners with respect to lack of knowledge, liability, security risks e.t.c.) thus this option might not be feasible or of limited effectiveness;
iii. Initial pilot testing to dispense marihuana for medical purposes through pharmacies at the onset of the current program was abandoned due to a lack of sufficient interest to effect required changes in P/T legislations;
iv. Pharmacy retail might be contingent on compensating pharmacists for dispensing, adding extra costs to clients; and
v. Regulation of pharmacies is a P/T jurisdiction. This option might require P/Ts to amend their legislations/regulations, and might also entail lengthy discussions and negotiations, the end of which could not be confidently predicted.

3. **Cannabis dispensaries**: Under this option, marihuana is produced by LPs and sold to cannabis dispensaries from where individuals purchase their supply. These dispensaries (which would include compassion clubs) would be legally recognized as retail outlets that dispense marihuana for medical purposes. LP does not directly sell to authorized users.

Pros:

i. Establishes a distribution system that would be based, in part, on a network of retail outlets that have functioned as alternative means of accessing marihuana for medical purposes for many years;
ii. Most likely to be favoured by dispensaries and patient groups;
iii. Compassion clubs have expressed an interest in being regulated by Health Canada to undertake this role, and are willing to meet security and quality requirements as established by the Department in order to do so; and
iv. Individuals might benefit from in-person interaction with staff.

b. Cons

i. Might result in many storefronts from where marihuana could be legally purchased and at least, a greater public perception of increased abuse and diversion;
ii. Increases the complexity of the regulatory framework and subsequent monitoring of the program and regulated parties;
iii. Would increase compliance and monitoring costs to the federal government;
iv. Does not treat marihuana as much as possible like a medication because it places it outside the traditional retail distribution model for other controlled drugs;
v. Opposed by majority of municipalities, communities, law enforcement agencies and fire officials who view this as the least secure distribution

option as it increases the number of access points, thus increasing the potential for diversion;

vi. Business communities might oppose co-location with dispensaries due to stigma; and

vii. Increases opportunities for unauthorized or outsider interference in distribution of the product.

CONSIDERATIONS

- Secure mail options include: Tracked delivery (e.g. chain of signatures), Registered mail.
- The proposed framework does not contemplate direct distribution to individuals by importation or by exportation. In other words, entities outside of Canada would not be licensed to produce and distribute unless they established a facility within Canada. Nor could individuals who order marihuana from a licensed producer have it shipped outside of Canada by virtue of these regulations.
- Whereas mail order could be implemented as a stand-alone option, storefront retail (i.e. pharmacy or dispensary) must include the option to mail product to clients unwilling or unable to visit the store or for clients in communities where a store is not established.
- A multi-distribution channel approach could be seen as accommodating regional differences but could also increase the complexity of program monitoring.
- Regardless of the option chosen, some program participants might be attracted to the illicit market if they perceive that the distribution model unduly inhibits their access.
- [redacted]
- Certain stakeholders (compassion clubs and individuals) have indicated that storefronts are valuable not only because an individual could access marihuana immediately, but also because alternative services, such as counseling, education and dissemination of information, could be provided. The latter issues will be explored separately.
- Educational materials regarding the use of marihuana for medical purposes could be developed and posted online for participants (or included in product orders by sellers) to mitigate stakeholder concerns about the lack of education and information dissemination in a "no storefront' distribution system. Health Canada will examine this option further.
- The means by which to ensure secure methods of transportation of marihuana for medical purposes would be considered during regulatory drafting.
- The *Controlled Drugs and Substances Act* provides the federal government the authority to make regulations including those regulating the production or sale of controlled substances. In this regard, the federal government has jurisdiction over aspects of retail that are linked to its public health, safety and security mandate.

RECOMMENDATION

Given the competing goals of access and control, it is recommended that secure mail be the

Issue Analysis Summary

FINAL (Protected B)

Product Distribution

Solicitor-Client Privilege/Protected

preferred method of retail distribution of marihuana for medical purposes from LPs to clients because it's the option that best satisfies the selection criteria and also provides reasonable access to marihuana for medical purposes while respecting that sale and distribution is minimally exposed to abuse and criminal interference.

Issue Analysis Summary

FINAL (Protected B)

Product Distribution

Solicitor-Client Privilege/Protected

APPENDIX

Overview of the Pilot Project to distribute Marihuana for Medical Purposes through Pharmacies in Canada.

- In June 2005, the *Marihuana Medical Access Regulations (MMAR)* were amended to provide for the distribution of marihuana for medical purposes produced under contract for Health Canada to be distributed through pharmacies, like other drugs containing controlled substances.

- The process to establish a pilot project to assess the feasibility of pharmacy distribution of marihuana was initiated soon after the amendments were made. In September 2005, a project proposal and a draft training guide for participating pharmacists were distributed to P/T Ministries of Health and pharmacy licensing authorities and professional associations in each province and territory.

- In February 2006, HC convened a one-day workshop to discuss the proposal and the draft training guide. The workshop was attended by 7 P/Ts and the National Association of Pharmacy Regulatory Authorities (NAPRA). A significant issue raised was legislative barriers at the P/T level.

- Most P/T legislation governing pharmacy authorizes pharmacists to dispense narcotics further to a prescription. In the case of marihuana, no prescription is provided by the authorized person. Thus changes to P/T legislation were deemed necessary in order for the pilot to proceed.

- Though some provinces (BC, SK and NB) expressed interest in the project, none of them have ever made the necessary legislative change.

This is **Exhibit "DD"** referred to in the
Affidavit of **JEANNINE RITCHOT**
Affirmed before me at the City of Ottawa,
in the Province of Ontario,
this 15th day of January 2015.

A Commissioner for Taking Affidavits

Issue Analysis Summary

Solicitor-Client Privilege/Protected

Proof of Possession

Issue:

Under the new Program, individuals lawfully authorized to possess marihuana for medical purposes will require a means by which to demonstrate lawful proof of possession.

Current Program:

Unless authorized by regulation, the possession of cannabis is prohibited under the *Controlled Drugs and Substances Act*. Individuals who wish to have access to marihuana for medical purposes must apply and obtain an authorization to possess from Health Canada. As part of the authorization process, Health Canada currently issues an authorization to possess and/or production license document, which serve as demonstration that possession and/or production is legal. Although there is no legal requirement to do so, Health Canada also issues an accompanying photo identification which contains the same information as the authorization and/or licence document and which is often used by individuals to demonstrate to law enforcement that they are in legal possession of marihuana for their personal medical use.

Individuals have expressed concerns that absent such documents issued by Health Canada, they would be unable to demonstrate to law enforcement that they are in fact in legal possession of marihuana for medical purposes.

For other narcotics, a person is authorized to possess a narcotic when the person has obtained the narcotic under the Narcotic Control Regulations (NCR) for their own use from a practitioner or pursuant to a prescription that is not issued or obtained in contravention of the NCR. Generally, the pharmacy-dispensed product label provides evidence that an individual is allowed to possess this substance. Health Canada does not issue accompanying documentation or identification in these cases. However, marihuana is distinct in a number of ways:

- an illicit supply of marihuana is more readily available than illicit supplies of most narcotics;
- marihuana obtained from any source is unlikely to have as distinct or consistent an appearance as narcotics other narcotics e.g., film-coated tablets of a certain shade of blue, stamped with their trademark and strength are more difficult to counterfeit than dried plant material;
- law enforcement may be more likely to question a person using marihuana because except as authorized for medical purposes, possession is illegal
- law enforcement may be more likely to question a person using marihuana because it is difficult to smoke marihuana discretely, in contrast with swallowing a tablet.

For these reasons, police and program participants see value in making some kind of evidence of legal possession available.

Proposed Changes:

Issue Analysis Summary

Proof of Possession

Under the proposed changes, Health Canada would cease to receive applications for authorisations to possess marihuana, and would therefore cease to issue authorisation and/or production license documents and identification cards. Under the new Program, individuals lawfully authorized to possess marihuana for medical purposes will require a means by which to demonstrate lawful proof of possession.

For additional context on the proposed changes to the MMAP, please refer to Health Canada's consultation document entitled *Proposed Improvements to Health Canada's Marihuana Medical Access Program.*

Assumptions:

The following assumptions were made when considering the options discussed:

(1) That the possession of marihuana for one's personal medical use would be handled in a manner similar to the possession of any narcotic for one's person medical use under the *Narcotic Control Regulations*:

> 3. (1) A person is authorized to have a narcotic in his or her possession where the person has obtained the narcotic under these Regulations, in the course of activities performed in connection with the enforcement or administration of an Act or regulation, or from a person who is exempt under section 56 of the Act from the application of subsection 5(1) of the Act with respect to that narcotic, and (d) the person has obtained the narcotic, other than diacetylmorphine (heroin), for his own use:
> (i) from a practitioner,
> (ii) pursuant to a prescription that is not issued or obtained in contravention of these Regulations, or
> (iii) from a pharmacist pursuant to section 36

(2) That at a minimum, to verify if the possession of marihuana is authorized, law enforcement would need to confirm the following information:

- the identity of the individual, which could be done through production of government-issued photo identification
- the name, address and licence number of the LP who supplied the marihuana for medical purposes (verifying that the person whose name is on the label is actually a registered client of the LP) .

(3) That in keeping with the principle to treat marihuana as much as possible like a medication, the dosage and period of use would be dictated by the practitioner which would mean that proof of possession, regardless of the form that it takes, would be valid only for the period that the product lasts and renewals would only be available if supported by the health care practitioner. This means that a new proof of possession, either label or identification card, would have to be re-issued whenever an order is refilled, or whenever there is an amendment of any kind (i.e. when an individual opts to use a new LP as a supplier).

Issue Analysis Summary

(4) That any proof of possession, regardless of format, should contain, at a minimum, information similar to that which appears on a narcotic prescription label. Such prescription labels include the distributor's name, the client's name, the date the prescription was packaged/shipped, simple instructions on how to take the medication, the prescribing practitioner's name, the brand name of the drug and the active ingredient and the amount of drug (e.g. 20 x 1 mg tablets). Note that prescriptions also contain a drug identification number (DIN), but one has never been issued for dried marihuana.

