



The YEAR IN REVIEW

AN ANNUAL SURVEY OF INTERNATIONAL LEGAL DEVELOPMENTS AND
PUBLICATION OF THE ABA INTERNATIONAL LAW SECTION

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International Legal Developments Year in Review: 2020

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JASON S. PALMER AND KIMBERLY Y. W. HOLST

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South Asia/Oceania & India

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Life Sciences & Health Law

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This article examines selected international legal developments relating to life sciences and health law in 2020.

I. Australia

A. VOLUNTARY ASSISTED DYING

The discussion of voluntary assisted dying continues to evolve in Australia.² Victoria was the first state to pass voluntary assisted dying laws in 2019. The Voluntary Assisted Dying Act 2017 became effective June 19, 2019.³ This Act provides a safe legal framework for people who are suffering to end their lives.⁴ To avoid death tourism, the 2020 amendments of this law require that the person seeking voluntary assisted dying to be an Australian citizen or permanent resident and ordinarily be a resident in Victoria for the last 12 months.⁵ Western Australia passed legislation this year to enable voluntary assisted dying as a choice as well.⁶ This legislation is currently in its implementation phase and will most likely be enacted in mid-2021.⁷ Queensland is set to vote on voluntary assisted dying soon, and the legislation is currently undergoing consultation.⁸ Queensland will have a “conscience vote,” where elected politicians can vote with their “conscience”

1. Contributors to the 2020 YIR Life Sciences and Health Law Committee are: Adalberto López López (CAAM Legal, Mexico), Yevgeniya Ocheretko (Arzinger Law Firm, Ukraine), Carly M. Toepke, editor (University of Texas School of Law), Arina Zadorozhna (Arzinger Law Firm, Ukraine) José Alan Zamarripa Miramontes (CAAM Legal, Mexico) with special thanks to Rocky Ruperto (Avant Mutual, Australia).

2. *Voluntary Assisted Dying*, VIC. STATE GOV'T, <https://www2.health.vic.gov.au/hospitals-and-health-services/patient-care/end-of-life-care/voluntary-assisted-dying> (last visited. Nov. 4, 2020).

3. *Voluntary Assisted Dying Act 2017* (Vic), 61 (Austl.), amended 19 June 2020.

4. *Voluntary Assisted Dying*, *supra* note 2.

5. *Voluntary Assisted Dying Act 2017* (Vic) pt 2 ¶ 9(1) (Austl.).

6. *Voluntary Assisted Dying*, GOV'T OF WA DEP'T OF HEALTH, <https://www2.health.wa.gov.au/voluntaryassisteddying> (last visited. Nov. 4, 2020).

7. *Id.*

8. Ben Smee, *Queensland Election: Labor Pledges to Allow Vote on Voluntary Assisted Dying*, THE GUARDIAN (Oct. 18, 2020), <https://www.theguardian.com/australia-news/2020/oct/19/queensland-election-labor-pledges-to-allow-vote-on-voluntary-assisted-dying>.

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rather than toeing the party line.⁹ Politicians normally make a conscience vote on topics that are heavily ethical or controversial, especially when there are active campaigns on both sides of the issue.

B. MANDATORY HEALTH PRACTITIONER REPORTING

Under the Health Practitioner Regulation National Law,¹⁰ healthcare practitioners are required to notify regulators of certain types of conduct of a healthcare practitioner who is their patient.¹¹ In 2020, the law changed to make the hurdle “higher” for doctors treating other health professionals (not only doctors but nurses, psychologists, etc.), so that they are less likely to be obligated to report a health practitioner being treated to the regulator if they are seeking help (because they are no longer “putting the public at substantial risk of harm”).¹² This is a positive change to the National Law in that it allows the treating practitioner to consider the treatment as mitigating the risk, and therefore not meet the threshold to report their patient practitioner.¹³ One risk that this change averts is that health practitioners avoid seeking treatment in fear that they will be reported by their treating provider to the regulator.¹⁴

II. Mexico

A. CANNABIS REGULATION¹⁵

On July 27, 2020, the Secretary of Health (SSA) submitted a draft of a cannabis medical use regulation, namely Rules for the Sanitary Control of the Production, Research and Use of Medical Cannabis and its Pharmacological Derivates (*Reglamento en Materia de Control Sanitario para la Producción, Investigación y Uso Medicinal de la Cannabis y sus Derivados Farmacológicos; Medical Use Rules*) to the National Commission for Regulatory Improvement (CONAMER).¹⁶ The Medical Use Rules follow the Mexican Supreme Court’s mandate to regulate medical cannabis,¹⁷ although its publication has been delayed since mid-2017.

9. *Id.*

10. *Health Practitioner Regulation National Law Act*, 2009 (Cth) (Austl.).

11. *Mandatory Notifications About Health Practitioners*, AVANT (Mar. 16, 2020), <https://www.avant.org.au/Resources/Public/Mandatory-notifications-about-health-practitioners/>.

12. *Id.*

13. Rocky Ruperto, Hannah Shiel & Ushma Narsai, *Where is the Harm? Mandatory Reporting Requirements for Treating Practitioners*, 21 MED. TODAY 55–58 (2020).

14. *Id.*

15. Information current through October 21, 2020.

16. Luis Armendariz, *Mexico Cannabis Update #19*, CAAM LEGAL (Aug. 10, 2020), <https://www.caamlegal.mx/web/wp-content/uploads/2020/09/MexicoCannabisUpdate-19.pdf>.

