

German medicinal cannabis update

MARKET INTELLIGENCE REPORT

Summary

Prepared by: New Zealand Embassy Berlin, in consultation with NZTE

- Detailed regulations on the prescription and funding of medical cannabis have been adopted in Germany at the request of the legislator and as a result of a survey assessing more than 20,000 medical cannabis treatments. The regulations aim to support and provide greater clarity around treatment and include a caveat on the use of cannabis flower.
- New legislation is also being drafted that aims to decriminalise private and non-commercial cultivation and consumption of recreational cannabis but stops short of the initially intended legalisation and commercialisation of recreational cannabis.
- German imports of cannabis flowers and extracts continue to increase, reaching a total of 25 tonnes in 2022.

Report

Relevant national body adopts detailed rules for the prescription of medicinal cannabis

The Federal Joint Committee (G-BA), the highest decision-making body of the joint self-administration of physicians, hospitals and health insurance funds in Germany, has adopted long awaited regulations that will apply to the prescription of medicinal cannabis paid by statutory health insurance (see press release <a href=here and regulations <a href=here and <a

Importantly for the medicinal cannabis industry, there are no additional requirements and restrictions on the prescription of dried flowers or extracts, in comparison to pharmaceutical cannabis products. However, the regulations include a caveat: "Before prescribing cannabis in the form of dried flowers or extracts, it must be checked whether other finished medicinal products containing cannabis are available which are suitable for treatment. The prescription of cannabis in the form of dried flowers shall be justified." In consultation with stakeholders, the regulatory body had to weigh up the benefits of an additional therapy option with the safety, efficacy and quality of cannabis products that have not been approved as medicinal products or for this type of treatment.

The G-BA's decision further clarifies that medicinal cannabis requires a minimum THC content of 0.2%. Its initial prescription or a fundamental change in therapy requires the health insurer's approval, but not subsequent prescriptions, dose adjustments or the change to other dried flowers or extracts. Furthermore, approval may only be refused in "justified exceptional circumstances". The decision confirms current practice that all doctors may prescribe medicinal cannabis, not just specialists.

These G-BA regulations, which should enter into force in June, follow the release of a dedicated <u>survey</u> (German only) by the Federal Institute of Drugs and Medical Devices (BfArM) assessing more than 20,000 treatments with medicinal cannabis since 2017. Accordingly, patients treated with cannabis flowers rated the success of the therapy higher and reported side effects less frequently. However, more frequently reported "euphoric effects", high THC doses and a high proportion of young men in that subgroup led BfArM to urge doctors to "consider the danger of abuse and dependence".

Relevant stakeholders – including the medicinal cannabis sector and patient organisations – have jointly welcomed the decision in principle but criticised the caveat on the use of cannabis flower and extracts, which it claims was not intended by the legislator and could create new hurdles for their use. They have therefore called for clarification and suggested a review of German medicinal cannabis legislation six years

after its entry into force. Health insurers allegedly still reject 30-40% of the requests for prescription authorisation (see their joint statement <u>here</u> – German only).

New legislation to decriminalise recreational cannabis but not to legalise commercial cultivation

Meanwhile but unrelated to the above, the Federal Government has presented draft legislation that if adopted will decriminalise private and non-commercial cultivation and consumption of recreational cannabis. In a second step later this year, it plans to test the full legalisation of recreational cannabis in selected pilot regions, where an entire value chain involving commercial production and licensed shops would be set up for a trial period of five years. The aim of this pilot is to evaluate the effects of legalisation including on the black market, product quality and youth protection. The Government had initially intended (as noted here) to legalise recreational cannabis nationwide, but it was determined that this could violate relevant European and international law.

Potential domestic producers of recreational cannabis, some of which are also active in medicinal cannabis cultivation, are disappointed with this `liberalisation light´ and could cut down investment plans accordingly. It had been estimated that full legalisation would create a market for about 400 tonnes of cannabis worth approximately €4 billion. There may still be a limited role for commercial producers in providing seeds for non-commercial cultivation and become active in the pilot regions once established, but the intended step change has become a more distant and uncertain prospect.

Whilst the German markets for medicinal and recreational cannabis will be subject to different regulations and market conditions, they will not be entirely separate. Domestic producers in particular could potentially serve both or switch between the two, and there have been concerns that in case of full liberalisation and strong demand the availability of medicinal cannabis could suffer as a result.

Latest German import statistics

The German market, the largest in Europe, is now in its 7th year. Since the previous report of 2021, imports have continued to grow and domestic supply has commenced. Imports reached nearly 25 tonnes of cannabis flower (or their equivalent needed for extracts) in 2022, up from nearly 21 tonnes in 2021 and marking yet another record. Three domestic producers are entitled to provide up to a further combined 2.6 tonnes per year, acquired and offered to pharmacies by BfArM's Cannabis Agency (as of July, its price will increase from €4.30/g to €5.80/g). The total amounts actually acquired by pharmacies continue to be considerably lower, reaching 15 tonnes in 2022, after 11 tons in 2021.

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