Draft bill

of the Federal Ministry of Health

Draft First Act amending the Medicinal Cannabis Act

A. Problem and objective

With the Act amending legislation on narcotic drugs and other provisions of 6 March 2017 (Federal Law Gazette I p. 403), the legislator has expanded the possibilities for prescribing cannabis-based medicines. Since then, physicians have also been able to prescribe pharmaceutical-grade cannabis flowers and cannabis extracts for medicinal purposes with a narcotics prescription, covered by statutory health insurance under the conditions of § 31(6) of Book V of the Social Security Code.

With the entry into force of the Cannabis Act of 27 March 2024 (Federal Law Gazette 2024 I No 109) on 1 April 2024, the use of cannabis for medicinal purposes has been re-regulated in the Medicinal Cannabis Act. At the same time, cannabis for medicinal purposes has been removed from the Annexes to the Narcotic Drugs Act (Betäubungsmittelgesetz [BtMG]) and therefore no longer constitutes a narcotic substance as defined by the Narcotic Drugs Act. Since then, cannabis for medicinal purposes has been a prescription-only medicine that can be prescribed by physicians.

Since the entry into force of the Cannabis Act, it has been observed that imports of cannabis flowers for medicinal purposes are increasing beyond expected levels. According to data from the Federal Institute for Medicinal Products and Medical Devices, the import of cannabis flowers for medicinal purposes increased by 170% from the first half of 2024 to the second half of 2024. During the same period, however, prescriptions for cannabis flowers for medicinal purposes covered by statutory health insurance have only increased by 9%.

This disparity suggests that the rising import figures are primarily attributable to the supply of an increasing number of self-payers with private prescriptions outside the statutory health insurance system. At the same time, remote-medicine platforms are increasingly active on the market, allowing cannabis flowers to be obtained for medicinal purposes without any physician-patient contact (or without any contact in person). If the prescription is issued after completing an online questionnaire on a remote-medicine platform and the cannabis flowers are sent for medicinal purposes via cooperating mail-order pharmacies, patients have no personal contact with a physician or the pharmaceutical staff at the pharmacy. It must be taken into account that cannabis flowers for medicinal purposes are a medicinal product with an addiction risk and other health risks, in particular effects on brain development in young people. In addition, this medicinal product is marketable without a marketing authorisation under pharmaceutical law and is therefore prescribed exclusively in non-label use without scientific evidence from clinical studies in patients reviewed within the framework of a marketing authorisation. This special status of cannabis flowers for medicinal purposes, in conjunction with the care practice described above, necessitates specific measures to ensure patient safety without affecting the supply of medicinal products.

The aim of this Act is therefore to correct the aforementioned undesirable development while ensuring the appropriate care of patients with serious diseases.

B. Solution

The Medicinal Cannabis Act is being refined and the provisions governing the prescription and dispensing of cannabis flowers for medicinal purposes are being specified in greater detail.

C. Alternatives

Retaining the former provisions is not an option in view of the aforementioned undesirable development, as well as drug safety and patient safety.

D. Budgetary expenditure without compliance costs

The Federal Government and the Federal States do not incur any budgetary expenditure.

E. Compliance costs

E.1 Compliance costs for citizens

There are no compliance costs for citizens.

E.2 Compliance costs for businesses

Physicians will not incur any additional compliance costs due to the prohibition of remote prescriptions.

The ban on marketing by mail order to end consumers results in a one-off compliance burden for pharmacies that cannot be quantitatively estimated at this stage as a result of having to change distribution practices.

Of which administrative costs due to information duties

There are no administrative costs for businesses due to new or increased information duties.

E.3 Compliance costs for the administration

There may be a small additional enforcement burden for the supervisory authorities of the Federal States.

F. Other costs

No effects are expected on individual prices, general price levels or consumer price levels.

Draft bill of the Federal Ministry of Health

Draft First Act amending the Medicinal Cannabis Act

Dated ...