IDENTIFICATION AND ANALYSIS OF OPTIONS

1. LP issues a pharmacy-like label

Under this option, Health Canada would require that LPs label each marihuana package with specific client information, similar to a narcotic drug prescription label. However, there would be no DIN as marihuana is not authorized by Health Canada and the distributor's information would be the LP's name, phone number and address. The label along with a piece of valid government-issued photo identification (like a drivers licence) could be used by participants as proof that they are in legal possession of marihuana for medical purposes.

PROS

- Familiar format
- Likely to be minimal additional burden on LP as they will already have to comply with other labeling requirements and produce a label for their product;
- Keeping with reform in that we are treating marihuana as much as possible like a medication;
- Participants will be able to demonstrate proof of legal possession to law enforcement. (have something tangible that can then be verified by law enforcement)
- Although not the preferred option for law enforcement, during consultations, representatives agreed that, as long as the label was not easily replicable, this would be a viable option and that they could request supporting photographic identification from an individual;
- If a program participant decides to change supplier or cease to order from an LP they would not have to worry about returning an identification card to the original LP or to Health Canada to request a new one with the amended information regarding their new supplier. This option would also minimize the risk that an individual carries multiple identification cards from multiple LPs.
- Consistent with regulations of possession of other controlled substances (i.e. prescribed narcotics).

CONS

- Participants have expressed a clear preference for a form of photographic identification issued either by Health Canada or by LPs so that their proof of possession is more easily recognizable by police.
- Similar to other narcotics, if a participant does not have their photo identification on them, they may not be able to readily demonstrate to law enforcement that they are in possession of a legal supply.
- LP-issued labels may not all resemble one another and may be stylistically different, unless a standard format is adopted in regulation. This may lead to confusion among law enforcement regarding the validity of cards.
- There is a potential for misuse of the label, as participants may simply refill a package that is labeled by an LP with marihuana obtained from an illicit source and may reuse this package after they no longer have support from their health care practitioner to use marihuana for medical purposes.
    - Additional mitigation strategies could also be examined, including an expiry date on the label.

2. LP issues Identification Card.

Under this option, LPs would be required to issue an identification (ID) card that consists of all the information similar to a narcotic drug prescription label. Under such an option, Health Canada would need to stipulate in regulation whether such a card should contain a photo or not (as a more recognizable form of identification).If the participant is questioned by law enforcement they would demonstrate legal possession by providing their ID card (and another piece of valid government photo ID should the ID not include a photo).

PROS

- Preliminary review of consultation feedback indicates that stakeholders feel that ID cards serve a useful purpose and that they would be extremely concerned with its removal. They also indicate a strong preference for a photo identification card;
- Cards could be convenient, wallet-sized and would not require that individuals carry their labeled package of marihuana with them at all times as proof of possession. This could decrease risks of diversion related to individuals being required to carrying around a certain quantity of marihuana.

CONS

- If the ID card would contain a photo, this would create added burden on program participants as they would have to have photos taken and pay for them;

- Law enforcement are most supportive of a government issued ID card as opposed to one issued by a LP. In their opinion, an identification issued by a LP may be easier to forge than one issued by a government agency.
- LP issued identification cards might not all resemble one another and might be stylistically different, unless a standard format is adopted in regulation. This could lead to confusion among law enforcement regarding the validity of cards;
- If a program participant decided to change supplier or cease ordering from a LP they would need to return their ID card to the LP and have a new one issued by a new LP. Failure to do so could result in increased risk of diversion, as they could be in possession of additional identification cards demonstrating their ability to possess a controlled substance. Additionally, this could lead to a period of time in which program participants would not be able to prove their legal possession;
- Since individuals are not required to have the original package, this makes it easier for them to carry marihuana from an illicit source – there is an increased risk of abuse and diversion with using on the card for proof of possession;
- It could be expected that LPs would pass along any additional administrative costs – such as the production of an identification card – to the consumer. The production of identification cards could be more expensive than the production of labels, and this may increase the cost of marihuana to the consumer. Based on an estimate of current Program costs to print cards versus the costs of printing licence documents (similar to labels in that they would also require special paper) demonstrates that a single card could cost at least 12 times more than a single sheet of licence document[1]. Considering that multiple labels can be printed on a single sheet, the cost of labels becomes negligible compared to cards.
- There is a potential for misuse of the card, as participants could have a card issued by a LP and may use it long after they no longer have support from their doctor to use marihuana for medical purposes.

3. Health Canada issues Identification Card

Under this option, Health Canada would continue to issue ID cards to program participants. The process could be such that individual would receive a signed document from their practitioner supporting their access to marihuana for medical purposes. This document could then be forwarded to their chosen LP, which would register the patient and forward the information necessary for the production of a card to Health Canada. The Department could then issue an ID card directly to the individual. Health Canada would determine through regulation whether the ID card could be paper or plastic, photo or without photo. If the participant is questioned by law enforcement they could prove legal possession by providing their ID card and another piece of valid government photo ID, should the ID not include a photo.

1 The cost of producing one card is approximately $1.53 while the cost of producing one sheet of a licence document is $0.12.

Issue Analysis Summary

Solicitor-Client Privilege/Protected

Proof of Possession

PROS

- This is the option most favoured by program participants;
- Law enforcement support a government issued ID card. In their opinion it would be more difficult for organized crime to forge a government issued ID than one issued by an LP.
- Convenient, wallet-sized and they do not require that individuals carry their labeled package of marihuana with them at all times as proof of possession. This may decrease risks of diversion.
- May keep costs lower for program participants.
- High integrity as HC would be producing the card which could include security features such as a hologram (similar to the current ID card). In a report on abuses of the current Program produced for the Minister by the RCMP and Canadian Association of Chiefs of Police, law enforcement did not present any evidence of abuse based on forging HC documents.

CONS

- Inconsistent with the goal of reform, which is to treat marihuana as much as possible like a medication;
- Since individuals are not required to have the original package on them, this makes it easier for them to carry marihuana from an illicit source – there is an increased risk of abuse and diversion with using the card for proof of possession;
- Inconsistent with the goal of reform, which is to remove Health Canada from receiving applications and from receiving and keeping personal health information;
- Inconsistent with the goal of reform, which is to no longer be required to have direct interaction with program participants through the issuance of "authorization" documents;
- Continues to be an administrative burden on Health Canada. As such, this could require that the Program maintain a core staff to deal with this aspect.
- Additional steps would result in delays in access for program participants.
- If Health Canada did not issue a card in advance of the LP sending the marihuana to the patient, a patient could be left without lawful proof of possession. This option would require a mechanism by which the LP and Health Canada could coordinate the sending of the supply and the proof of possession, which would add to the administrative burden for industry and the department.

CONSIDERATIONS

- Regardless of the format chosen for proof of possession there is no definite way of verifying that the marihuana the participant has in their possession is actually from a legal

source – this would only demonstrate "legal possession". For example, an individual could use either a card or a package and label to attempt to demonstrate lawful possession of marihuana procured from an illicit source.

- Regardless of option chosen, Health Canada should consider a means by which to ensure consistency of proof of possession. Health Canada would work with law enforcement to ensure that they are aware of what the proof of possession looks like and what it signifies.
- A sticker on a provincial health card was considered; however, this would require negotiation with provinces and territories, who are individually responsible for the administration of such cards. This option has been ruled out for a number of reasons: it is beyond the scope of federal jurisdiction; agreement with all P/Ts would be required to ensure consistency of approach; and such a sticker may cover information on a health card that is important.
- Under the current program, law enforcement can contact a 24/7 pager service offered by Health Canada and receive certain information about individuals authorized to possess and/or licensed to produce. While they are mostly interested in production, consideration would have to be given to whether or not such a service will be offered under the new program. It is assumed that if it is offered, it would be offered by the entity responsible for producing the proof of possession (i.e. the LP under options 1 and 2 and HC under option 3). This issue will be examined during regulatory drafting.
- Regardless of the format chosen, Health Canada could also consider requiring LPs to issue an official receipt, which could also serve as one means to demonstrate that possession is lawful. Mechanisms could be put in place to also ensure that this receipt is not easily replicable.

CONSULTATIONS

During consultations, program participants, compassion clubs, law enforcement and fire officials all indicated a preference that some type of identification, preferably government-issued, be given to individuals who require marihuana for medical purposes. Compassion clubs, on behalf of their clientele, raised concerns that the elimination of the Health Canada identity card would render individuals at risk of having negative encounters with law enforcement. It was noted that if Health Canada will not issue an authorization to possess marihuana, licensed producers could do so instead. Participants in consultations did acknowledge, however, that proof of possession could take any form, including that of a label, as long as law enforcement will be aware of the look and feel of such proof. Education and training for law enforcement was highlighted as an essential component of any form of proof of possession. Law enforcement also expressed an interest in being able to verify whether or not an individual in possession of marihuana is legally able to do so, in a manner similar to the pager service currently offered by Health Canada. While the identification card was touted as a useful tool, law enforcement representatives noted that it would be important to ensure that any proof of legal possession would not be issued in a format that is easily susceptible to counterfeit.

Issue Analysis Summary

Proof of Possession

RECOMMENDATION

Option 1 is recommended for the following reasons:

- It is most consistent with the principles of reform:
  - Health Canada will no longer receive, process or issue elements of applications for authorizations;
  - The administrative burden will be reduced for program participants as they will not be required to await approvals from both an LP and Health Canada (i.e. if Health Canada were to issue the card);
  - Treats marihuana as much as possible like a medication by relying on a form of proof of possession consistent with prescription labels
- This is the most cost effective option:
  - For Health Canada, as the department will no longer be required to produce cards;
  - For patients, as LPs will not have to produce additional cards, a cost that would likely be passed on to consumers.

This is **Exhibit "EE"** referred to in the
Affidavit of **JEANNINE RITCHOT**
Affirmed before me at the City of Ottawa,
in the Province of Ontario,
this 15th day of January 2015.

A Commissioner for Taking Affidavits

Issue Analysis Summary
FINAL (Protected B)

QUALITY

ISSUE

HC will need to determine what minimum quality requirements should apply to marihuana for medical purposes under the Marihuana Medical Access Program (MMAP).

CONTEXT

Current Status:

Marihuana (cannabis) is an unapproved drug and as such has not been comprehensively evaluated in terms of safety, efficacy, quality and therapeutic usefulness as required under the *Food and Drugs Act*. Despite this, Health Canada's MMAP provides access to marihuana for Canadians who suffer from serious medical conditions.

