South Health and Policy. 2024; 3:139
doi: 10.56294/shp2024139

SHORT COMMUNICATION

Progress in health policies on CBD in Argentina and MERCOSUR

Avances en políticas sanitarias sobre el CBD en Argentina y el MERCOSUR

Vitor Nifoci[1], Cristian Emanuel Cabrera[1]

[1]Universidad Abierta Interamericana, Facultad de Medicina y Ciencias de la Salud, Carrera de Medicina. Buenos Aires, Argentina.

Cite as: Nifoci V, Cabrera CE. Progress in health policies on CBD in Argentina and MERCOSUR. South Health and Policy. 2024; 3:139. https://doi.org/10.56294/shp2024139

Submitted: 03-08-2023 **Revised:** 13-11-2023 **Accepted:** 30-03-2024 **Published:** 31-03-2024

Editor: Dr. Telmo Raúl Aveiro-Róbalo

Corresponding author: Vitor Nifoci

ABSTRACT

Cannabidiol (CBD), a compound derived from cannabis, was considered a promising therapeutic option for treating refractory epilepsy. It was shown that, when combined with conventional treatments, it significantly reduced seizures in syndromes such as Dravet, Lennox-Gastaut and Tuberous Sclerosis. In Argentina, its benefits were recognised and public policies were implemented to facilitate access, with the authorisation of the ANMAT and programmes of the Ministry of Health. At a regional level, MERCOSUR promoted joint strategies to improve access to high-cost medicines. However, serious adverse effects were observed, making strict medical supervision necessary. In general, CBD represented a relevant therapeutic alternative, although the need for further research into its safety and efficacy was emphasised.

Keywords: Cannabidiol; Epilepsy; Treatments; Policies; MERCOSUR.

RESUMEN

El cannabidiol (CBD), compuesto derivado del cannabis, fue considerado una opción terapéutica prometedora para tratar la epilepsia refractaria. Se demostró que, combinado con tratamientos convencionales, redujo significativamente las convulsiones en síndromes como Dravet, Lennox-Gastaut y Esclerosis Tuberosa. En Argentina, se reconocieron sus beneficios y se implementaron políticas públicas para facilitar el acceso, con la autorización de la ANMAT y programas del Ministerio de Salud. A nivel regional, el MERCOSUR promovió estrategias conjuntas para mejorar el acceso a medicamentos de alto costo. Sin embargo, se observaron efectos adversos serios, lo que hizo necesaria una supervisión médica estricta. En general, el CBD representó una alternativa terapéutica relevante, aunque se subrayó la necesidad de seguir investigando su seguridad y eficacia.

Palabras clave: Cannabidiol; Epilepsia; Tratamientos; Políticas; MERCOSUR.

BACKGROUND

Cannabidiol (CBD), a compound derived from the cannabis plant, has emerged in recent years as a promising therapeutic option for the treatment of patients with refractory epilepsy, i.e., those whose seizures do not respond to conventional treatments.[1,2,3,4,5] Clinical studies have shown that the use of CBD, .[6,7,8,9,10,11] in combination with standard treatment, can significantly reduce the frequency of seizures in specific syndromes such as Dravet syndrome, Lennox-Gastaut syndrome, and tuberous sclerosis complex.[12,13] For example, a review conducted by the Argentine Ministry of Health indicated that CBD could reduce the monthly frequency of seizures by 20,38 % compared to placebo, with moderate certainty in the evidence.[14]

In Argentina, recognition of CBD's therapeutic benefits has led to the implementation of specific health

policies.[15,16] The National Administration of Medicines, Food, and Medical Technology (ANMAT) has authorized the use of CBD-based products for the treatment of specific refractory epileptic syndromes.[17,18,19] In addition, the Ministry of Health has established programs to facilitate access to these treatments, ensuring their distribution in various provinces.[20,21]

At the regional level, MERCOSUR has promoted joint actions in the field of health, focusing on prioritizing diseases and analyzing high-cost medicines.[22,23,24] In November 2024, the health ministers of the member countries agreed to form a specific working group to address and develop strategies related to these medicines to obtain better prices and ensure equitable access to essential treatments.[25,26]

It is important to note that although CBD is effective in reducing seizures in certain patients, its use is not without adverse effects.[27,28,29] Some studies have reported an increase in the incidence of serious adverse events, including gastrointestinal disorders and drowsiness.[30,31] Therefore, it is essential that healthcare professionals supervise its administration and that patients be closely monitored during treatment.