The Federal Parliament has adopted the following Act:

Article 1

Amendment to the Medicinal Cannabis Act[1]

The Medicinal Cannabis Act of 27 March 2024 (Federal Law Gazette 2024 I No 109, p. 27), as amended by Article 2 of the Act of 20 June 2024 (Federal Law Gazette 2024 I No 207) is amended as follows:

1. § 3 is replaced by the following § 3:

‘§ 3

Dispensing and prescribing cannabis for medicinal purposes

(1) Cannabis for medicinal purposes may only be prescribed by physicians or administered as part of medicinal treatment or given to another person for immediate consumption if its use is medically justified. Dentists and veterinarians are not authorised to prescribe, administer or dispense cannabis for immediate consumption. §§ 2 and 4 of the Ordinance on Prescription-Only Medicinal Products [AMVV] apply accordingly.

(2) The flowers referred to in § 2(1) may only be prescribed after personal contact between the patient and the prescribing physician in his or her practice or during a home visit to the patient by the prescribing physician. Follow-up prescriptions may only be issued without further personal contact as referred to in Sentence 1 if the prescribing physician of the patient has prescribed the flowers referred to in § 2(1) within the last four quarters, including the current quarter, after personal contact in accordance with Sentence 1. Notwithstanding Sentence 2, repeat prescriptions may also be issued without the prescribing physician having prescribed the patient the flowers referred to in § 2(1) within the last four quarters following personal contact in accordance with Sentence 1, provided that another physician from the same medical practice has prescribed the flowers referred to in § 2(1) to the patient within the last four quarters, including the current quarter, following personal contact as referred to in Sentence 1, and the prescribing physician is standing in for that physician.

(3) Cannabis for medicinal purposes prescribed in accordance with Paragraph 1(1) may only be supplied to final consumers in a pharmacy upon presentation of a prescription. For the flowers referred to in § 2(1), dispensing to end consumers by mail order is not permitted pursuant to § 43(1)(1) of the Medicinal Products Act. § 14(7) of the Pharmacies Act is not affected.

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[1] Notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17/9/2015, p. 1).

(4) Cannabis for medicinal and scientific purposes may only be administered by a physician or made available to another person for direct consumption in the scope of clinical trials as defined by § 4(23) of the Medicinal Products Act. Dentists and veterinarians are not authorised to administer or provide cannabis for immediate consumption.'

2. § 25 is amended as follows:

a) Paragraph 1(2) is replaced by the following Subparagraphs 2 to 2b:

1. ' in violation of § 3(1)(1) or (2), prescribes, administers or makes available cannabis for medicinal purposes,

2a. in violation of § 3(3)(1), dispenses cannabis for medicinal purposes,

2b. in violation of § 3(4), administers or supplies cannabis for medicinal or scientific purposes,'.

b) In Paragraph 3, the reference '1, 2, 3' is replaced by the reference '1 to 3'.

c) Paragraph 4(2) is amended as follows:

a%6) In Subparagraphs 1 and 2, the words '1, 2, 3' are replaced by the words '1 to 3';

b%6) In Subparagraph 3(a), the words 'Subparagraph 2 or Subparagraph 3' are replaced by the words 'Subparagraphs 2 to 2b or 3'.

d) In Paragraph 5(2) the words 'Subparagraph 2,' are replaced by the words 'Subparagraphs 2 to 2b or'.

e) In Article 6, the words 'Subparagraph 2, 3 or 5' are replaced by the words 'Subparagraphs 2 to 3 or 5'.

Article 2

Entry into force

This Act shall enter into force on the day after promulgation.

Justification

A. General part

I. Objective of and need for the provisions

With the Act amending legislation on narcotic drugs and other provisions of 6 March 2017 (Federal Law Gazette I p. 403), the legislator has expanded the possibilities for prescribing cannabis-based medicines. Since then, physicians have also been able to prescribe pharmaceutical-grade cannabis flowers and cannabis extracts for medicinal purposes with a narcotics prescription, covered by statutory health insurance under the conditions of § 31(6) of Book V of the Social Security Code.

With the entry into force of the Cannabis Act of 27 March 2024 (Federal Law Gazette 2024 I No 109) on 1 April 2024, the use of cannabis for medicinal purposes has been re-regulated in the Medicinal Cannabis Act. At the same time, cannabis for medicinal purposes has been removed from the Annexes to the Narcotic Drugs Act (Betäubungsmittelgesetz [BtMG]) and therefore no longer constitutes a narcotic substance as defined by the Narcotic Drugs Act. Since then, cannabis for medicinal purposes has been a prescription-only medicine that can be prescribed by physicians.