Marihuana sold or provided under Designated Person Production Licences, or by Prairie Plant Systems Inc., (PPS) is exempt from the *Food and Drugs Act and its Regulations*, by virtue of the *Marihuana Exemption (Food and Drugs Act) Regulations (MER)* (unless it is used in a clinical trial). However, in the case of PPS, quality requirements are imposed by contract.

Marihuana imported or produced for sale by persons other than those exempted under the MER, would be required to comply with drug GMPs in order to do so legally. In addition, any fabricator, packager, labeler, distributor, importer, wholesaler or tester of marihuana intended for sale would be required to hold an Establishment Licence (EL) under the FDR. In order to obtain an EL, a person must submit an application to Health Canada. Health Canada reviews the application, performs an initial inspection of the site, and issues a licence to conduct the relevant activities if appropriate. Establishments are inspected from time to time to verify compliance with the GMP requirements set out in the FDR.

Proposed Changes:

For context on the proposed changes to the MMAP, please refer to Health Canada's consultation document entitled *Proposed Improvements to Health Canada's Marihuana Medical Access Program.*

The FDA and the FDR apply to dried marihuana. Thus, a regulatory amendment to fully or partially exempt dried marihuana from the FDR would be required to allow its production and sale without a marketing authorization. The scope of the exemption is yet to be determined.

Originally drafted Nov 17th 2011, Finalized unchanged Sept 13, 2012

Issue Analysis Summary
FINAL (Protected B)

QUALITY

IDENTIFICATION AND ANALYSIS OF OPTIONS

Criteria:

- There is an expectation on the part of Canadians that a regulated product is of sufficient quality to be safe for consumption.
- Quality requirements imposed by the regulations must be clearly linked to potential health risks so as not to create an undue regulatory burden, which in turn could result in high costs or access issues.
- The program overall should treat marihuana as much as possible like any other drug.

Options:

- Two options were set aside:
    - The option of not imposing a quality standard was set aside because there will be an expectation on the part of Canadians that marihuana produced by regulated commercial producers is safe for human consumption.
    - The option of imposing the requirements set out in Health Canada's contract with PPS was set aside because the contract sets out prescriptive, detailed requirements that pertain to the single product offered by HC, rather than minimum requirements that could apply to a variety of products. For example, the contract prescriptively sets out packaging materials, storage temperatures and inventory control measures. Obligating an industry to comply with these prescriptive measures is likely inappropriate in addition to being inconsistent with the way other drugs are regulated.

Option 1: Drug GMPs

Marihuana will not be exempted from the drug GMP requirements.

PROS

- Treats marihuana like any other drug.
- Increases overall site security by way of closer oversight on processes.
- Reduces the risk of potentially haphazard practices which may lead to batch failure.

CONS

- Imposing the most rigorous GMP requirements that exist under the FDA could be viewed as incompatible with the program's mandate to ensure reasonable

access to marihuana for medical purposes.

- The drug GMPs require that products are tested and meet specifications prior to sale. Specifications are identified by manufacturers and reviewed by HC in the context of a drug submission. Under the proposed changes, Licensed Commercial Producers (LCPs) will not have to apply for a marketing authorization for the product. Further thought on how specifications would be established is required.
- As per the FDR, LCPs would have to employ a qualified person to supervise the fabrication, packaging, labeling and storage of marihuana. Some prospective LCPs may object to this.
- Compliance verification activities for Division 2 of the FDR are handled in the context of Establishment Licensing (Division 1A of the FDR). HC would need to assess whether an Establishment Licence would also be required for these activities.
- Consultation and coordination with HC staff that are responsible for conducting compliance and enforcement activities under the FDR would be required.

Option 2: Rely solely on finished product specifications

Regulations would only require that dried marihuana meet quantitative specifications in order to be sold for medical purposes. (Purity requirements would likely prescribe maximum tolerances, whereas potency requirements would likely impose a range of accuracy, e.g., 80% - 120 %.)

PROS

- The regulatory requirements would be simple and quantitative. This has the following effects:
    - Companies could comply relatively easily, particularly if they contract the services of a qualified laboratory. Thus, the market would be more attractive to less experienced companies. (This could be viewed as a con.)
    - Compliance activities would be relatively simple for HC.

CONS

- Does not address quality issues that may arise after testing in the event that the product is not stored correctly. For example, a batch could to be tested and released for sale, but be stored in a moldy pest-infested storage area for several months before it is sold. (In the case of a natural health product, if the applicant complies with the quantitative specifications of dried marihuana, this means that the quality of the finished product is valid within the life cycle of the product, meaning until the expiry date specified on the label or for the whole batch. When the product is stored under the recommended condition, the quality of the finished product should not be changed, otherwise, the product is non-

compliant.)

- Licensed commercial producers would have to employ a person capable of interpreting/understanding the test results. This would likely be a person who holds a Bachelor of Science in a relevant discipline, at a minimum. Some prospective licensed commercial producers may object to this.
- Companies without experience in cultivating or processing without standard procedures might have difficulty ensuring that consistent batches are produced. While this difficulty would be remedied by experience with growing, repeated production of unsellable batches could result in an access issue as well as higher costs.
- Specifications would have little meaning without some level of control on good laboratory practices, validation, sampling protocols, and testing methods, to ensure that the specifications are correctly measured and recorded. Health Canada would have to consider how these would be handled, e.g., by regulatory requirements, by requiring testing by a lab that holds an EL.
- Inconsistent with the approach to regulating quality for any other drug. Finished product testing is typically coupled with more fulsome process and quality controls.

Option 3: Develop quality requirements specifically for dried marihuana

HC would develop minimum quality requirements for marihuana, likely using the natural health product (NHP) GMPs as a starting point.

PROS

- Requirements would be tailored to this program and limited to what is necessary to avoid placing consumers at risk due to inadequate safety and quality.
- Reduces the risk of potentially haphazard practices which may lead to batch failure.
- Increases overall site security by way of closer oversight on processes.
- PPS and Bedrocan have demonstrated that some form of GMP is achievable for marihuana production and processing.

CONS

- The NHP GMPs require that products meet their specifications prior to sale. Specifications are set by manufacturers and reviewed by HC in the context of a product licence application. Under the proposed changes, LCPs will not have to apply for a marketing authorization for the product. Further thought on how specifications would be established is required.
- Inspections for LCPs will be more complicated than typical CDSA inspections.
- It will be challenging to develop quality requirements within the required timelines for program reform.

Issue Analysis Summary — FINAL (Protected B)
QUALITY

CONSIDERATIONS

- Marihuana is unique from other drugs in that the Government has an obligation under the *Charter of Rights and Freedoms* to ensure that there is reasonable access to marihuana for medical purposes in Canada. The impact of quality requirements on access is an important consideration:
    - Insufficient requirements could compromise access by compromising crops;
    - Excessive requirements could compromise access by limiting interest in the market.
- Program participants raised quality-related issues during public web consultations (see consultations section). Given the variety of perspectives, non-prescriptive requirements may yield a market offering more options to consumers, which would likely be viewed favourably.

CONSULTATIONS

Program participants expressed concerns regarding the presence of chemical residues, as well as the potency of commercially produced marihuana. There were also concerns regarding the availability of organic marihuana or marihuana that has not been irradiated. The varied perspectives and expectations relating to quality that were voiced during consultations are an important consideration in this analysis.

Provincial and territorial health officials, as well as representatives from Canadian medical associations, reacted favourably to the concept of standardized marihuana.

Companies with a current licit business interest in marihuana had differing views on what quality requirements should entail. One suggested comprehensive prescriptive requirements and another suggested that quality standards relate largely to an overall quality management system and qualified personnel.

Compassion clubs had varying views, but generally saw the creation of quality requirements as a positive step. They emphasized that onerous requirements could produce barriers to entry into commercial production. At least one compassion club suggested that GMPs set out in an HC guideline were a viable starting point. It is unknown whether this refers to the drug GMP guidelines or NHP GMP guidelines. It was also suggested during consultations that some dispensaries are operating under WHO guidelines. It is unknown which WHO guidelines were being adhered to, or whether such controls were placed on production, processing and packaging as well as dispensing.

RECOMMENDATION

Option 3 is recommended because requirements would be tailored to this program and limited to what is necessary to avoid placing consumers at risk due to inadequate safety and quality.

NEXT STEPS

Consultation materials will be developed for discussion with prospective licensed commercial producers. An analysis of feedback and issues raised in the context of those discussions will inform the development of requirements. It is recommended that HC form an internal GMP working group following these consultations to ensure that individuals with appropriate expertise are engaged in the development of requirements.

This is **Exhibit "FF"** referred to in the
Affidavit of **JEANNINE RITCHOT**
Affirmed before me at the City of Ottawa,
in the Province of Ontario,
this 15th day of January 2015.

A Commissioner for Taking Affidavits

Issue Analysis Summary DRAFT (Protected B)
Security Intelligence Background Section (SIBS)

ISSUE:
Whether the *Marihuana for Medical Purposes Regulations* (MMPR) should require an enhanced background check in order to improve measures to prevent diversion

CONTEXT:

The Current Program
Under the current *Marihuana Medical Access Regulations* (MMAR), Health Canada issues personal-use and designated-person production licences. Holders of a personal use production licence (PUPL) are not required to undergo a criminal record check as a condition of their eligibility. Applicants for a designated-person production licence, however, are required to show proof that they have not been found guilty in the past 10 years (as an adult) of a designated drug offence as defined in the MMAR.

Holders of production licenses under the MMAR are not, subject to prescriptive security or record-keeping requirements, as are holders of licenses under other regulatory regimes (i.e. licensed dealers under the *Narcotic Control Regulations* (NCR)). As a result, Health Canada's compliance activities are generally limited to counting the number of plants and measuring the quantity of dried marihuana in storage to ensure that it is consistent with the amounts indicated on a production license.

Law enforcement groups, specifically the Canadian Association of Chiefs of Police (CACP) and the Royal Canadian Mounted Police (RCMP) have, over the years, expressed significant concerns that the current MMAR is subject to abuse. Specifically, they have provided Health Canada with evidence that personal use and designated person production licences are being exploited such that large quantities of marihuana produced for medical purposes are actually being diverted to the illicit market.