17. Suprema Corte (@SCJN), TWITTER (Aug. 14, 2019, 3:28 PM), <https://twitter.com/SCJN/status/1161751594330779648> (“La Corte amparó a un niño con discapacidad que necesita THC para mejorar su salud. Se le ordenó a la Secretaría de Salud armonizar las disposiciones

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On September 9, 2020, the deadline passed again for drafting medical cannabis rules in Mexico.¹⁸ Nevertheless, the competent authority published no official communication by that date. On September 21, 2020, Margarita Garfias (whose son's case motivated the mentioned Supreme Court's mandate) was notified that the deadline was extended an additional 70 business days.¹⁹

The Medical Use Rules' object includes the regulation of cannabis-based medication. Medication is defined as "[a]ny substance or mixture of substances of natural or synthetic origin that has therapeutic, preventive, rehabilitative, or palliative care effects and that is presented in pharmaceutical form and identified as medication by its pharmacological activity, physical, chemical, and biological characteristics containing cannabis or its pharmacological derivatives."²⁰ Under these rules, authorized doctors will prescribe medication, registering any cannabis-related prescription to patients, following traceability principles.²¹

Furthermore, it is important to note that the Medical Use Rules do not include any specific regulation for hemp products, such as CBD oil or less than one percent THC tinctures.²² Also, no "pharmaceutical form" or "pharmacological activity" definition has been provided within the Medical Use Rules, nor in the Mexican General Health Law (*Ley General de Salud; LGS*)²³ and/or its ancillary regulation. This gap results in a legal loophole for CBD products, such as oil and tinctures, which usually are not required to be treated as a medication, due to their general palliative use.

Additionally, medical cannabis use is actually regulated by articles 234, 235 through 245, and 290 of LGS, and there is no clear specification of whether CBD or THC shall be considered as a pharmaceutical compound.²⁴ This results in continuing uncertainty regarding these products. Therefore, it is unclear if 1% THC products will be subject to the Medical Use Rules, and consequently, to prior medical prescription.

If these products are considered to be medication by Federal Commission for the Protection of Sanitary Risks (COFEPRIS) or SSA in the near future,

sobre el uso terapéutico de la cannabis en un plazo de 180 días hábiles y garantizarle un tratamiento médico integral.”).

18. *Rules for Medical Cannabis in Mexico*, HOBAN LAW GRP. (Sept. 10, 2020), <https://hoban.law/2020/09/rules-for-medical-cannabis-in-mexico/>.

19. Margarita Garfias (@Mar_Garfias), TWITTER (Sept. 23, 2020 9:27 PM), https://twitter.com/Mar_Garfias/status/1308956121101672451 (“El día de ayer se nos notificó lo que expongo en el video, @COFEPRIS @SSalud_mx siguen vulnerando derechos de las y los pacientes.”).

20. *Draft Regulations Published for the Regulation of Cannabis (Marijuana) in Mexico*, GREENBERG TRAURIG (Aug. 26, 2020), <https://www.gtlaw.com/en/insights/2020/8/draft-regulations-published-for-the-regulation-of-cannabis-marijuana-in-mexico#main-content/>.

21. *Id.*

22. Armendariz, *supra* note 16.

23. *Ley General de Salud [LGS]*, *Diario Oficial de la Federación [DOF]* 07-02-1984, últimas reformas DOF 19-02-2020 (Mex.).

24. *Id.*

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access to <1% THC products will be burdened by legal provisions.²⁵ Such measures will probably encourage the use of illegal CBD products (currently found in the market), compromise users' health, and diminish products' quality.

This cannabis-based products classification loophole will force importers and/or producers to file a preliminary, non-binding technical classification request before COFEPRIS prior to a product's import or sale, to know the sanitary treatment each product shall have.²⁶

The regulation of cannabis and its derivatives for medical purposes has taken longer than legally foreseen as well as what patients and users want. The next months will show the outcome of this important industry for Mexico and the rest of the world.

III. New Zealand

A. VOLUNTARY ASSISTED DYING

New Zealand just had a referendum on Voluntary Assisted Dying—the first country in the world to do so.²⁷ The binding New Zealand End of Life Choice referendum was held on October 17, 2020.²⁸ This referendum was on the question of whether the End of Life Choice Act 2019 should be enforced, legalizing voluntary euthanasia for those terminally ill with less than six months to live.²⁹ Further requirements for voluntary euthanasia/voluntary assisted dying are that the person is 18 years or older, is a New Zealand citizen or permanent resident, is in an advanced state of irreversible decline, experiences unbearable suffering that cannot be relieved, and is competent to make an informed decision.³⁰ The final result of the referendum was that approximately sixty-five percent of voters supported the End of Life Choice Act being enforced.³¹

B. MARIJUANA

A different October 2020 referendum regarding the Cannabis Legalisation and Control Bill failed 50.7% to 48.4%.³² The Bill's purpose was to reduce cannabis-related harm to individuals, families, and

25. Armendariz, *supra* note 2.

26. *Id.*

27. End of Life Choice Act 2019, ¶ 2 (N.Z.); Charlotte Graham-McLay, *New Zealand to Vote in Referendum on Euthanasia*, THE GUARDIAN (Nov. 13, 2019), <https://www.theguardian.com/society/2019/nov/13/new-zealand-to-vote-in-referendum-on-euthanasia-cannabis>.

28. *2020 New Zealand Euthanasia Referendum*, WIKIPEDIA (Mar. 20, 2021), https://en.wikipedia.org/wiki/2020_New_Zealand_euthanasia_referendum.

29. End of Life Choice Act, p 1, s 5 (N.Z.).

30. *Id.*

31. *Referendum Results*, ELECTIONS, https://electionresults.govt.nz/electionresults_2020/referendums-results.html (last visited Nov. 12, 2020).

32. *Id.*