I, Jan Bouwen de Snaijer, civil law notary, practising in Amsterdam (the "**Notary**") certify that on 13 October 2014, in my presence:

(a) **Hendrik J. van den Bos**, a Counsel in the law firm of Hogan Lovells International LLP, Keizersgracht 555, 1017 DR Amsterdam, holder of passport of the Kingdom of the Netherlands number NX706J745 (the "**Appearer**") signed the affidavit to which this notarial certificate is attached (the "**Document**"); and

(b) the Appearer put his oath into my hands (*heb ik de eed afgenomen*) and under the oath the Appearer declared (*heeft onder ede verklaard*) that the contents of the Document are true and correct.

Signed in Amsterdam on 13 October 2014.

J.B. de Snaijer,

Civil law notary

Court File No.: T-2030-13

FEDERAL COURT

BETWEEN:

NEIL ALLARD
TANYA BEEMISH
DAVID HEBERT
SHAWN DAVEY

Plaintiffs

and

HER MAJESTY THE QUEEN IN RIGHT OF CANADA

Defendant

AFFIDAVIT OF HENDRIK J. VAN DEN BOS

I, Hendrik J. van den Bos, a Counsel in the law firm of Hogan Lovells International LLP, Keizersgracht 555, 1017 DR Amsterdam, the Netherlands, SWEAR THAT:

1. I am a Counsel in Hogan Lovells International LLP, resident in the firm's Amsterdam office. I am an attorney admitted to practice law in the Netherlands. I have personal knowledge of the matters hereinafter deposed to by me, except where same are stated to be based on information and belief and where so stated I verily believe them to be true.

2. I have been retained by the Attorney General of Canada in the above proceeding to provide an expert report for the Court on the regulation of medical marihuana in the Netherlands. Attached at **Exhibit "A"** is my expert report, dated 10 October 2014

3. On June 3, 2014, the Attorney General of Canada provided me with an instruction letter to complete my expert report. Attached as **Exhibit "B"** is a copy of the instruction letter.

4. Further, on June 3, 2014, I was provided with a copy of the Code of Conduct for Expert Witnesses. Attached as **Exhibit "C"** is a signed copy of the Certificate Concerning Code of Conduct for Expert Witnesses.

5. Attached as **Exhibit "D"** is a copy of my current Curriculum Vitae.

Hein van den Bos
Dated 13 October 2014

Exhibit A

Hogan Lovells

MEMORANDUM

FROM Hein van den Bos **TELEPHONE** +31(0)20-55 33 675
AMS

DATE 10 October 2014

SUBJECT Exhibit A: expert report from Hein van den Bos regarding the regulation of cannabis for medical use in the Netherlands

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Background to regulation of cannabis for medical use in the Netherlands

1. The Netherlands is a party to the Single Convention on Narcotic Drugs (New York, 30 March 1961) as amended by the Protocol amending the Single Convention on Narcotic Drugs (25 March 1972) (hereinafter referred to as the "Single Convention"). The Single Convention was ratified in the Netherlands by law of 2 March 1964.[1] The protocol was ratified in the Netherlands by law of 19 November 1986.[2]

2. The implementation into Dutch law of the Single Convention on Narcotic Drugs is laid down in the Controlled Substances Act ("*Opiumwet*", hereinafter referred to as "CSA").

3. The CSA prohibits the import, export, growth, manufacturing, processing, sale, supply, transport and having present of inter alia, cannabis.[3] I will use the wording "cannabis" instead of "marihuana" as the wording "cannabis" is used in the CSA and as the Dutch legislator and competent authorities use the wording "cannabis" in order to, as the legislator noted, make a distinction between the use for medical purposes and the use for recreational purposes, for which it mentions that the words "marihuana", "hash" or "weed" are commonly used.[4]

4. Cannabis or hemp ("*hennep*"), defined as every part of the plant of the species Cannabis (hemp), from which the wax has been removed, excluding the seeds, is listed as a controlled substance in List II to the CSA. List II to the CSA is the least restrictive List.
Violation of this prohibition of the CSA constitutes a criminal offense and may be punished by criminal penalties.