The RCMP Criminal Intelligence Section deems that a criminal record check of applicants attempting to obtain production licences is insufficient in reducing the probabilities of exploitation by criminals. They suggest that a more comprehensive background screening of individuals to identify criminal associations would greatly contribute to mitigating the risks of exploitation. Some of the threats to the current MMAR from organized crime groups (OCGs) are:

- Marihuana production in excess of a MMAR licence designation, and sale on the illicit market;
- Criminal participation in medical marihuana grow operations;
- Criminal networks deliberately utilizing Health Canada MMAR licences to

commercially produce licit marihuana.[1]

Specifically, the RCMP has provided a criminal intelligence brief on the *Criminal Exploitation of Marihuana Medical Access Regulations* to demonstrate that criminal networks are currently using associates and family members (i.e. spouses) who do *not* have criminal records to apply for and obtain DPPL's to produce marihuana for medical purposes. With these licences, criminal networks are able to divert large amounts of marihuana produced for medical purposes to the illicit market by exploiting Health Canada issued licenses (Annex A).

Proposed Changes to the Program

Under the proposed new MMPR, licensed producers would have to meet strict requirements related to security, record-keeping and reporting, in order to ensure that Health Canada could effectively track and monitor activities with a controlled substance, including a requirement to undergo a pre-licensing security inspection. The proposed changes as outlined in the public consultation document did not elaborate on required background checks for applicants. For other regulated industries who deal in controlled substances (i.e. licensed dealers under NCR), Health Canada requires a criminal record check (CRC) for key personnel (the Qualified person in charge (QPIC) and alternates) to demonstrate that they have not been found guilty, in the past 10 years, of a designated drug offence or a designated criminal offence. These offences include:

- Financing of terrorism;
- Fraud;
- Laundering proceeds of crime;
- Involvement in a criminal organization;
- Trafficking of controlled substances;
- Production of controlled substances; and
- Import or export of controlled substances and precursors.

Beyond the CRC, Health Canada does not require any additional enhanced background checks for producers of controlled substances, including narcotics.

The new regulations would also require that, before submitting an application to Health Canada, the applicant must provide written notification of intent to seek a license to the local police force or RCMP detachment, local fire officials and the local government of the area in which the site in respect of which a license would be sought is located. As part of their application submission to Health Canada, they must also provide a signed declaration that they have issued these notices together with copies of the notices. It should be noted that this is not a requirement for applicants for a dealer's license under the NCR. The justification for this decision is discussed in detail under separate cover (see IAS entitled

[1] Royal Canadian Mountain Police. *Criminal Intelligence Brief: Criminal Exploitation of Marihuana Medical Access Regulations*. May 23, 2012. See Annex A.

Interaction with local authorities).

The new regulations also contemplate more significant grounds for refusal of a license than in the current MMAR. With respect to preventing diversion of marihuana, the Minister *must* refuse to issue, renew or amend a license if:

- the applicant has provided false or misleading information/documentation (i.e. has falsely declared that they have notified local law enforcement of their intent to apply for a licence);
- a peace officer (law enforcement), competent authority or the UN provide information that raises a reasonable belief that the applicant has been involved in diversion of narcotics (e.g., if, upon notification of intent to apply for a license to local law enforcement, the detachment submits information such as an applicant's involvement with OCG for the purposes of diverting narcotics);
- the issuance, renewal or amendment would likely create a risk to security, public health or safety (i.e. diversion);
- the applicant does not have the appropriate security measures in place; or
- the applicant is in contravention or has contravened in the past 10 years a provision of the CDSA or its regulations.

Finally, the new regulations contemplate more significant revocation powers than those which exist in the MMAR. Specifically, the Minister *must* revoke in the following circumstances:

- it is found that the license was issued on the basis of false or misleading information/documents (e.g. it is discovered after the fact that the applicant falsely declared that they notified local law enforcement of their intent to apply for a license);
- a peace officer, competent authority or the UN have provided information to HC that raises a reasonable belief that the licensed producer has been involved in diversion activities (i.e. through the course of an investigation, law enforcement has found evidence of a licensee's involvement with OCG for the purposes of diverting narcotics); and
- A licensed producer has failed to comply with a provision of the Act or the regulations, a term or condition of the licence, or a term or condition of an import/export permit.

These powers do not exist under the current MMAR and are similar to what exists under the Narcotic Control Regulations for other narcotics. These powers would provide Health Canada with both a proactive ability to refuse to issue, amend or renew a license, and a reactive ability to revoke a license, if the department were presented with evidence to demonstrate the involvement of OCG in the operations of a licensed producer.

The new regulations would also authorize the Minister to suspend a licence without notice if the Minister has reasonable grounds to believe that it is

necessary to do so to protect security, public health or safety, including preventing a narcotic from being diverted to an illicit market or use.

Consultations

During consultations, law enforcement officials were highly supportive of the proposal to eliminate personal and designated production by individuals in their homes. Law enforcement generally acknowledges that the reform would greatly reduce public safety and security risks associated with growing marihuana in homes, including diversion to the illicit market, by eliminating the production of marihuana by individuals in their own homes.

Despite the more significant refusal and revocation powers, the more stringent security, record-keeping and reporting requirements, and the more effective capacity to inspect licensed producers as compared to individuals in their own private dwellings, law enforcement continues to express concerns that criminal networks, in particular OCGs, will pose a threat to the new program. They believe that the new regime remains vulnerable to infiltration by OCG, either by setting up a "legitimate" licensed production facility and then falsifying records, or by planting associates in other production entities along the supply chain (i.e. packaging/labelling) in order to divert marihuana to the illicit market. To substantiate this assertion, they have provided Health Canada with the following information from intelligence reports:

- The illegal marihuana market in Canada is estimated to be a multi-billion dollar industry, in annual revenue, for criminal organizations. Canada was identified as a global top 10 producer of illicit marihuana, and as such, OCGs have strong incentive to pursue any mechanism which would assist them. The capital derived from the profits of marihuana is used by OCGs to sustain themselves and finance other criminal enterprises such as importing cocaine and guns into communities across Canada.[2] The scope and heavy involvement of organized crime in the illicit marihuana industry within Canada compared to other illegal commodities speaks directly to the need for robust security measures.

- According to RCMP criminal intelligence reports, Canadian criminal networks engaged in the licit marihuana market have access to millions of dollars of start-up capital. As such they have the financial resources to commercially enter a sophisticated MMPR Program.[3]

- Based on past investigations, the RCMP alleges to have obtained intelligence that high-level criminal organizations engaged in illicit drug markets (cocaine, methamphetamine, and marihuana) are actively

[2] Criminal Intelligence Services Canada, *Report on Organized crime 2010*. See Annex B.
[3] Royal Canadian Mountain Police. *Criminal Intelligence Brief: Criminal Exploitation of Marihuana Medical Access Regulations*. May 23, 2012. See Annex A.

strategizing and adapting to enter and exploit Health Canada's developing MMPR Program. Marihuana is the most trafficked illicit drug in North America and the World (UN World Drug Report). The ease with which OCGs have been able to exploit the current MMAR has, according to law enforcement, emboldened them to get involved in the new industry that Health Canada is developing.[4] Analysis from 2010 RCMP study showed that 50% of the MMAR licencees captured in the study had a criminal record.

- They have also presented evidence that OCGs are heavily involved in other large and legitimate industries such as the trucking industry and in airports. Their involvement in these industries provides them with access to and the ability to traffic drugs on the illicit market, both domestically and internationally.[5]

Given these factors, the RCMP has recommended that the new MMPR include a requirement for a more comprehensive background screening of applicants in order to identify any potential criminal associations prior to issuing a licence. Specifically, they recommend that key personnel be required to consent to an enhanced background check – similar to that undergone to obtain top secret clearance for Government employees – which would be undertaken by the Security Intelligence Background Section (SIBS) of the RCMP.

How enhanced background checks work[6]

The Security Intelligence Background Section of the RCMP conducts Law Enforcement Record Checks (LERC) for various clients (i.e. other law enforcement agencies, federal departments) to determine whether a named individual has been engaged in or associated with criminal activity. A LERC involves an extensive review of police databank holdings which track intelligence related to national security and to criminal intelligence, including the Canadian Police Information Centre (CPIC) to determine if the individual has a criminal record.

Transport Canada currently uses the services of SIBS to conduct a LERC prior to issuing a transportation security clearance (TSC) to individuals applying for key positions in airports (i.e. baggage handlers or others with access to restricted

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[4] Royal Canadian Mountain Police. *Criminal Intelligence Brief: Criminal Exploitation of Marihuana Medical Access Regulations*. May 23, 2012. See Annex A.

[5] Intelligence from The RCMP to Health Canada in two reports: 1) RCMP Criminal Intelligence Project STALL, *An Assessment of Organized Crime in the Trucking Industry* (Annex C) 2) RCMP Criminal Intelligence Project SPAWN, *A Strategic Assessment of Criminal Activity and Organized Crime Infiltration at Canada's Class 1 Airports* (Annex D).

[6] The description of enhanced background checks is based on discussions held between Health Canada and the RCMP on May 28, 2012 (see Annex E for agenda) and on July 10, 2012, as well as a discussion held with Transport Canada on July 11, 2012.

locations) and marine ports (i.e. harbor master or wharfinger). The objective is to ensure that individuals holding these positions do not represent a significant threat to civil aviation or marine transportation systems as a result of participation in or close association with terrorist organizations or OCGs.[7]

To apply for a TSC, the applicant submits a security clearance application form in person at an enrolment site, and has a facial image and fingerprints taken (see Annex I for a copy of the form). The application form includes extensive information about the individual (and if applicable, their spouse), including their activities and places of residence over the past five years. The application is then sent to TC for processing, and the department sends limited information (applicant's full name and applicable alias', gender, date of birth and present address) to the RCMP to undertake a LERC by conducting a criminal record check and a check of the relevant files of law enforcement agencies, including intelligence gathered for law enforcement purposes, both nationally and internationally (see Annex F for a process map).[8]

If the individual's name does not appear in any law enforcement databases, the RCMP immediately advises TC and the latter issues the TSC. If the individual's name registers a possible "hit", then the RCMP will ask TC to provide them with additional information collected during the application process and further investigate the applicant's history. This includes contacting the agency who is the primary holder of the information that registered the "hit" (i.e. if there is an ongoing, active investigation, they will contact the responsible law enforcement agency). If there is no "hit" following the subsequent checks (i.e. the information proves to not be relevant or the identity of the subject is confirmed as being that of an individual other than the applicant), the RCMP informs TC, who issues the TSC. If there is a "hit", the RCMP obtains the permission of the originating agency to release information to TC, and prepares a report outlining the information that they have received. TC must then determine whether or not the information received by the RCMP is significant enough to deny issuance of a TSC.