Since the entry into force of the Cannabis Act, it has been observed that imports of cannabis flowers for medicinal purposes are increasing beyond expected levels. According to data from the Federal Institute for Medicinal Products and Medical Devices, the import of cannabis flowers for medicinal purposes increased by 170% from the first half of 2024 to the second half of 2024. During the same period, however, prescriptions for cannabis flowers for medicinal purposes covered by statutory health insurance have only increased by 9%.

This disparity suggests that the rising import figures are primarily attributable to the supply of an increasing number of self-payers with private prescriptions outside the statutory health insurance system. At the same time, remote-medicine platforms are increasingly active on the market, allowing cannabis flowers to be obtained for medicinal purposes without any physician-patient contact (or without any contact in person). If the prescription is issued after completing an online questionnaire on a remote-medicine platform and the cannabis flowers are sent for medicinal purposes via cooperating mail-order pharmacies, patients have no personal contact with a physician or the pharmaceutical staff at the pharmacy. It must be taken into account that cannabis flowers for medicinal purposes are a medicinal product with an addiction risk and other health risks, in particular effects on brain development in young people. In addition, this medicinal product is marketable without a marketing authorisation under pharmaceutical law and is therefore prescribed exclusively in non-label use without scientific evidence from clinical studies in patients reviewed within the framework of a marketing authorisation. This special status of cannabis flowers for medicinal purposes, in conjunction with the care practice described above, necessitates specific measures to ensure patient safety without affecting the supply of medicinal products.

II. Main content of the draft

The Medicinal Cannabis Act is being refined and the provisions governing the prescription and dispensing of cannabis flowers for medicinal purposes are being specified in greater detail.

III. Executive footprint

Stakeholders as well as the Federal States were involved in the consultation procedure.

IV. Alternatives

Retaining the former provisions is not an option in view of the clearly undesirable development, as well as drug safety and patient safety.

V. Legislative competence

With regard to the proposed provisions on the prescription and placing on the market of cannabis flowers for medicinal purposes, the legislative competence of the Federal Government follows from Article 74(1)(1) (criminal law) and Subparagraph 19 (pharmacy and pharmaceutical law).

VI. Compatibility with European Union law and international treaties

The Act is compatible with the existing international and European legal framework. The international legal framework for the handling of narcotic substances is governed by three international drug conventions. These include the 1961 Single Convention on Narcotic Drugs, as amended in 1972 (Single Convention). This serves as the basis for global drug control. It divides drugs into four classes according to their marketability (to which various provisions of the single convention apply in some cases) and includes cannabis. Under Article 4(c) of the Single Convention, the Contracting Parties shall take all necessary legislative and administrative measures to restrict the extraction, manufacture, export, import, distribution, use and possession of narcotic drugs and trade therein to exclusively medicinal and scientific purposes, in accordance with the provisions of this Convention.

The requirements of Union law also do not preclude the Act. Although the ban on remote prescriptions constitutes an interference with the freedom to provide services, in view of the considerable risks of addiction associated with cannabis flowers, this intervention is justified on the grounds of health protection. Cannabis flowers for medicinal purposes do not have a medicinal product authorisation for a specific indication. Due to the lack of authorisation, there are increased due diligence obligations for the prescribing physician to ensure safe and effective use in the patient. A detailed medical history, physical examination, education and consent should be carried out when prescribing cannabis flowers for medicinal purposes in personal physician-patient contact as part of medical treatment and consultation on site. Cannabis flowers for medicinal purposes have a particularly negative effect on brain development in young people, but also pose other health risks. The remote prescription ban can curb the abusive issuance of prescriptions of prescription cannabis flowers, thus guaranteeing drug and patient safety. The possibility of remote treatment does not release the physician from the obligation to provide treatment with due care in accordance with professional standards. In the case of cannabis, which is addictive, this cannot be done on the basis of a written medical history alone (Munich District Court I, judgment of 02 June 2025, ref. 4 HK O 11377/24). A mandatory consultation with a physician at the practice ensures that the prescription is medically necessary, thereby preventing misuse by private and occasional consumers. Medicinal cannabis is a medicinal product with a significantly increased risk of addiction and other medical effects, which justifies a special consideration of the medicinal product compared to others. The special treatment of addictive substances by means of national bans and restrictions in the interests of health protection can, in principle, justify the restriction of European fundamental freedoms and is therefore particularly subject to the discretion of the Member States.