5. In 2001, the Office for Medicinal Cannabis ("*Bureau voor Medicinale Cannabis*", hereinafter referred to as "BMC") of the Ministry of Health was established. The Minister of Health is the national agency in the Netherlands within the meaning of Article 28 read in conjunction with Article 23 of the Single Convention. The Minister of Health is assigned with the task to supply cannabis for medical use and the Minister of Health has appointed the BMC to perform these tasks on the Minister's behalf.[5] The BMC's tasks relate to scientific research regarding the medical use of cannabis and supply of cannabis for medical use to pharmacists in

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[1] *See* Staatsblad 1964, 111.
[2] *See* Staatsblad 1986, 720.
[3] *See* CSA, Article 3.
[4] See Kamerstukken II, 2001-2002, 27 874, nr. 6.
[5] *See* Kamerstukken II, 2000-2001, 27 400 XVI, nr. 60.

order for the pharmacists to be able to dispense cannabis for medical use to patients upon a physician's prescription.

6. In her letter to parliament of 19 October 2001, the Minister of Health explained her policy initiative to allow medical prescription of cannabis.[6] The Minister noted that there was a demand in society for cannabis for medical use. She noted that in practice patients used cannabis for medical purposes and that in several instances physicians prescribed and pharmacists dispensed cannabis to patients, despite the fact that this was in violation of the law at the time. The Minister considered that this situation was undesirable, because (i) it was illegal, (ii) there was often no medical support or treatment for patients using cannabis for medical purposes, (iii) there was no control of the quality and composition of the cannabis and (iv) there was no control of the distribution of the cannabis. The already established BMC would be assigned with the task to arrange for the growth of cannabis for medical use as well as with the wholesale distribution, i.e. supply to pharmacists. The statutory framework for controlled substances of the CSA was subsequently amended to allow the prescription of cannabis for medical purposes. Since 1 September 2003 cannabis has been made available in the Netherlands through the BMC for the treatment of patients.[7]

The process by which individuals become authorized to consume medical marihuana

7. It follows from the CSA,[8] read in conjunction with Annex 1 under b of the Controlled Substances Act Decree ("*Opiumwetbesluit*", hereinafter referred to as "CSAD"), that physicians may prescribe cannabis to patients. There is no specific process that must be followed for a physician to be allowed to prescribe cannabis to a patient. The physician's prescription authorizes the patient to consume cannabis for the medical use prescribed by the physician.

The amount of medical marihuana an individual user is permitted to possess and/or consume and how those amounts are determined

8. When prescribing cannabis to a patient, the physician must include in the prescription the amount of cannabis that is being prescribed.[9] The prescription must contain a clear description of the way the cannabis should be used, including a description of the maximum amount of cannabis that may be used in a period of 24 hours.[10]

How individual dosages are determined

9. There are no statutory restrictions regarding the dosage of cannabis for medical use. The physician determines the dosage for an individual patient. The BMC has provided recommendation that the initial dosage should be low and that it can subsequently be increased.

10. The BMC recommends the oral use of one cup of tea (0.2 liter) in the evening. The BMC recommends preparing the tea by boiling 0.5 grams of cannabis in 0.5 liter of water. The BMC notes that on average it takes two weeks before the maximum effect is reached and that if after 1-2 weeks the effect is insufficient or unsatisfactory one additional cup (0.2 liter) can be taken in the morning. The BMC further notes that the dosage can be slowly increased if necessary.[11]

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[6] *See* Kamerstukken II, 2001-2002, 28 000 XVI, nr. 10.
[7] *See* Kamerstukken II, 2004-2005, 24 077, nr. 140.
[8] *See* Controlled Substances Act, Article 4.
[9] *See* CSAD, Article 3(2)(b),
[10] *See* CSAD, Article 3(3)(b).
[11] *See* Ministerie van Volksgezondheid, Welzijn en Sport, Bureau voor Medicinale Cannabis, *Medicinale Cannabis: Informatie voor medische en farmaceutische beroepsbeoefenaren*, versie maart 2014 and CIBG, Ministerie van Volksgezondheid, Welzijn en Sport, *Medicinale Cannabis: Informatiebrochure voor artsen en apothekers*.

11. Alternatively the BMC recommends the inhalation once or twice daily of a few puffs at the start of treatment. The BMC notes that in principle it advises against smoking the cannabis for medical use and that nebulizers can be used for the inhalation.[12]

12. According to information available on the BMC's website, the following four types of cannabis for medical use are currently available:[13]

	% dronabinol (THC)	% cannabidiol (CBD)
Bedrobinol	Approx. 13.5	<1
Bedrocan	Approx. 22	<1
Bediol	Approx. 6.3	Approx. 8
Bedica	Approx. 14	<1

13. These types of cannabis for medical use are available to patients through the pharmacist and upon a prescription from a physician and may thus legally be provided within the conditions set pursuant to the CSA and CSAD. No marketing authorisation has however been granted for these forms of cannabis as a medicinal product ("*geneesmiddel*") pursuant to the Dutch Medicines Act ("*Geneesmiddelenwet*") in accordance with the EU regulatory framework for medicinal products laid down in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

Restrictions, if any, on the forms of medicinal marihuana that may be consumed

14. The four available forms of cannabis for medical use all consist of the dried flower buds of the female cannabis plant. Of those available products, Bediol is the only one that differs in form: the dried flower buds have been crushed. Although the CSA and the CSAD do not contain restrictions on the forms of cannabis for medical use that may be produced, sold and consumed, the only forms of cannabis that are legally available in the Netherlands for medical use are dried cannabis, i.e. no oils or extracts.

