In this article, the author discusses the Ukraine's Draft Law No. 7457 on the legalization of the use of medical cannabis for patients suffering from severe ailments. As a positive example of such regulation, the author observes the German law of March 6, 2017 as well as relevant case law, namely the cases of the Land Social Court of Baden-Württemberg, and the Federal Supreme Social Court. Within the prism of jurisprudence, the author researches of how does the adopted legislation work in relation to supply of medical cannabis to the patients suffering from severe ailments. The findings of the author are that this administrative procedure is in fact quite difficult to fulfill and has got a number of precautions: the patient has to prove he or she suffers from a severe disease, and no alternative means of treatment are either available, or are unacceptable for a concrete case. Hence, in case the dispute arrives to the court, it is the patient’s task to fulfill the provisions of Art. 31 (6) of the Fifth Book of the Social Code of 1988 by proving the severity of the condition and the lack or alternative therapy, or its insufficiency by appropriate medical records and certificates of physicians. The existing case law shows that courts consider this evidence with a large scrutiny and it may be very complicated for a patient to prove that a medical cannabis-based therapy is the only means of treatment that is available. The cases, discussed in the article, are commented in much detail, so the reader may acquaint himself or herself of how do disputes in this field of social law proceed, and whether patients are able to prove the necessity of a medical cannabis-based therapy to them.

**Key words:** social security law, legalization of medical cannabis, patients with severe ailments, draft laws.
Introduction

The use of different medicinal products, containing cannabis is legalized in a number of European states, and the number of clinical trials and statistical information is enough to confirm that the use of medical cannabis is effective for treatment of over 50 diseases and pathological conditions. Hence, the issue of legal regulation of using cannabis for medical purposes, as well as scientific and scientific-technical purposes is becoming crucial, since then, many Ukrainian patients suffering from serious health impairments would enable access to medical treatment, which would alleviate the symptoms and the flux of their ailments, and the scientists and pharmacy industry would be able to conduct clinical trials according to international standards. The harmonization of Ukrainian legislation with the European standards is one of the key tasks within Ukraine’s path to the integration with the European Union, and the sphere of healthcare and pharmacy is not an exception. Precisely considering the European experience in terms of legalizing cannabis in treating, scientific and industrial needs, there is an ultimate necessity to review and adopt the Draft Law No. 7457 (June 10, 2022) «On regulation of the turnover of the cannabis plant in medical, industrial needs for creating conditions concerning broadening the access of the patients to necessary treatment of cancerous diseases and post-traumatic stress disorders because of the war» [1]. It is a very progressive draft law, which was elaborated in strict compliance with international-legal standards, as well as the experience of the most progressive states of the world. From a medical point of view, adopting such law would allow broadening the possibility of patients’ access of necessary medical assistance and provide effective medical treatment on basis of cannabis. According to the Chairman of the Ukraine’s Supreme Council’s Committee’ on the Health of the Nation, Mykhajlo Radutskyi, over two millions of citizens are deprived from the possibility of efficient medical treatment on basis of cannabis, among which over 20,000 resistant epilepsy minors, over 100,000 palliative care patients and several hundreds of thousands of cancer patients are accounted, as well as several dozens of thousands of war veterans, suffering from post-traumatic stress syndrome [2]. However, the currently-acting Law of Ukraine «On Drug Means, Psychotropic substances and Precursors» inhibits any activity in terms of cannabis or cannabis resin, the extracts and infusions of cannabis, which are considered as especially hazardous drug substances, that are forbidden according to the Cabinet of Ministers’ Decree No. 770 (May 6, 2000). It should be denoted that in this case we are presupposing that the application of cannabis explicitly for treatment purposes. As of the substance, we mean it is the Cannabis plant with an eligible quantity of the percent of retaining and concentration of tetrahydrocannabinol, or the so-called cannabinol, which is one of at least 120 cannabioids, found in the cannabis plant, and is a fitocannabioid, whose part in the plant extract tolls up to forty percent, hence it does not possess any psychoactive proper-
ties which tetrahydrocannabinol does. Its therapeutic effect and its efficient application in medical purposes has been affirmed by a multitude of scientific research, and the Expert Committee of the World Health Organization have its respective conclusions upon pre-clinical and clinical research, according to which cannabidol cannot be considered as a psychoactive substance, and does not lead towards a drug condition or addiction, but has explicit therapeutic potential. The European Monitoring Center on Drugs and Drug Addiction, which is functioning as an EU agency, researching issues on drug policy in EU Member States, has renewed its recommendations in 2018, which relate to using cannabidol in medical purposes, having therapeutic effect already in 56 states, such as United States, Canada, the Netherlands, Italy, the Czech Republic, France, Portugal, Poland, Greece, Austria, Denmark, Belgium, Norway, Israel and especially Germany, where legalization of medical cannabis in 2017 by the «Law on Passing Changes to the Drug Act and other normative-legal acts» (BGBl. I 2017 S. 403), hereinafter – the Law of March 6, 2017, which has already attained the status of safety and ecological durability [3].