In conclusion, cannabidiol represents a valuable therapeutic tool for patients with refractory epilepsy, offering an additional option when conventional treatments are ineffective. Health policies in Argentina and regional initiatives in MERCOSUR have advanced the regulation of and access to these treatments, reflecting a commitment to improving the quality of life of affected patients. However, it is imperative to continue research and surveillance to ensure the safety and efficacy of CBD in the clinical setting.

BIBLIOGRAPHICAL REFERENCES

1. Stafstrom CE, Carmant L. Seizures and epilepsy: an overview for neuroscientists. Cold Spring Harb Perspect Med. 2015 Jun 1;5(6):a022426. doi:10.1101/cshperspect.a022426. PMID: 26033084; PMCID: PMC4448698.

2. Fisher RS, van Emde Boas W, Blume W, Elger C, Genton P, Lee P, Engel J Jr. Epileptic seizures and epilepsy: definitions proposed by the International League Against Epilepsy (ILAE) and the International Bureau for Epilepsy (IBE). Epilepsia. 2005 Apr;46(4):470-2. doi:10.1111/j.0013-9580.2005.66104.x. PMID: 15816939.

3. Fisher RS, Cross JH, French JA, Higurashi N, Hirsch E, Jansen FE, et al. Operational classification of seizure types by the International League Against Epilepsy: Position Paper of the ILAE Commission for Classification and Terminology. Epilepsia. 2017 Apr;58(4):522-30. doi:10.1111/epi.13670. PMID: 28276060.

4. Walker MC, Köhling R. The problems facing epilepsy therapy. Neuropharmacology. 2013 Jun;69:1-2. doi:10.1016/j.neuropharm.2013.02.007. PMID: 23435169.

5. Dorj G. Pharmacotherapy: A Pathophysiologic Approach, 8th Edition. Cent Asian J Med Sci [Internet]. 2017 Nov 25 [cited 2024 Jul 14];3(3):318-9. Available from: https://www.mongoliajol.info/index.php/CAJMS/article/view/2732

6. Patra PH, Barker-Haliski M, White HS, Whalley BJ, Glyn S, Sandhu H, et al. Cannabidiol reduces seizures and associated behavioral comorbidities in a range of animal seizure and epilepsy models. Epilepsia. 2019 Feb;60(2):303-14. doi:10.1111/epi.14629. PMID: 30588604; PMCID: PMC6378611.

7. Stafstrom CE, Carmant L. Seizures and epilepsy: an overview for neuroscientists. Cold Spring Harb Perspect Med. 2015 Jun 1;5(6):a022426. doi:10.1101/cshperspect.a022426. PMID: 26033084; PMCID: PMC4448698.

8. Campos AC, Fogaça MV, Sonego AB, Guimarães FS. Cannabidiol, neuroprotection and neuropsychiatric disorders. Pharmacol Res. 2016 Oct;112:119-27. doi:10.1016/j.phrs.2016.01.033. PMID: 26845349.

9. Cabral GA, Griffin-Thomas L. Emerging role of the cannabinoid receptor CB2 in immune regulation: therapeutic prospects for neuroinflammation. Expert Rev Mol Med. 2009 Jan 20;11:e3. doi:10.1017/S1462399409000957. PMID: 19152719; PMCID: PMC2768535.