15. The BMC recommends that cannabis for medical use should be consumed either orally in the form of tea or by inhalation for which a nebulizer may be used.[14]

Restrictions, if any, on the medical conditions for which the consumption of medical marihuana may be authorized

16. There are no statutory restrictions on the medical conditions for which the consumption of cannabis may be authorized. The physician is free to decide in each specific case whether he or she believes the medical use of cannabis is appropriate for an individual patient. The BMC however issued an information document for medical and pharmaceutical healthcare professionals, which states that treatment with cannabis is only appropriate if regular treatment and authorised medicinal products are not effective or are related to too many adverse reactions.

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[12] Ibidem.

[13] *See* www.cannabisbureau.nl/MedicinaleCannabis/

[14] *See* Ministerie van Volksgezondheid, Welzijn en Sport, Bureau voor Medicinale Cannabis, *Medicinale Cannabis: Informatie voor medische en farmaceutische beroepsbeoefenaren,* versie maart 2014, and CIBG, Ministerie van Volksgezondheid, Welzijn en Sport, *Medicinale Cannabis: Informatiebrochure voor artsen en apothekers.*

According to the BMC, sufficient evidence is available that cannabis for medical use can be effective in the following situations:

- Disorders of spasticity in combination with pain (multiple sclerosis, spinal cord injury);
- Nausea and vomiting, as a result of inter alia chemotherapy or radiotherapy;
- In addition to HIV combination therapy or in addition to medication for hepatitis C;
- Chronic pain (in particular of a neurogenic nature);
- Gilles de la Tourette syndrome;
- Palliative for cancer and Aids inter alia in order to arouse the appetite, reduce pain and prevent weight loss and nausea;
- Therapy resistant glaucoma.

17. The BMC further notes that experience of patients and physicians indicate the potential clinical efficacy of cannabis for medical use for a range of other conditions. The BMC also notes that cannabis for medical use does not cure the disease but that it may help to reduce the symptoms of the disease and/or to reduce adverse reactions of other medication.[15]

Whether the production of medical marihuana in residences is permitted and, if not, how medical marihuana is supplied to users

18. The Dutch Minister of Health has a duty of care to ensure that sufficient cannabis is grown in the Netherlands for scientific research regarding medical use or for the manufacturing of medicinal products.[16]

19. The growth of cannabis is prohibited, unless one holds an exemption from the Minister of Health.[17] The Minister of Health may grant an exemption from the prohibition to grow cannabis if the applicant needs such an exemption in order to produce cannabis on the basis of an agreement with the Minister of Health.[18]

20. The agreement between the State of the Netherlands (Minister of Health) and the entity that grows the cannabis, shall contain an obligation for the entity that grows the cannabis to sell and deliver the grown cannabis exclusively to the Minister of Health and to destroy any remaining cannabis.[19] The Policy rules on exemptions to the Controlled Substances Act ("*Beleidsregels opiumwetontheffingen*") contain further requirements for the growth of cannabis for medical use, including for example requirements regarding personnel, premises, machinery, seed, soil, fertiliser, irrigation, harvest and first processing which includes for example washing, cutting, freezing and drying. These requirements were derived from the Good Agricultural Practice of the Working Group on Herbal Medicinal Products of the European Medicines Agency. The Policy rules on exemptions to the Controlled Substances Act provide that these requirements concerning the growth of medical cannabis should be read in relation to the European Good Manufacturing Practice (GMP) Guidelines.

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[15] *See* Ministerie van Volksgezondheid, Welzijn en Sport, Bureau voor Medicinale Cannabis, *Medicinale Cannabis: Informatie voor medische en farmaceutische beroepsbeoefenaren*, versie maart 2014, and CIBG, Ministerie van Volksgezondheid, Welzijn en Sport, *Medicinale Cannabis: Informatiebrochure voor artsen en apothekers*.
[16] *See* CSA, Article 8h.
[17] *See* CSA, Article 3.
[18] *See* CSA, Article 8(2).
[19] *See* CSA, Article 8i(4).