A summary of the SIBS report is sent to the applicant along with any other relevant information. The applicant is then given a reasonable opportunity to respond to the information.

In such cases, all information is reviewed by a TC Advisory Body. This body consists of the Director, Security Screening Programs who is the Chairperson,

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[7] For additional information, see the *Marine Transportation Security Regulations* at Annex G, and the Transport Canada criteria for the Transportation Security Clearance Program at Annex H.

[8] Transport Canada also shares information with the Canadian Security Intelligence Service (CSIS) for a CSIS indices check and security assessment, and with Citizenship and Immigration Canada (CIC) for a check of the applicant's immigration and citizenship status, if applicable. This will be further discussed in the considerations section of this document.

and at least one other member selected by the Director, Security Screening Programs based on his or her familiarity with the aim and objective of the Transportation Security Clearance Program. The RCMP sits at the table as a non-voting member, to answer any questions that the group may have about its report. The body considers the application and any representations from the applicant, and makes a recommendation to the Minister or delegate concerning the issuance of the TSC. The Minister or delegate must then make their own decision, taking into consideration the Advisory Board's recommendation. The applicant then receives written reasons for the decision.

In the aviation sector, there is no recourse mechanism that allows for review of ministerial decisions regarding the issuance of TSC's. Applicants who are refused must go straight to a request for judicial review in the Federal Court of Canada. In the marine sector, the MTSR include a 30-day reconsideration process, during which time the applicant can request the opportunity to make representations on their behalf and to have the matter reconsidered. An applicant who has been refused may then ask for judicial review of the decision. There have been multiple judicial reviews of these Transport Canada decisions, primarily on grounds of procedural fairness.

The RCMP provide this service to TC on the basis of a Memorandum of Understanding (MOU). The fee attached to this service is $250-$280 per individual check. The RCMP service standard is 10 working days when there is a "no hit", and up to 90 working days when there is a "hit".[9] Last year, the RCMP conducted 47,000 checks for TC. In conversation with TC officials, they estimate that approximately 10% of the checks come back with a "hit".

ANALYSIS OF OPTIONS:

Option 1: Standard Criminal Record Check (CRC)
The applicant, the senior person in charge (SPIC), the responsible person in charge (RPIC) (who supervises activities with marihuana) and his/her alternate(s), and the executive directors/officers of a corporation must undergo a criminal record check and demonstrate to Health Canada that, within the last 10 years, they have not been found guilty, as an adult, of a designated criminal or designated drug offense. As a condition of licence renewal, these individuals would have to resubmit criminal record checks with every renewal application (up to five years). Whenever there is a change in the ownership structure or the responsible personnel, Health Canada's approval would have to be sought and that individual would have to demonstrate that they meet this requirement.

[9] Both the RCMP and Transport Canada have confirmed that there was a delay in being able to meet this service standard as a result of a backlog. Both also confirm that the RCMP is now able to meet its service standards.

Pros:

- Consistent with the principle of treating marihuana as much as possible like any other medication, as this is what is required for all licensed dealers under the NCR and under the *Industrial Hemp Regulations* (IHR);
- Inexpensive for Health Canada, as the onus is on the applicant to demonstrate that they meet this requirement;
- Not onerous for applicants, who would supply Health Canada with a document issued by a Canadian police force ($25 from the RCMP, plus fees that vary from police force to police force for fingerprinting and processing)[10] setting out their criminal record for the last ten years. Alternatively, the regulation could authorize these individuals to consent to providing relevant information and consent for Health Canada to conduct the criminal record verification on their behalf;
- This is a known requirement to industry for all regulated parties who conduct activities with Health Canada. Interested LPs confirmed during consultations that they expect this to be the case for them as well;
- The requirement to notify local law enforcement of an intent to apply to become an LP, along with the significant powers to refuse to issue, amend, or refuse a license, and to revoke a license, will provide Health Canada with the a more robust way to prevent infiltration by OCG, particularly when/if the RCMP can provide evidence to reasonably demonstrate threats to public safety and security.

Cons:

- The RCMP is a strong supporter of enhanced background checks. They maintain that a simple criminal record check, particularly one focused on drug offenses, will not pick up associations to criminal networks that could render a licensed producer vulnerable to infiltration by organized crime. This is because a simple criminal record check will not verify for criminal associations, leaving Health Canada vulnerable to the possibility of licensing LPs who have such associations. It may therefore be easier for OCGs to infiltrate the market as a licit LP either by finding someone who can pass a standard CRC to front an organization or by planting a similar person within an organization.

Option 2: Security Intelligence Background Section (SIBS) Enhanced Background Check

As a condition of eligibility for a license, the same personnel as outlined under Option 1 would be required to undergo a LERC. They would equally be required to undergo these checks every five years, and when there are any changes of personnel.

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[10] *Royal Canadian Mounted Police, Criminal Record Verification for Civil Purposes Fee Regulations*. The fee to be paid by an individual for the verification by the Royal Canadian Mounted Police of a criminal record for civil purposes is $25. The federal processing fee is in addition to any local service fees required for fingerprinting by a police service and/or an accredited fingerprinting company.

Through regulations, applicants would have to consent to provide Health Canada with extensive personal information, and to allow Health Canada to share this information with the RCMP. The regulations would also outline the conditions for refusal to grant a license based on the information uncovered during such enhanced background checks.

The MMPR will also contain general provisions related to refusals to issue, amend or renew a license or decisions to revoke a license. These will require the Minister to send a notice to the applicant/holder of the license along with a written report that sets out the reasons for refusal. The applicant/license holder must be given the opportunity to be heard in respect of the decision. As a result, the MMPR would not contain additional reconsideration clauses specific to enhanced background checks, as the requirement already exists.

Operationally, the process would closely resemble the TC process outlined above and outlined in the process map at Annex F. Health Canada would therefore enter into an MOU with the RCMP. Health Canada will also have to give consideration to who the appropriate individuals are to sit on an advisory body that can make recommendations to the Minister in cases where the LERC reveals associations or ties to criminality.

Pros:

- SIBS is a more thorough search, catching potential associations to criminal organizations and groups, thus responding to one of the more significant concerns raised by law enforcement with respect to vulnerabilities of the new program.
- As noted by the RCMP, marihuana remains the most highly trafficked drug in Canada. It may therefore be appropriate to conduct proactive security clearances beyond what is required for producers of other drugs prior to granting licenses to applicants.

Cons:

- This is inconsistent with how Health Canada currently treats other licensed entities who conduct activities with narcotics, including those that are also highly available on the illicit market. Specifically, licensed dealers under the NCR are merely required to demonstrate that they have not been found guilty of a designated drug or criminal offense in the past 10 years. This is a much more onerous requirement for LPs than for other entities dealing in controlled substances.
- It is likely that potential LPs who may be rejected due to heightened security screening will challenge Health Canada's decision. While the Transport Canada regulations have been upheld despite numerous challenges, this has been done on the basis of threats to national security based on terrorism, and with deference to the security expertise of those making the decisions within Transport Canada. Any defense of this

mechanism or of a specific decision by Health Canada will require making a strong case that OCG participation in the illicit drug market, specifically marihuana, represents a significant threat to Canada's national interests, and that the appropriate Health Canada expertise exists to make reasonable decisions based on the nature of associations between individuals and organized crime.

- SIBS provides this service on a user fee basis. Each check would cost HC 250-280$ per individual, and would have to be done each time an LP is required to renew.[11] While the cost is not excessive, Health Canada currently does not collect user fees for any of its *Controlled Drugs and Substances Act* (CDSA) regimes.
- In cases where there is a hit, it could take the RCMP up to 90 days to provide a report to Health Canada, thus causing potential licensing delays.
- Unlike the similar process established at Transport Canada, Health Canada does not currently have the extensive security expertise necessary to make recommendations to the Minister regarding issuance of a license. The TSC decisions which have been challenged in court have been given deference by on the basis that the Advisory Committee is made up of experts in the fields of aviation and maritime security.

CONSIDERATIONS:

[redacted]

Unlike Transport Canada, Health Canada's security requirements may be challenged under s.7 of the Charter as putting in place unnecessary barriers to licensed producers which prevent reasonable access to marihuana for medical purposes. This risk can be mitigated with evidence on how SIBS will address the infiltration of organized crime into the new medical marihuana regime and why it is a requirement only for marihuana and not for other narcotics.

The RCMP, as subject matter experts in the area of the involvement of OCG in the illicit drug market, have noted their willingness to partner with Health Canada and to provide evidence as required with respect to the particular vulnerability of this industry to infiltration.

Public Health and Safety

According to law enforcement, the involvement of organized crime in marihuana production is a widespread problem in Canada. Violence continues to be a part of the illegal production, trafficking and distribution stages of the drug trade, and are associated with the presence of marihuana grow operations (MGOs), both illicit and those authorized by Health Canada under the MMAR. According to the RCMP, the establishment of a legal commercial production industry as proposed under the MMPR may make the new program even more attractive to organized crime, continuing the threat of violence in our communities from OCGs.[13]

Through the adoption of the CDSA, Parliament has determined that the consequence of controlled substances being available to the general populace, except on a regulated basis, is unacceptable. Cost to society of drugs reaching the illicit market includes, but is not limited to, police and court costs as well as a variety of health and social service costs.

Consistency with Other Drug Control Regimes

SIBS record checks are not consistent with how Health Canada treats other drug producers and manufactures in terms of CRC requirements. One of the goals of program reform is to treat marihuana like other controlled medications. Another goal of reform is to move Health Canada away from a program administrator role, to its typical regulatory role for the drug industry. SIBS record checks counters each of these goals as the requirements for marihuana production will be higher then those of other controlled substances, and will cost Health Canada time and resources to go through each and every SIBS record check (more of an administrative role vs. acting as a regulatory body).

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of the Federal Courts Act, R.S.C. 1985, c. F-7 as amended, of questions or issues of the constitutional validity, applicability or operability of an Act of Parliament or of Regulations made under an Act of Parliament that have arisen in proceedings before the Canadian Industrial Relations Board, 2009 FCA 234.

