

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

Summary

- The German medical cannabis* market – the largest in Europe – continues to grow. Quarterly imports now exceed three tons, and from a greater diversity of foreign sources.
- There is greater pressure on prices. Health insurers and pharmacies have agreed on a lower final price; for domestic producers, the average farm gate price will be €2.20/g.
- As the market matures, patients, physicians, and health insurers have different views on whether access to medical cannabis should be made easier or more restrictive.

Report

The German medical cannabis market, the largest in Europe, is entering its 5th year, following legislation in 2017 that allowed and regulated its wider use for medical treatment. Demand has been met by imports so far but domestic supply is expected to kick in this year. This report takes stock of recent trends. For a broader overview, see the [European Cannabis Report](#).

How the German medical cannabis market is organised

Germany has established specific channels for supply and demand of medical cannabis. The Federal Opium Agency regulates the import of medical cannabis, whilst the Cannabis Agency controls its domestic production. Both sit within the Federal Institute for Drugs and Medical Devices (BfArM). Complementing this federal regulatory regime specific to medical cannabis, authorities at the state level quality test and verify for compliance all drugs, including medical cannabis, imported from outside the EU.

Once on the market, medical cannabis is distributed by importers and wholesalers. The product is delivered through pharmacies to the patient (upon prescription only), or as required to processors. Health insurers are expected to cover the cost but have to formally give permission in each case.

Imports: still growing with sources diversifying

So far, demand has been entirely met by imports, initially almost exclusively from Europe and Canada, but more recently also from Australia. Medical cannabis flower imports increased from 1.2 tons in 2017 to 9.4 tons in 2020 and amounted to 3.3 tons in Q1 this year. There is no overall quota for imported quantities, but importers have to apply for permission to import specific quantities and qualities. Medical cannabis can be imported from any country that has established a cannabis agency or similar public authority supervising its cultivation. Proof of this has to be provided by the importer by way of a licence or similar document held by the relevant grower. To ensure compliance with the quality requirements for any drug marketed in Germany, exporters also need to work with their importer and seek permission from the relevant state authority.

*For the purpose of this report, medical cannabis refers to cannabis flower and extracts, whereas pharmaceutical cannabis refers to finished, market-authorized products and generics.

Domestic developments: price reform and domestic production

With the aim of reducing the margins of distributors and pharmacies and thereby the final price for medical cannabis (previously up to €30/g), a new price regime was agreed in April 2021. The regime set a fixed end price health insurers will accept, of €9.52/g plus fixed surcharges (between €2.60-€9.52/g) depending on the prescribed quantity but irrespective of the strain. This has reportedly created some pressure on prices up the supply chain. Patients who cover the cost themselves may still be charged more, however.

The first domestic harvest is expected later this year. In 2019, in a highly competitive bidding process, BfArM commissioned three companies to establish domestic production of cannabis flower with high, medium or balanced THC content. The initial total volume is 10.4 tons over four years (with provisions for possible increases): 1 ton per year each from Aphria and Aurora, and 600kg per year from Demecan.

All three are adding domestic production to their wholesaling business, sourcing medical cannabis from Canada, Europe and now also Australia. However, their domestic harvest will be collected and distributed by Cansativa on behalf of the Cannabis Agency, which will reportedly pay the three producers an average farm gate price of €2.20/g (low prices were a key criterion in the bidding process). The Agency will then determine the price for on-selling to pharmacies and possibly processors, taking into account administration costs, but without adding a profit margin for itself.

BfArM has stated that domestic production will not trigger new regulations or quotas for imports, leaving it to the market to establish absorption capacity beyond (relatively cheap) domestic supplies. The market has arguably been growing to an extent (+3.6 tons in 2019, +2.7 tons last year, an estimated >3 tons this year) so 2.6 tons of domestic production should not have a disruptive effect on imports, although it will limit their growth rate and could have a dampening effect on prices.

Issues: prescribing medical cannabis and getting health insurers' approval remain challenging

Demand from patients remains high and is growing, but regulatory hurdles remain. Physicians considering the prescription of medical cannabis may be put off by the bureaucratic burden, and even if they are not, health insurers still decline 30-40% of cases. The proponents of medical cannabis claim that up to half of the patients in need are being refused treatment, whereas critics claim approval rates are too high. They also take issue with the preference for "archaic" therapies based on cannabis flower and extracts as opposed to standardised and market-authorized products. Pharmaceutical cannabis products have a market share below 20%, whereas cannabis flower takes more than 40% and extracts nearly 40% of the market (with the former declining and the latter growing).

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