21. The Minister of Health has a statutory monopoly right to sell and supply cannabis, which monopoly was introduced into Dutch law as a result of the Single Convention.[20]

22. The Minister of Health has appointed the BMC to perform these tasks on his behalf and the BMC can thus supply cannabis for medical use to pharmacists. Pharmacists may dispense cannabis to patients upon a medical prescription.[21]

23. The production of cannabis for medical use in residences is thus not permitted.

24. Pursuant to criminal enforcement policy, the priority for criminal prosecution of illegal growth of cannabis lies with commercial growth.[22] The growth of up to five cannabis plants by an adult for personal use is considered to be non-commercial if the growth does not have a commercial purpose and if the growth is not considered commercial on the basis of the way it is performed (e.g. in view of lighting, heating, ventilation, irrigation etc.). If the growth is considered non-commercial it does not have priority for criminal prosecution, but there is no statutory legal basis allowing for such small-scale growth of cannabis. In a letter to parliament, the Minister of Security and Justice confirmed in April 2014 that any form of growth of cannabis, except by the BMC, is and remains illegal.[23]

Conclusion

25. The growth and supply of cannabis is prohibited in the Netherlands. By way of exception, physicians may prescribe cannabis for medical use to patients and pharmacists may subsequently dispense the cannabis to the patient. The cannabis for medical use may only be grown by a company that has an agreement with the Minister of Health.

[20] *See* CSA, Article 8i(5).
[21] *See* CSAD, Article 4.
[22] *See* Indication Controlled Substances Act ("*Aanwijzing Opiumwet*").
[23] *See* Kamerstukken II, 2013-2014, 24 077, nr. 317.

Exhibit B

Department of Justice Canada
Ministère de la Justice Canada

900-840 Howe Street
Vancouver, British Columbia
V6Z 2S9

Telephone: 604-666-4304
Facsimile: 604-775-5942
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June 3, 2014

By Email to: hein.vandenbos@hoganlovells.com

Heins van den Bos
Hogan Lovells International, LLP
Keizersgracht 555
1017 DR Amsterdam
Netherlands
Phone: 31-20-55-33-600
Fax: 31-20-55-33-777

Re: ***Allard et al. v. Her Majesty the Queen in Right of Canada***
Instruction Letter for Expert Report

Thank you for agreeing to provide the Attorney General of Canada ("AGC") with an expert report in the matter of *Allard et al. v. Her Majesty the Queen in Right of Canada*. As discussed, this Federal Court litigation involves a constitutional challenge to the *Marihuana for Medical Purposes Regulations* (the "MMPR").

Background Information

The plaintiffs in this litigation, all of whom are medical marihuana users, are challenging the constitutionality of the MMPR on the basis that they cause several unjustified violations of their rights to liberty and security of the person under the Canadian *Charter of Rights and Freedoms*.

The plaintiffs' constitutional challenge in *Allard* focuses on four aspects of the MMPR that differ from the old medical marihuana regime: (1) the elimination of personal cultivation of marihuana in favour of requiring approved individuals to purchase from licensed producers; (2) the restriction that licensed producers may not cultivate marihuana in dwelling places or outdoor areas; (3) the limit on possession of marihuana to either 150g or 30 times the amount prescribed for daily consumption by the individual's medical practitioner, whichever is less; and (4) the failure of the MMPR to permit the production and possession of non-dried marihuana such as cannabis oils, salves, tinctures and edibles.

The plaintiffs have obtained an injunction from the Court that permits them to continue personal production of medical marihuana until the constitutionality of the MMPR is decided by the Court.

The AGC is the defendant and it is the AGC's position that the current medical marihuana regime is constitutionally sound, a position that will be defended by legal counsel on behalf of the AGC.

Facts and Assumptions

The facts alleged by the plaintiffs are outlined in the Amended Notice of Civil Claim which is enclosed.

Questions for Your Expert Report

Please address the following matters in your expert report:

Discuss the law in the Netherlands with respect to the use of medical marihuana and, in particular, the following issues:

a) The process by which individuals become authorized to consume medical marihuana;
b) The amount of medical marihuana an individual user is permitted to possess and/or consume and how those amounts are determined;
c) How individual dosages are determined;
d) Restrictions, if any, on the forms of medical marihuana that may be consumed;
e) Restrictions, if any, on the medical conditions for which the consumption of medical marihuana may be authorized;
f) Whether the production of medical marihuana in residences is permitted and, if not, how medical marihuana is supplied to users.