[13] Royal Canadian Mountain Police. *Criminal Intelligence Brief: Marihuana Grow Operations and Related Violence in Canada.*. April 2012. See Annex J.

Issue Analysis Summary DRAFT (Protected B)
Security Intelligence Background Section (SIBS)

RECOMMENDATION:
Based on the strong recommendation of the RCMP, and based on the stated objectives of reform (i.e. to mitigate against risks to public health, safety and security), Option 2 is recommended.

This is **Exhibit "GG"** referred to in the
Affidavit of **JEANNINE RITCHOT**
Affirmed before me at the City of Ottawa,
in the Province of Ontario,
this 15th day of January 2015.

A Commissioner for Taking Affidavits

Issue Analysis Summary

FINAL (Protected B)

Solicitor-Client Privilege/Protected

Seeds and other Starting Materials

ISSUE

Under the proposed changes to the Marihuana Medical Access Program (MMAP) announced by the Minister of Health, how will licensed producers (LPs) legally obtain access to seeds and other "starting materials", which could include seedlings, cuttings, or other propagating material, for cultivation?

CONTEXT

Current Status:

Activities such as the possession, sale, import and export of cannabis, including viable cannabis seeds, are prohibited by the *Controlled Drugs and Substances Act* (CDSA) unless authorized by regulation. Currently, certain activities with cannabis may occur under the *Narcotic Control Regulations* (NCR), the *Industrial Hemp Regulations* (IHR), and the *Marihuana Medical Access Regulations* (MMAR). The MMAR authorizes the Minister to import and possess seeds for the purpose of selling or providing to a license holder and authorizes a licensed dealer who is producing seeds under contract with the Government of Canada, to provide or send seeds to the holder of a license to produce under the MMAR.

Health Canada adopted the *Policy on Supply of Marihuana Seeds and Dried Marihuana for Medical Purposes*, along with certain regulatory provisions on the sale of seeds and dried marihuana, in response to a decision rendered in 2003 by the Ontario Court of Appeal in *Hitzig v. Canada*. In its decision, the Court declared specific provisions of the MMAR unconstitutional and invalid on the grounds that the regulations failed to adequately resolve issues related to providing access to a legal source and supply of marihuana for medical purposes, because in the absence of a licit supply, program participants had to resort to the black market in order to obtain seeds, or dried marihuana.

A single strain of marihuana is currently available through the MMAP. This strain was initially derived from seeds seized by the RCMP. Since then, other test strains have been developed as part of the contract with the supplier.

The *Seeds Act and Regulations*, enforced by the Canadian Food Inspection Agency (CFIA), govern the testing, inspection, quality and sale of seeds for plant propagation in Canada. The regulations ensure the importation, sale, packaging; distribution and

storage of agricultural and horticultural seeds conform to accepted standards for quality and for proper identification in the marketplace. The *Seeds Act* and its regulations apply to the importation or sale of seeds including marihuana seeds. Cannabis spp. (i.e. hemp) is not a designated crop kind under the Act or its regulations and is not subject to variety registration. However, marihuana seeds imported into or sold in Canada would need to meet a standard for purity and quality that generally applies to all seeds, including freedom from prohibited noxious weeds. There are no other significant implications of the Act for the method of seeds supply and sale being proposed under the new framework.

Persons importing seed or plant parts into Canada must also comply with the *Plant Protection Act and Regulations.* Imported seed may require an import permit or phytosanitary certificate. Seeds or other starting materials contaminated with soil, pests and/or weeds may be refused entry into Canada.

Proposed Changes:

Under the proposal, all production of marihuana for medical purposes will be carried out by licensed producers (LP) in a regulated commercial market. LPs will be permitted to produce different strains. For more information on the proposed changes to the MMAP, please refer to Health Canada's consultation document entitled *Proposed Improvements to Health Canada's Marihuana Medical Access Program.*

CONSULTATIONS

During consultations, law enforcement representatives expressed a preference for licensed producers to obtain seeds from legal sources. Currently these sources could include Prairie Plant Systems (PPS), the company currently contracted by Health Canada to produce and distribute marihuana for medical purposes, and Bedrocan, a private company which grows marihuana for medical purposes for the government of the Netherlands. Law enforcement were also amenable to licensed producers potentially obtaining seeds from their seized stock [redacted]. Health risks could be further mitigated by incorporating quality requirements into the regulatory framework.

During targeted consultations with stakeholders, it was mentioned that seed breeding could be a potential niche market within this program. This contrasts with PPS' perspective that generally speaking, the Canadian market is too small to merit breeding activities. However, Bedrocan has indicated that the sale of genetic material may be an aspect of the Canadian market that would be of interest to them.

There was at least one organization that identified itself as a "seed bank" (i.e. a grower which specializes in producing seeds of different strains of marihuana) during consultations, which also expressed interest in becoming licensed as a LP. Although "marihuana seed banks" are not currently licensed by Health Canada, it may be possible to allow provisions to be made for existing seed growers to supply seeds to other licensed producers not interested in producing their own seeds/material.

RECOMMENDED APPROACH

Criteria:

The recommended course of action must satisfy a set of criteria for a successful transition including:

- timely access to seeds to avoid delays that could compromise the successful implementation of regulations;
- availability of seeds from a legal source to overcome the initial hurdle posed by the absence of a market;
- supporting the goal to eventually end the federal government's role as a supplier of marihuana; and
- providing greater flexibility in sources to allow for more strains to be available in the marketplace as desired by stakeholders.

Description of Recommended Approach

LPs will have to secure access to a legal source of starting material. Such access is likely to be required only in the initial phases of setting up. Once they are established, LPs will be permitted to use their own clones and clippings in order to propagate their crops.

In securing access to starting materials, Health Canada does not want to encourage licensed producers to turn to illicit sources. At present, there are only two known "legal" sources, and these may not be enough to satisfy market demands. They are:

1. The Crown, which includes:
    a. the strain currently produced and distributed by Prairie Plant Systems (PPS), as well as additional test strains and lines (10 in total); and
    b. seized marihuana turned over to Health Canada for disposal by law enforcement (Note: the original PPS strain was obtained in this matter).

2. Importation from countries that operate a national marihuana for medical purposes program (i.e. Israel and the Netherlands).

It is not certain at this time that the above-mentioned sources would prove sufficient to establish a licensed market that could meet demands for marihuana for medical purposes (see Annex A for full evaluation of feasibility of sources). It is therefore necessary to consider additional sources of supply which could, through specific inclusion in this new regulation become legitimate sources of seeds. These include:

1. Holders of personal-use production licenses (PUPLs) or designated person production licenses (DPPLs) under the current MMAR. It is important to note that this option would be viable only so long as the MMAR continues to operate. Once the MMAR is repealed, PUPL and DPPLs will no longer exist. This would merely serve as a transition measure in order to establish a sufficient supply in the early days of the new regulated market.

2. Licensed producers licensed specifically to provide starting materials. Such entities would be required to meet all of the same requirements as LPs, but their sole activity would be to provide starting materials to other LPs. This would be enhanced by a regulatory provision that permits LPs to sell cannabis.

It is therefore proposed that regulations include provisions that would specify four sources for obtaining seeds and other propagation material for cultivation by start-up businesses licensed to grow marihuana under the proposed framework: (1) Crown stock; (2) importation; (3) PUPLs and DPPLs; and (4) each other.

It is further recommended that the list of sources of starting materials defined in regulation not be exclusive. This would provide Health Canada with the flexibility to allow for other potential sources of starting materials which may be unknown at this time, but which may become known at a later date. Health Canada would also have the flexibility to introduce other potential sources of starting materials if it is found that there are still not enough sources to supply the market.

Analysis of Recommended approach

Pros

- Provides for number of legal source(s) of starting materials, provides alternatives to potential producers and ensures consistency of sources of supply for LPs;
- responds to concerns of law enforcement that LPs will have access to a legal sources of marihuana seeds and plant material for propagation;
- provides a legal framework for transferring existing domestic stock into the

regulated market;
- offers an avenue for currently available strains to continue in legal use rather than being pushed underground into the black market;
- makes provisions for a legal source(s) of seeds, which would be supportive of the government's goal of minimizing criminal interference in the program; and
- likely provides for multiple sources of seeds, which is preferable from an access and supply perspective, and which could facilitate the availability of multiple strains for patients.

Cons
- regulation of source of seeds is not consistent with the regulation of narcotics under the NCR;
- a Crown role as the supplier of seeds could be required in the long-term, which may run counter to the objective of reducing Health Canada's role in this program;
- could provide an unintended incentive to PUPLs and DPPLs to illegally initiate or expand seed or plant production beyond legal limits in the interim period if they perceive a potential for profits to be made under the new regime

Solicitor-Client Privilege/Protected

Annex A: Analysis of Potential Sources of Seeds Supply

1. International Sources

There are currently two countries which operate national programs that provide access to marihuana for medical purposes: the Netherlands and Israel. At the national level, the United States operates a research program. At the state level, there are currently 16 states that operate a marihuana for medical purposes program. Therefore, an international source of marihuana does exist. During consultations, Bedrocan, the company supplying marihuana for medical purposes to the Netherlands, indicated an interest in providing seeds to LPs.

While there are additional international sources today which are available, cost and quality considerations may still be factors for LPs, and they may not wish to incur additional costs that international sources could carry.

Pros

- Provides for a licit source of supply for LPs who wish to explore international sources
- Provides for access to a variety of marihuana strains (as many as are produced by foreign suppliers)
- Consistent with practices for other drugs, where drug manufacturers are able to procure internationally

Cons

- May not resolve the question of initial access to a sufficient supply of seeds, because:
  - there are few countries that operate an international program at present date, thus limiting the options for LPs;
  - based on Health Canada experience, it could take time for companies to identify and negotiate with international sources; and
- In some cases, starting material may not come from well characterized strains. This could create a time hurdle for authorized producers in terms of selecting a strain to scale-up.

2. Crown Stocks – Short Term

(i) Prairie Plants Systems

Health Canada currently has a contract with Prairie Plant Systems to supply dried marihuana and seeds to individuals authorized to possess marihuana under the MMAR,

who choose the Government of Canada as their supplier. PPS produces and distributes only one strain of dried marihuana, but also maintains ten additional research lines which also belong to the Crown. Given the requirements imposed on PPS through contract, the profile of these sources is well known to the Crown.