10. Lazarini-Lopes W, Do Val-da Silva RA, da Silva-Júnior RMP, Leite JP, Garcia-Cairasco N. The anticonvulsant effects of cannabidiol in experimental models of epileptic seizures: From behavior and mechanisms to clinical insights. Neurosci Biobehav Rev. 2020 Apr;111:166-82. doi:10.1016/j.neubiorev.2020.01.014. PMID: 31954723.

11. Kochen S, Villanueva M, Bayarres L, Daza-Restrepo A, Gonzalez Martinez S, Oddo S. Cannabidiol as an adjuvant treatment in adults with drug-resistant focal epilepsy. Epilepsy Behav. 2023 Jul;144:109210. doi:10.1016/j.yebeh.2023.109210. PMID: 37196452.

12. Anwar A, Saleem S, Patel UK, Arumaithurai K, Malik P. Dravet Syndrome: An Overview. Cureus. 2019 Jun 26;11(6):e5006. doi:10.7759/cureus.5006. PMID: 31497436; PMCID: PMC6713249.

13. Connolly MB. Dravet Syndrome: Diagnosis and Long-Term Course. Can J Neurol Sci. 2016;43(S3):S3–8. doi:10.1017/cjn.2016.243.

14. Asadi-Pooya AA. Lennox-Gastaut syndrome: a comprehensive review. Neurol Sci. 2018 Mar;39(3):403-14. doi:10.1007/s10072-017-3188-y. PMID: 29124439.

15. Registro del Programa Cannabis [Internet]. 2024 Apr 15 [cited 2024 Jul 14]. Available from: https://reprocann.msal.gob.ar/auth

16. Silva GD, Del Guerra FB, de Oliveira Lelis M, Pinto LF. Cannabidiol in the Treatment of Epilepsy: A Focused Review of Evidence and Gaps. Front Neurol. 2020 Oct 19;11:531939. doi:10.3389/fneur.2020.531939. PMID: 33192966; PMCID: PMC7604476.

17. Golub V, Reddy DS. Cannabidiol Therapy for Refractory Epilepsy and Seizure Disorders. Adv Exp Med Biol. 2021;1264:93-110. doi:10.1007/978-3-030-57369-0_7. PMID: 33332006.

18. Golub V, Reddy DS. Cannabidiol Therapy for Refractory Epilepsy and Seizure Disorders. Adv Exp Med Biol. 2021;1264:93-110. doi:10.1007/978-3-030-57369-0_7. PMID: 33332006.

19. Devinsky O, Marsh E, Friedman D, Thiele E, Laux L, Sullivan J, et al. Cannabidiol in patients with treatment-resistant epilepsy: an open-label interventional trial. Lancet Neurol. 2016 Mar;15(3):270-8. doi:10.1016/S1474-4422(15)00379-8. PMID: 26724101.

20. Lattanzi S, Trinka E, Striano P, Rocchi C, Salvemini S, Silvestrini M, et al. Highly Purified Cannabidiol for Epilepsy Treatment: A Systematic Review of Epileptic Conditions Beyond Dravet Syndrome and Lennox-Gastaut Syndrome. CNS Drugs. 2021 Mar;35(3):265-81. doi:10.1007/s40263-021-00807-y. PMID: 33754312; PMCID: PMC8005394.

21. Stockings E, Zagic D, Campbell G, Weier M, Hall WD, Nielsen S, et al. Evidence for cannabis and cannabinoids for epilepsy: a systematic review of controlled and observational evidence. J Neurol Neurosurg Psychiatry. 2018 Jul;89(7):741-53. doi:10.1136/jnnp-2017-317168. PMID: 29511052.

22. Villanueva V, Carreño-Martínez M, Gil Nagel-Rein A, López-González FJ. New therapeutic approach in Dravet syndrome and Lennox-Gastaut syndrome with cannabidiol. Rev Neurol. 2021 Apr 30;72(S01):S1-S10. doi:10.33588/rn.72S01.2021017. PMID: 33908026.