Format of Your Expert Report

Your report must be prepared in accordance with the Federal Courts Rules. As such, we ask that you do the following within the body of your report:

1. Set out the issues to be addressed in the report;
2. Describe your qualifications on the issues to be addressed;
3. Attach your current curriculum vitae as a schedule to the report;
4. Attach this letter of instruction as a schedule to the report;
5. Provide a summary of your opinions on the issues addressed in the report;
6. Set out the reasons for each opinion that is expressed in the report;
7. Attach any publications or other materials specifically relied on in support of the opinions;
8. If applicable, provide a summary of the methodology used in the report;
9. Set out any caveats or qualifications necessary to render the report complete and accurate, including those relating to any insufficiency of data or research and an indication of any matters that fall outside of your field of expertise; and,
10. Particulars of any aspect of your relationship with a party to the proceeding or the subject matter of your report that might affect your duty to the Court.

Please number each paragraph of your report as this will aid us in referring to your report in Court.

Please sign and date your report.

Duty to the Court

As an expert witness, you have a duty to the Court which is set out in the attached Code of Conduct for Expert Witnesses. Please carefully review this Code of Conduct and, after doing so, sign the attached Certificate and send it back to us.

Due Dates and Procedural Matters

We are required to file our expert reports on or before November 1, 2014. The trial has been set for three weeks commencing February 23, 2015. You may be required to attend the trial for cross-examination and, if so, we will attempt to accommodate your schedule to the extent possible.

Please keep all correspondence pertaining to this assignment in a separate "Expert Witness Report" folder.

We look forward to receiving a draft of your report the **first week of September, 2013**.

Please do not hesitate to contact me by telephone at 604-666-4304 if you require further information or have questions regarding the foregoing.

Yours truly,

BJ Wray
Counsel

Enclosures: Certificate for Expert Witnesses; Code of Conduct for Expert Witnesses; Amended Notice of Civil Claim

Exhibit C

Court File No. T-2030-13

FEDERAL COURT

BETWEEN:

NEIL ALLARD
TANYA BEEMISH
DAVID HEBERT
SHAWN DAVEY

PLAINTIFFS

and

HER MAJESTY THE QUEEN IN RIGHT OF CANADA

DEFENDANT

Certificate Concerning Code of Conduct for Expert Witnesses

I, Hein van den Bos, having been named as an expert witness by the Defendant, Her Majesty the Queen in Right of Canada, certify that I have read the Code of Conduct for Expert Witnesses set out in the schedule to the *Federal Courts Rules* and agree to be bound by it.

Date: 10 Oct., 2014

Hein van den Bos
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Phone: 31-20-55-33-600
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Exhibit D

Hogan Lovells

Exhibit D: CV

Hein van den Bos

Counsel, Amsterdam

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hein.vandenbos@hoganlovells.com

Hein van den Bos specialises in European and Dutch regulatory law in the Life Sciences sector (pharmaceuticals, biotechnology, medical devices and food). He assists companies in this sector with advice, litigation and contracts in matters relating to, e.g. marketing authorisations, product classification, regulatory data protection, cross-border EU regulatory litigation, pharmacovigilance, clinical trials, advertising and compliance, pricing and reimbursement, privacy and inspections and enforcement by the competent authorities. He regularly lectures and publishes about these topics.
Hein also has experience in advising about regulation of controlled substances in the Netherlands, for example concerning prescription, pharmacy dispensing, distribution and promotion of controlled substances.

Hein obtained a law degree from Groningen University in 2003 and graduated in International Relations at the same university in 2004. Before joining Hogan Lovells in 2011, he had worked as a Life Sciences regulatory lawyer with Dutch law firm NautaDutilh since 2004.

Representative Experience

- Hein assists innovative pharmaceutical companies with Dutch and European law advice and cross-border litigation throughout the European Union concerning marketing authorisations and regulatory data protection.
- Hein assists pharmaceutical companies with setting up and implementing compliance programs concerning pharmaceutical advertising, anti-corruption and interaction with healthcare professionals.
- Hein advises on pharmacovigilance related questions and drafts and negotiates safety data exchange agreements.

Practices

Health
Food, Drug, Medical Device and Agriculture
Government Regulatory
Global Policy Advocacy

Industry Sectors

Life Sciences and Healthcare
Medical Devices
Pharmaceutical and Biotechnology

Education

Master of Laws, University of Groningen, 2003
Master of Arts, International Relations, University of Groningen, 2004

Awards/Rankings

Who's Who Legal, Life Sciences, 2012, 2013, 2014

Memberships

Dutch Association for Pharmacy and Law

Languages

Dutch
English
French
Spanish
German