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Abstracts

The legal framework for medicinal use of cannabinoids in Germany

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On 10th March 2017, the Act Amending Narcotics and Other Regulations¹ took effect in Germany and legalised the off-/no-label prescription of cannabis-based medicines (CBMs; e.g. dried cannabis flowers, plant-based cannabinoid extracts [such as tetrahydrocannabinol, cannabidiol and combination products] and synthetic tetrahydrocannabinol analogues) for patients suffering from severe diseases according to the definitions given in Code V, section 31, passage 6 of the Social Law. This Act obligates statutory health insurers to reimburse all costs associated with these prescriptions for patients who are resistant to other treatments.

According to data from the Federal Institute for Drugs and Medical Devices (BfArM)² and a cross-sectional questionnaire by the Occupational Union of Pain Specialists (BVSD),³ 69% of these legalised CBM treatments prescribed until mid-2019 were for patients with pain and 66% of these prescriptions were for neuropathic pain. This finding is in line with the currently available scientific evidence, as well as several international/national guidelines. Evaluations of data from the German pain e-registry confirmed the beneficial use of CBMs for these patients.⁴⁻⁶ The evaluations also provided further insights into the specific effects of the medicinal product nabiximols (Sativex®), which proved more effective and significantly better tolerated than handmade cannabis preparations containing dronabinol.⁴⁻⁶

Based on this evidence and the huge price differences between the available CBMs, the German Pain League developed an evidence-based algorithm for the sequential use of CBMs, which recommends nabiximols as a first-line CBM for patients with severe neuropathic pain, refractory to other (recommended and formally approved) drugs.⁷

References

1. Gesetz zur Änderung betäubungsmittelrechtlicher und anderer Vorschriften. Bundesgesetzblatt 2017. Available at: https://www.bgbl.de/xaver/bgbl/start.xav?start=%2F%2F%5B%40attr_id%3D%27bgbl117s0403.pdf%27%5D#_bgbl_%2F%2F%5B%40attr_id%3D%27bgbl117s0403.pdf%27%5D_1537108060099.
2. Cremer-Schaeffer P, Schmidt-Wolf G, Broich K. *Schmerz* 2019; 33: 415–23.
3. Gastmeier K. *Schmerz* 2019; 33: 408–14.
4. Überall MA, Müller-Schwefe GH. *Schmerzmedizin* 2019; 35: 42–50.
5. Überall MA, Essner U, Mueller-Schwefe GH. *J Pain Res* 2019; 12: 1–28.
6. Überall MA, Essner U. Presentation at the World Congress of the World Institute of Pain 2020.
7. Überall MA. *Zeitschrift Schmerzliga* 2018; 3: 6–8.