Pros

- Health Canada would have control over the initial seed supply, and could thus ensure that it is equitably distributed.
- Provides for a licit source of seeds.
- Provide access to one marihuana strain that is well characterized and familiar to some current Program participants.

Cons

- There may be additional costs to the Crown to produce more seeds to meet demand, including expansion of the strains which have not been used to supply current Program participants.
- Not a diversified source of supply - only the current strain of marihuana has been commercially tested (i.e. produced and sold to patients). Some of the test strains are also identified as clones and may therefore not be genetically different from the commercial strain.
- Perpetuates a federal government role in the supply of marihuana for medical purposes, even if temporarily.
- It is unlikely that many LPs would be interested in the PPS strains, given that only 10% of current program participants use this strain and given their interest in competing with PPS.

(ii) Seized Products

Health Canada could obtain ownership of marihuana strains seized by law enforcement. These materials are turned over to Health Canada for disposal (Note: the original PPS strain was obtained this way).

These strains, however, are not usually characterized by enforcement agencies and would need to be so that they are properly identified for distribution. In cases where an LP may wish to have access to such a strain, Health Canada may wish to work with CFIA and Agriculture and Agri-Food Canada (AAFC) to ensure that the strain is appropriately characterized and to make sure that it meets acceptable standards of purity and quality for seeds.

Pros

- Health Canada would have control over the initial seed supply..

- Provides for a licit source of seeds.
- Could provide access to a variety of marihuana strains, once they are characterized.

Cons

- Seized products are typically not characterized by enforcement agencies:
  - If Health Canada chose to undertake characterization of the strains, either itself, via Agriculture and Agri-Food Canada, or via third party contract, additional costs to Health Canada would result.
  - If Health Canada did not undertake characterization of the strains, authorized producers could face a time hurdle in terms of selecting a strain to scale-up.
- Though precedent exists for this activity, the negative stigma of organized crime may negatively affect the public's perception of accessing seized seeds from criminal sources.

Crown Stocks – Long- term Contingency Supply

It is expected that, Health Canada's role as seed supplier would be limited to the transition and early parts of the regulated market. As the market establishes and grows, seed production could be expected to become a sustainable niche activity for which there will be LP interest and involvement. In the long term, new entrants into the market should have a ready source of supply from licensed seed producers. As a contingency measure, however, some residual crown stocks could be kept in storage after the end of the PPS contract to mitigate any potential seed supply shortages as the market establishes itself. It is possible for Health Canada to have marihuana seeds stored by any of the following providers for 15-20 years and to have the supplies rejuvenated, replenished and distributed during this period, as often as necessary.

- **Agriculture and Agri-Food Canada**: Expertise currently exists in the Research Branch at AAFC to store seeds for the long term and to multiply and distribute these seeds when necessary. An AAFC scientist who was involved in the characterization and selection of the original Crown strain provided to PPS remains at his post and is interested in providing this service once an agreement is reached between AAFC and HC. AAFC's ability to multiply and replenish any stocks in future is however uncertain since it is closely tied to the license, knowledge and expertise of an individual.
- **Plant Gene Resources of Canada (PGRC):** – PGRC (under AAFC) is part of the plant germplasm conservation system in Canada. Its Seed Genebank, is housed at the Saskatoon Research Centre on the University of Saskatchewan campus and stores over 110,000 seed samples including foreign and indigenous plants, wild and weedy relatives of crop species,

cultivars and inbred parental lines, elite breeding lines, and some rare and threatened species and genetic stocks. The Seed Genebank has facilities to store and rejuvenate (and if necessary replenish and distribute) up 1kg of marihuana seeds on behalf of Health Canada. The facility however does not currently hold a license to possess marihuana and therefore does not have samples in its collection. Long term storage of seeds would be provided free of charge.

- **Other (Private firms, Universities):** Private firms involved in commercial seed production, biotechnology or plant breeding who have long term storage facilities could be contracted to maintain a supply of marihuana seeds for the future. As well, universities involved in agricultural sciences have facilities that can enable them to fulfill the role of contingency seed supplier. In any of these instances, the storage provider must be a licensed dealer.

3. Authorized Producers

(i) Current Licensed Producers (PUPL/DPPL)

Individuals who hold personal use production licenses (PUPLs) or designated person production licenses (DPPLs) under the current MMAR are authorized to produce marihuana for the personal medical use of an identified authorized person, but not for other purposes (such as sale to other individuals or entities for commercial purposes). Although compassion clubs are not licensed to operate by Health Canada, some are illicitly run by current holders of a DPPL or PUPL under the MMAR. By allowing sale of marihuana seeds/genetic material by such license holders in the new regulatory framework, they could become a legitimate sources of seeds for potential LPs. This could be beneficial because many PUPL and DPPL holders already produce a variety of different strains.

Pros

- PUPL and DPPL holders may favour an option to legally transfer their left-over stocks to the regulated market for compensation.
- In the absence of the option to grand-father existing producers preferred by PUPL and DPPL holders, licit sales of existing stocks may be perceived as the next viable option during a transition
- Allowing legal transfer of PUPL/DPPL stocks could be viewed positively especially in light of some stakeholder concerns about the lack of compensation for investments made under the current licensing scheme when PUPL/DPPLs are eventually phased out
- Allows program participants to access a variety of marihuana strains, potentially including the strain they currently use.

Issue Analysis Summary

Solicitor-Client Privilege/Protected

Cons

- It is unlikely that Health Canada will be able to put DPPL and PUPL holders in contact with authorized producers.
- May be negatively perceived by some PUPL and DPPL. The fact that this would simply be an alternative to destruction will need to be made clear.
- DPPL and PUPL holders are not a viable source in the long-term, because, under the proposed changes, they would be phased out. This can only serve as a transition measure, until the current MMAR is rescinded.
- DPPL and PUPL holders may have an incentive to increase their production beyond what is legally allowed in anticipation of greater compensation during the transition phase

This is **Exhibit "HH"** referred to in the
Affidavit of **JEANNINE RITCHOT**
Affirmed before me at the City of Ottawa,
in the Province of Ontario,
this 15th day of January 2015.

A Commissioner for Taking Affidavits

PROPOSED IMPROVEMENTS TO HEALTH CANADA'S MARIHUANA MEDICAL ACCESS PROGRAM

CONSULTATION DOCUMENT

June 17, 2011

TABLE OF CONTENTS

1. Introduction

The Marihuana Medical Access Program (the Program) provides seriously ill Canadians with access to marihuana for medical purposes[1]. In recent years, a wide range of stakeholders including police and law enforcement, fire officials, physicians, municipalities, and program participants and groups representing their interests, have identified concerns with the current program.

Some of the key concerns raised include:

- the potential for diversion of marihuana produced for medical purposes to the illicit market;
- the risk of home invasion due to the presence of large quantities of dried marihuana or marihuana plants;
- public safety risks, including electrical and fire hazards, stemming from the cultivation of marihuana in homes;
- public health risks due to the presence of excess mould and poor air quality associated with the cultivation of marihuana plants in homes;
- the complexity and length of the application process for individuals who wish to obtain an authorization to possess and/or a licence to produce marihuana;
- the impact of increasing participation in the Program on the efficiency and timeliness of the application and review process;
- the fact that Health Canada only supplies one strain of dried marihuana; and,
- the need for more current medical information pertaining to the risks and benefits associated with the use of marihuana for medical purposes, as a means of supporting discussions between physicians and their patients as to whether such treatment is appropriate;

To address these concerns, Health Canada is considering improvements to the Program. The proposed improvements would reduce the risk of abuse and exploitation by criminal elements and keep our children and communities safe.

In this regard, Health Canada would like to hear from Canadians about the improvements under consideration. You are invited to provide comments on this document.

The legalization or decriminalization of marihuana is not part of these changes. Marihuana will continue to be regulated as a controlled substance under the *Controlled Drugs and Substances Act* (CDSA).

Until any of the proposed improvements to the Program are in place, the process for applying for an authorization to possess and/or a licence to produce marihuana for medical purposes under the *Marihuana Medical Access Regulations* (MMAR) will remain the same.

[1] For more information about the existing Program and its history, please see the Annex..

2. How to Comment on this Document

The proposed improvements outlined in Sections 3 to 7 of this document represent the foundation of a redesigned program that addresses many of the concerns the Government of Canada has heard about the current program.

If you are interested in providing comments on this document, please do so by July 31, 2011.

By Email:	consultations-marihuana@hc-sc.gc.ca
By Fax:	(613) 946-4224
By Mail:	Marihuana Consultations Controlled Substances and Tobacco Directorate Health Canada Mail Room, Federal Records Centre - Bldg 18 1st Floor, 161 Goldenrod Driveway, Tunney's Pasture Ottawa ON K1A 0K9

Please note that Health Canada is committed to reviewing and considering all comments received by July 31, 2011.

3. The Improvements under Consideration

The improvements being considered would not alter the Program's intent to provide seriously ill Canadians with reasonable access to a legal source of marihuana for medical purposes, where conventional treatments are not appropriate and/or have failed to provide necessary relief.

The core of the redesigned Program would be a new, simplified process in which Health Canada no longer receives applications from program participants. A new supply and distribution system for dried marihuana that relies on licensed commercial producers would be established. These licensed commercial producers, who would be inspected and audited by Health Canada so as to ensure that they comply with all applicable regulatory requirements would be able to cultivate any strain(s) of marihuana they choose. Finally, the production of marihuana for medical purposes by individuals in homes and communities would be phased out.

Individuals wishing to use marihuana for medical purposes would still be required to consult a physician who is licensed to practice medicine in Canada.

4. How the Proposed Redesigned Program Would Work

4.1 Physician-Patient Interaction

- Health Canada maintains that the determination as to whether the use of marihuana for medical purposes is appropriate for a particular individual is best made further to discussion with their physician. In this regard, Health Canada is proposing to eliminate the categories of conditions or symptoms for which an individual may possess marihuana for medical purposes under the MMAR.

- Individuals would continue to be required to consult a physician to obtain access to marihuana for medical purposes. Since categories would be eliminated, there would no longer be a requirement for some individuals to obtain the support of a specialist in addition to their primary care physician in order to access marihuana for medical purposes.