The ban on mail order sales is neutral and does not burden medicinal cannabis flower sales from other European countries more than those from Germany. It does not therefore constitute discrimination against pharmacies or goods from other EU countries. This is because pharmacies which are not located in Germany are already constrained by the Constitution of the Universal Postal Union, which includes a prohibition on including narcotic drugs - which still include medicinal cannabis flowers in accordance with the definition of the 1961 UN Single Convention - in a postal consignment, and sending medicinal cannabis flowers to Germany. In accordance with Article 9.1.1. of the Constitution of the Universal Postal Union, sending these substances is even an unlawful act. This prohibits the transport of narcotic drugs without exception. There is no possibility of sending narcotics by registered post for medicinal or scientific purposes.

VII. Impact of the legislation

1. Legal and administrative simplification

The draft does not provide for legal and administrative simplification.

2. Sustainability aspects

The draft Act is in line with the objectives and principles of the German sustainability strategy (DNS) of the Federal Government. By stipulating that cannabis flowers may only be prescribed for medicinal purposes after prior personal contact between physician and patient, and by further stipulating that cannabis flowers for medicinal purposes may not be sold to end consumers by mail order, the draft law contributes to the achievement of Sustainable Development Goal 3, ‘Ensure healthy lives and promote well-being for all at all ages’. The proposed provisions also comply with Guiding Principle 3b of the DNS, ‘Avoid hazards and unacceptable risks to human health.’

3. Budgetary expenditure without compliance costs

The proposed provisions have no impact on the budgetary revenue and expenditure of the Federal Government, Federal States or municipalities.

4. Compliance costs

4.1. Compliance costs for citizens

No additional compliance costs will arise for citizens.

4.2. Compliance costs for businesses

The ban on remote prescription does not create any added compliance costs for physicians, since, in compliance with the necessary due diligence obligations, unauthorised medicinal products which may cause addiction and other diseases should not be prescribed to unknown patients in the context of video appointments.

The prohibition on placing on the market by sending to end consumers results in a one-off and minor compliance cost for pharmacies that cannot be quantified. Mail-order pharmacies with corresponding medicinal products must take them out of their medicinal product offering for online mail orders.

4.3 Compliance costs for the administration

There may be a small additional enforcement burden for the supervisory authorities of the Federal States. This cannot be quantitatively estimated at this stage.

5. Other costs

No effects are expected on individual prices, general price levels or consumer price levels.

6. Other legal consequences

The provisions have no further impact on consumers, no impact on gender equality or demographics, and no impact on the preservation and promotion of equal living conditions.

VIII. Limitation; evaluation

There is no time limitation for the provisions. An evaluation of the proposed provisions will be carried out as part of the Federal Government's responsibility to carefully monitor developments in the field of drugs and to consider any necessary steps.

B. Specific part

Re Article 1 (Amendment to the Medicinal Cannabis Act)

Re Subparagraph 1

§ 3 is replaced by the following § 3:

Paragraph 1 corresponds in substance to the former Paragraph 1. Sentence 1 stipulates that a physician may only prescribe, administer or provide cannabis for immediate consumption for medicinal purposes if its use is medically justified. This provision follows the decision of the Health Ministerial Conference of 11/12 June 2025, through which the Conference requested the Federal Government to lay down in the Medicinal Cannabis Act that cannabis may only be prescribed for medicinal purposes if its use is medically indicated. Although cannabis for medicinal purposes is no longer classified as a narcotic, the special status of cannabis for medicinal purposes and the undesirable developments in prescribing practices necessitate provisions that expressly prohibit prescriptions that are not medically justified. Medical treatment, which also includes the prescription of medicines, must always be carried out in accordance with generally accepted professional standards, which requires a careful diagnosis. A prescription is considered justified if the prescriber has concluded, based on their own examination, that the use of the medicine is permissible and necessary according to the generally accepted state of medical science. Since tetrahydrocannabinol (THC) from the cannabis plant is a psychoactive substance and may cause brain damage, the use of cannabis for medicinal purposes must be weighed very carefully. When prescribing, the medical duty of care must be observed in accordance with the treatment contract and professional provisions within the framework of a properly conducted treatment. Physicians must not encourage the misuse of their prescriptions, see § 7(8) of the (Model) Professional Code for Physicians Practising in Germany (MBO-Ä). The state medical boards have essentially incorporated § 7(8) MBO-Ä into their respective professional codes of conduct.