23. Herrera ML, Burneo JG. Síndrome de Lennox Gastaut. Aproximación diagnóstica y avances terapéuticos: Fármacos antiepilépticos, Canabidiol y otras alternativas. Rev Neuropsiquiatr [Internet]. 2018 Jul 5 [cited 2024 Jul 14];81(2):82. Available from: https://revistas.upch.edu.pe/index.php/RNP/article/view/3337

24. Laux LC, Bebin EM, Checketts D, Chez M, Flamini R, Marsh ED, et al. Long-term safety and efficacy of cannabidiol in children and adults with treatment resistant Lennox-Gastaut syndrome or Dravet syndrome: Expanded access program results. Epilepsy Res. 2019 Aug;154:13-20. doi:10.1016/j.eplepsyres.2019.03.015. PMID: 31022635.

25. Belle-Isle L, Walsh Z, Callaway R, Lucas P, Capler R, Kay R, et al. Barriers to access for Canadians who use cannabis for therapeutic purposes. Int J Drug Policy. 2014 Jul;25(4):691-9. doi:10.1016/j.drugpo.2014.02.009. PMID: 24947993.

26. Aran A, Cayam-Rand D. Medical Cannabis in Children. Rambam Maimonides Med J. 2020 Jan 30;11(1):e0003. doi:10.5041/RMMJ.10386. PMID: 32017680; PMCID: PMC7000154.

27. Rojas-Jara C, Polanco-Carrasco R, Cisterna A, Hernández V, Miranda F, Moreno A, et al. Uso medicinal de cannabis: una revisión de la evidencia. Ter Psicol. 2019;37(2):166–80.

28. Durkin A. Legalization of marijuana for non-medical use: health, policy, socioeconomic, and nursing

implications. J Psychosoc Nurs Ment Health Serv. 2014 Sep;52(9):22-6. doi:10.3928/02793695-20140721-03. PMID: 25082163.

29. Grbic J, Goddard P, Ryder D. Observations of the role of science in the United States medical cannabis state policies: Lessons learnt. Int J Drug Policy. 2017 Apr;42:109-14. doi:10.1016/j.drugpo.2016.12.019. PMID: 28190671.

30. Silvestro S, Mammana S, Cavalli E, Bramanti P, Mazzon E. Use of Cannabidiol in the Treatment of Epilepsy: Efficacy and Security in Clinical Trials. Molecules. 2019 Apr 12;24(8):1459. doi:10.3390/molecules24081459. PMID: 31013866; PMCID: PMC6514832.

31. Guiard BP, Di Giovanni G. Central serotonin-2A (5-HT2A) receptor dysfunction in depression and epilepsy: the missing link? Front Pharmacol. 2015 Mar 17;6:46. doi:10.3389/fphar.2015.00046. PMID: 25852551; PMCID: PMC4362472.

FUNDING

None.

CONFLICT OF INTEREST

None.

AUTHOR CONTRIBUTION

Conceptualization: Vitor Nifoci, Cristian Emanuel Cabrera.
Data curation: Vitor Nifoci, Cristian Emanuel Cabrera.
Formal analysis: Vitor Nifoci, Cristian Emanuel Cabrera.
Research: Vitor Nifoci, Cristian Emanuel Cabrera.
Methodology: Vitor Nifoci, Cristian Emanuel Cabrera.
Project management: Vitor Nifoci, Cristian Emanuel Cabrera.
Resources: Vitor Nifoci, Cristian Emanuel Cabrera.
Software: Vitor Nifoci, Cristian Emanuel Cabrera.
Supervision: Vitor Nifoci, Cristian Emanuel Cabrera.
Validation: Vitor Nifoci, Cristian Emanuel Cabrera.
Visualization: Vitor Nifoci, Cristian Emanuel Cabrera.
Writing – original draft: Vitor Nifoci, Cristian Emanuel Cabrera.
Writing – review and editing: Vitor Nifoci, Cristian Emanuel Cabrera.