- The existing medical declaration would be replaced by a new document provided by the physician to the individual. Health Canada will consult the medical community on the form this document will take.

- Individuals would no longer be required to submit information to Health Canada to be authorized to possess dried marihuana. Instead, they would submit their physician's document directly to a licensed commercial producer.

- Health Canada will establish an Expert Advisory Committee to improve physician access to comprehensive, accurate and up-to-date information on the use of marihuana for medical purposes, thereby facilitating informed decision-making with respect to the use of marihuana for medical purposes.

- Health Canada would work with the medical community, their provincial/territorial licensing authorities and their associations on the proposed improvements to the program.

4.2 Dried Marihuana Production and Distribution

- Under the proposed redesigned program, Health Canada would no longer enter into a contract with a commercial entity to supply and distribute dried marihuana and marihuana seeds.

- The only legal source of dried marihuana would be commercial producers, who would be licensed by Health Canada to produce and distribute dried marihuana. Individuals would purchase their supply of dried marihuana from one of these licensed commercial producers.

- Personal and designated production would be phased out.

- In order to be licensed by Health Canada, licensed commercial producers would have to demonstrate compliance with requirements related to, for example, product quality, personnel, record-keeping, safety and security, disposal and reporting, as set out in new proposed regulations. These controls would aim to ensure the quality of the product being purchased by program participants, as well as the security of production sites.

- Health Canada would establish a comprehensive compliance and enforcement regime for licensed commercial producers, centered on regular audits and inspections.

- Licensed commercial producers would be required to comply with specific product labelling and packaging requirements. The label and/or the package itself could be one way by which a program participant could demonstrate that their supply of marihuana is legal.

- Licensed commercial producers would only be permitted to produce marihuana indoors.

- Licensed commercial producers would be able to produce any strain(s) of marihuana, thus giving individuals greater choice as to which strain(s) they wish to use.

- Licensed commercial producers would set the price for marihuana for medical purpose.

- Licensed commercial producers would only be able to send the dried marihuana they cultivate to individuals by registered mail or bonded courier.

5. Impact on Current Program Participants Holding an Authorization to Possess Marihuana for Medical Purposes

With the proposed redesigned Program, there would be no change to the important first step of an individual consulting with their physician in order to obtain access to marihuana for medical purposes. In response to concerns raised by the medical community regarding the clinical use of marihuana, Health Canada is committed to working with the medical community on the identification of reference information that supports appropriate physician-patient consultation on this issue.

Once it has been determined that the use of marihuana for medical purposes is appropriate, the physician would provide the individual with a document.

Individuals would then send the physician's document directly to a licensed commercial producer of their choice. The licensed producer would validate the document from the physician by confirming that the physician is licensed to practice medicine in Canada. The licensed producer would register the individual as a customer and would process the order for a specific amount of dried marihuana. Health Canada would maintain an up-to-date list of licensed producers on its

website, and work with the medical community to disseminate this information as widely as possible.

The distribution of dried marihuana by licensed commercial producers to program participants would be by registered mail or bonded courier only.

Participants would no longer receive an authorization to possess or an identification card from Health Canada. Health Canada will consult on how best to establish that an individual is in lawful possession of a legal source of dried marihuana.

6. Impact on Current Program Participants Who Hold a Personal-Use or Designated-Person Production Licence

Within the proposed redesigned Program, only licensed commercial producers will be legally allowed to supply individuals with marihuana for medical purposes. Personal and designated production would be phased out.

That said, as the Government of Canada is committed to ensuring access to an uninterrupted legal source of dried marihuana, it will notify all holders of personal-use and designated-person production licences well in advance of the coming-into-effect of any improvements to the Program. A detailed transition plan will be shared with stakeholders when proposed regulations are pre-published in *Canada Gazette*, Part I.

7. Opportunity for Those Interested in Becoming a Licensed Commercial Producer

Health Canada is aware that transition to the proposed redesigned Program requires access to an adequate supply of dried marihuana to meet the needs of current and future Program participants. In this regard, Health Canada has identified compliance with requirements relating to the following aspects of production and distribution as being key to obtaining a commercial producer licence:

Dried Marihuana Production, Distribution and Disposition

- indoor production in a non-residential area;
- physical security standards;
- product quality standards;
- packaging and labelling standards;
- requirements for the disposal of excess plant material, excess dried marihuana and/or expired dried marihuana.

Personnel

- designation of an individual responsible for managing the production and distribution of dried marihuana; and
- specific qualifications for all personnel involved in production and distribution.

Record-keeping and Reporting

- requirements to keep records relating to all on-site activities for a set period of time, and the ability to provide set records to Health Canada on request; and
- requirements for reporting on activities associated with the cultivation of marihuana and the distribution of dried marihuana.

Compliance and Enforcement

- pre-qualification audits and pre-licence inspections; and
- inspections and/or audits on an ongoing basis.

Annex: The Current Marihuana Medical Access Program

1. Regulation of Marihuana in Canada

Marihuana is included in Schedule II to the *Controlled Drugs and Substances Act* (CDSA), and as such, is regulated as a controlled substance in Canada. This means that all activities, e.g., possession, possession for the purposes of trafficking, production, importation, exportation, trafficking, and possession for the purposes of exporting, are illegal except as authorized by regulation. Illegal activities associated with marihuana are considered to be criminal offences and are subject to the penalties set out in the CDSA.

2. Program History

In 1999, Health Canada established the Marihuana Medical Access Program (the Program) so as to provide seriously ill Canadians suffering from grave and debilitating illnesses with access to a legal source of dried marihuana for medical purposes. In the original Program, Health Canada authorized individuals to possess marihuana and/or to produce a limited number of plants for medical use through exemptions issued under section 56 of the CDSA.

In July 2000, the Ontario Court of Appeal found fault with the discretionary way in which Health Canada was using Section 56 of the CDSA as the means of granting authorization to possess and/or produce dried marihuana for medical purposes. In response, Health Canada established the *Marihuana Medical Access Regulations* (MMAR).

The MMAR set out a scheme by which any seriously ill Canadian can, with a declaration from a physician, obtain an authorization to possess and/or a licence to produce dried marihuana for their own personal medical use. The MMAR also provide for an authorized person to designate someone to grow marihuana on their behalf. In 2003, the MMAR were amended to provide for the option for authorized persons to obtain dried marihuana or marihuana seeds for medical purposes by Health Canada. This supply is currently provided under contract by Prairie Plant Systems Inc.

Since 2003, the MMAR have been amended on a number of occasions, so as to streamline the Program, respond to stakeholder concerns and/or address additional court decisions.

3. How the Program Works Now

Eligibility

Under the current Program, individuals suffering from life-threatening or chronic medical conditions must first obtain the support of a licensed medical practitioner who completes a medical declaration stating that dried marihuana is going to be used to alleviate a specific symptom associated with an identified medical condition. The individual then includes this medical declaration in their application for an authorization to possess. To be authorized to possess marihuana, an individual's symptoms and conditions must fall within one of two possible categories:

Category 1: any symptom treated as part of compassionate end-of-life care or for symptoms related to specific medical conditions, namely:
• Severe pain and/or persistent muscle spasms from multiple sclerosis, a spinal cord injury;
• Severe pain, cachexia, anorexia, weight loss, and/or severe nausea from cancer or HIV/AIDS infection;
• Severe pain from severe forms of arthritis; or,
• Seizures from epilepsy.

Category 2: a debilitating symptom that is associated with a medical condition or with the medical treatment of that condition, other than those described in Category 1.

Authorization to Possess

If an individual's application meets all of the requirements set out in the MMAR, Health Canada must issue an authorization to possess marihuana for medical purposes to the applicant. The applicant's physician is always notified when an authorization to possess is issued.

Authorized individuals then have three options to obtain a supply of dried marihuana for medical purposes. They can:

1. Apply for a personal-use production licence authorizing them to grow their own supply of marihuana; or,

2. Designate someone to produce on their behalf under a designated-person production licence.

3. Purchase dried marihuana from Health Canada

Licensed Production
As set out above, there are two different types of licences to produce marihuana for medical purposes: personal-use production licences and designated-person production licences. All licences set out specific terms and conditions applicable to the licence, including the maximum amount of marihuana a licence holder may possess at any one time, and the maximum number of plants that are allowed to be in cultivation at any one time.

This is **Exhibit "II"** referred to in the
Affidavit of **JEANNINE RITCHOT**
Affirmed before me at the City of Ottawa,
in the Province of Ontario,
this 15th day of January 2015.

A Commissioner for Taking Affidavits

June 20, 2011

Dear Sir/Madam,

In response to concerns heard from Canadians, the Government of Canada announced on June 17, 2011 that it is considering improvements to Health Canada's Marihuana Medical Access Program. The proposed improvements would reduce the risk of abuse and exploitation by criminal elements and keep our children and communities safe.

As a program participant, Health Canada would like to hear from you about the proposed improvements to the Program. The details of this proposal are outlined in a consultation document titled: *Proposed Improvements to Health Canada's Marihuana Medical Access Program* available on the Health Canada website at:
http://www.hc-sc.gc.ca/dhp-mps/consultation/marihuana/_2011/program/index-eng.php

You are invited to submit comments on the proposed improvements to the Program on or before July 31, 2011. Comments may be provided, in English or French, using the feedback form on the website listed above, or by e-mail, fax, or mail using the coordinates provided below.

By E-mail: consultations-marihuana@hc-sc.gc.ca

By Fax: (613) 946-4224

By Mail: Marihuana Consultations
Controlled Substances and Tobacco Directorate
Health Canada
Mail Room, Federal Records Centre - Bldg 18
1st Floor, 161 Goldenrod Driveway, Tunney's Pasture
Ottawa, ON K1A 0K9

During the strike by Canada Post, Health Canada would like to remind its clients to use alternative means such as a licensed courier, email, or fax to submit comments to the Department.

Please note that in order to ensure that the Marihuana Medical Access Division can continue to process applications or call-back requests in a timely manner, individuals who call the toll-free number to provide comments on the proposed improvements will be redirected to the coordinates above.

Finally, please note that the process for applying for an authorization to possess and/or a licence to produce marihuana for medical purposes under the *Marihuana Medical Access Regulations* will remain the same until any changes to the Program are in place.

Sincerely,

Controlled Substances and Tobacco Directorate
Health Canada