The newly introduced Paragraph 2(1) provides that the prescription of cannabis flowers for medicinal purposes may only take place after personal contact between a physician and the patient in the medical practice of the prescribing physician. The medical practice is the physical place where a physician receives, advises, examines and treats his or her patients. A medical practice can be an individual practice where a physician works alone, or a cooperative form such as a community practice or a medical care centre (or a university outpatient clinic). A prescription may also be issued in the context of a physician's home visit.

Treatment exclusively with cannabis flowers for medicinal purposes in the context of video consultations is prohibited due to the special status of cannabis flowers for medicinal purposes. When treating patients with cannabis flowers for medicinal purposes, personal contact with the person being treated is advisable and necessary, among other things because of the risk of addiction and other health risks, side effects and undesirable drug reactions. Cannabis flowers for medicinal purposes do not have a medicinal product authorisation for a specific indication. There are still no systematic studies on the efficacy and safety of cannabis flowers for medicinal purposes, and only limited evidence of efficacy in individual medical indications. The legislature was also aware of this special status of cannabis as a medicinal product in 2017 when it authorised the sale and prescription of cannabis for medicinal purposes, see Bundestag Document 18/8965. This special status continues to this day. Treatments with cannabis for medicinal purposes constitute what are known as individual treatment attempts. Due to the lack of approval and thus also a lack of a tested medical indication and dosing recommendation, there are increased due diligence obligations for the prescribing physician in order to ensure safe and effective use in the patient. According to § 630c(2) of the German Civil Code (BGB), the person providing treatment is obliged to explain to the patient in an understandable manner at the beginning of the treatment and, if necessary, during the course of the treatment, all circumstances relevant to the treatment, in particular the diagnosis, the expected development of the patient's health, the therapy and the measures to be taken during and after the therapy. In addition, the person treating the patient must inform the patient of all the circumstances that are essential for the consent. These include in particular the type, scope, implementation, expected consequences and risks of the measure, as well as its necessity, urgency, suitability and prospects of success with regard to the diagnosis or therapy. Alternatives must also be pointed out during patient information if several medically equally indicated and usual methods can lead to significantly different burdens, risks or chances of recovery (cf. § 630e BGB).

When assessing the risks, the patient’s state of health, individual medical conditions and other medicines they are taking must be taken into account, which usually requires a careful medical history and physical examination of the patient. Such a detailed medical history, physical examination and education should be carried out when prescribing cannabis flowers for medicinal purposes in personal physician-patient contact in the scope of medical treatment and consultation on site. Regular personal contact between physician and patient is recommended in view of the special status of cannabis flowers for medicinal purposes, as the treatment constitutes an individual treatment attempt with increased duties of care and, in particular, the patient’s state of health must be checked by means of regular physical examinations. There is also a need for continuous information about the risk of addiction, as this and also the physical or psychological consequences of consumption can change with the scope and time span of consumption. The patient must also be examined and advised in this regard. Follow-up prescriptions should also be checked from this point of view.

It is true that the absolute ban on remote treatment in the MBO-Ä was deleted in 2018. However, exclusive consultation or treatment via communication media is only permitted in individual cases if this is medically justifiable and the necessary medical care is ensured, in particular through the manner in which the findings are obtained, consultation, treatment and documentation, and the patient is also informed about the special features of exclusive consultation and treatment via communication media (cf. § 7(4) MBO-Ä). The medical associations of the Federal States, which are guided by the MBO-Ä when drawing up their own professional codes, have largely incorporated this provision into their professional codes. Where cannabis flowers are prescribed for medicinal purposes solely on the basis of a written history or during consultation or treatment exclusively via communication media, the necessary medical care will probably not ordinarily be achieved solely on the basis of the special status referred to above. Therefore, for the prescription of cannabis flowers for medicinal purposes, the provisions specified by the self-governing body in § 11(2) of Annex 31 to the Federal Framework Agreement for Physicians are

transferred to the area of treatment for patients insured under the statutory health insurance scheme. Accordingly, the prescription of medicinal products that may cause addiction diseases is excluded in the case of unknown patients. Physicians are obliged to practise their profession conscientiously, which includes in particular observing the recognised state of medical knowledge and complying with the provisions applicable to the practice of their profession. Violations of these rules may be sanctioned by the boards, depending on the individual case.

Paragraph 2(2) stipulates that for repeat prescriptions, a consultation must take place once every four quarters, in which the previous contact within the specified period must be related to the prescription of cannabis for medicinal purposes. Prior contact in relation to another treatment not related to the prescription of cannabis for medicinal purposes is not sufficient. Under § 11(2) of Annex 31c to the Physicians Federal Framework Agreement (BMV-Ä), the prescription of medicinal products that can trigger addictions is not permitted by way of video consultations for unknown patients. An unknown patient within the meaning of this agreement is a patient who has not had any personal physician-patient contact at the practice conducting the video consultation during the last four quarters, including the current quarter prior to the video consultation, see § 2 Annex 31c BMV-Ä.

In the event of substitution, Paragraph 2(3) provides that, in the case of medical practices with several physicians, the follow-up prescription does not necessarily have to be issued by the same physician, but in the same medical practice. For a follow-up prescription by a physician other than the treating physician, it is necessary that he or she has access to the patient data and, in particular, to the diagnosis made at the time of the first prescription. Cases in which physicians share premises or rent for premises but do not have access to the same patient data and have different patient bases, meaning that they do not belong to the same medical practice, are not covered. It should be noted that personal contact in the context of a different treatment is not in itself sufficient; a prescription with personal contact in the last four quarters is required.

Paragraph 3(1) corresponds to the previous provision in Paragraph 2(1). The new Sentence 2 stipulates that cannabis flowers for medicinal purposes may not be supplied to end users by means of postal delivery.

Due to the many special features associated with cannabis flowers for medicinal purposes, there are comprehensive information and counselling obligations that must be fulfilled during a personal consultation at the pharmacy. Information is necessary with regard to addiction risks and health risks of cannabis flowers. Patients must also be advised and informed on site by the pharmaceutical staff about the appropriate use, possible side effects or interactions, as well as about the appropriate storage or disposal and the dangers of misuse of cannabis, for example by children, adolescents and young adults. Because of the risks and hazards, marketing via mail order is not appropriate from the point of view of patient safety. Furthermore, the exclusion of cannabis flowers from mail order by pharmacies does not constitute an unreasonable burden. In the interests of health protection and due to the addictive nature of cannabis flowers, which can also be used for intoxication purposes, for example by smoking, exclusion from mail order sales serves to minimise the risk of abuse. The ban on mail order sales does not jeopardise patient care, as any pharmacy can order cannabis flowers for medicinal purposes from wholesalers. If necessary, immobile patients can be supplied via the pharmacy’s courier service, which is provided by pharmaceutical staff of the pharmacy if necessary. In addition, other medicinal products are already excluded from mail order. Shipping on the basis of special safety precautions is also prohibited for T-prescriptions, i.e. prescriptions for certain highly teratogenic active substances (§ 17(2b) of the Regulation on the Operation of Pharmacies, § 43(1)(1) of the Medicinal Products Act). This idea of safety can also be applied to the cannabis flower in view of the risk of addiction and medical risks, in particular with regard to the effects on brain development in young people and, in

certain cases, even when used once. The exclusion of cannabis flowers for medicinal purposes from the mail order distribution channel is therefore justified.

Compared to other measures, such as subjecting medicinal cannabis flowers to narcotics legislation or removing them from the list of prescription drugs altogether, the ban on remote prescription and mail order sales is the mildest measure.

The new Paragraph 4 corresponds to the former Paragraph 3.

Re Subparagraph 2

These are amendments to § 25 that are formally necessary in terms of ancillary criminal law.

Re Article 2 (Entry into force)

This Act shall enter into force on the day after promulgation.