The German experience

In Germany, the Law of March 6, 2017 is aimed at legalizing a receipted prescription of watered-down cannabis flowers and extracts to the patients, who are suffering from a range of serious illnesses, wherein no alternative means of medical treatment are available. The Law of March 6, 2017 altered a number of acting German laws. Namely, Art. 19 (2) of the Drug Act of 1994 was amended, according to which, the Federal Institute of Medicines and Medical Appliances is the controlling organ of growing medical cannabis in the sense of Art. 23 (2) (d) and Art. 28 (1) of the Unified Convention on Drugs of March 30, 1961, and is the authority providing its procurement for medical purposes according to the Law on Public Procurement. Art. 31 of the Fifth Book of the Social Code of 1988 was amended with section 6, according to which, the insured people, suffering from severe ailments, have a right to be provided with medical cannabis, namely watered-down flowers or extracts, in case of a) traditional medical services for treating the said ailments are not available; b) there is a relatively close prospect of a considerable improvement for treating the ailments or alleviating the symptoms. The patients, who desired to use medical cannabis for alleviating ailment symptoms, have to apply to the Federal Institute of Medicines and Medical Appliances for an official permission, to which, a respective conclusion of the treating physician must be provided, upon which the Federal Institute of Medicines and Medical Appliances shall decide upon the patient’s situation; any additional medical evidence could be presented, i.e. records of undergoing rehabilitation, etc. Apparently, deciding upon the case of each of the patients may be substantially complexified by a variety of factors, such as addiction or the subsistence of psychiatric impairments altogether with severe physical ailments (e.g. see facts of the case: [3].
According to the judgment of the Federal Social Court of November 10, 2022 (case No. B 1 KR 9/22 R, at para. 14), the provision of Art. 32 (6) of the Fifth Book of Social Code is the precise legal provision, under which the patients have a right to lodge a request to obtain medical cannabis from the Federal Institute of Medicines and Medicinal Products in order to treat severe diseases and alleviate their symptoms [5]. The adoption of the law (BGBl 2017 I S. 403) has created a considerable number of legal precedents, resulting from different administrative disputes, for instance, relating to the supply of medical cannabis for the needs of inhalation [6], supply of medical cannabis to a patient suffering from severe pain [7], or to an insured person suffering from pain as well as different psychological conditions [8], compensation relating to the supply of medical cannabis to patients [9], etc. The courts are also very diligent to investigate of whether all kinds of other means of treatment were exhausted before they would allow the use of medical cannabis in order to alleviate pain and other chronic illness symptoms [10], and the courts may determine whether the patient’s disease, its symptoms and its consequences is severe enough that the patient may be granted a right to use medical cannabis for alleviation of the condition [13][14].

The case law of the Land Social Court of Baden-Württemberg

The practice of social courts relating to the patient’s right to use a cannabis therapy has so considerably enlarged, that we even find chains of precedents. For instance, several such cases were heard by the Land Social Court of Baden-Württemberg since 2017. The chain of precedents includes the following cases:

- LSG Baden-Württemberg, Beschluss vom 01.10.2018 – L 11 KR 3114/18 ER-B
- LSG Baden-Württemberg, Beschluss vom 30.03.2021 – L 11 KR 436/20

In the judgment of the Land Social Court of Baden-Württemberg of September 19, 2017, the plaintiff asked to reimburse the costs of supplying the flowers of medical cannabis, for which he applied to the defendant in March 2017, and the defendant undertook to provide a medical conclusion relating to the case by the medical service of social insurance, also asking to fill in an inquiry sheet during a visit to the treating physician. Plaintiff was ill with spondylolisthesis and used only an anti-pain therapy. The conclusion of the medical service of social insurance was that the plaintiff, despite being ill with a serious disease, could benefit with physiotherapy and such means, as a surgical fixation of the vertebral bodies and alleviating pain by an anti-pain therapy. Hence, upon such a conclusion, there were omnipresently recognized means of treatment available for the plaintiff. So, in its conclusion of March 28, 2017,
the defendant dismissed the claim of the plaintiff, who filed a lawsuit next month, seeking relief in court order. The plaintiff ascertained that he had been suffering from chronical pain syndrome as a consequence of several diseases, namely spondylolisthesis and osteoarthritis, which rendered him hard to walk, and all his movements were escorted by severe pain, the medicines he used were of low efficiency, and are connected with considerable side-effects, and that neither the anti-pain therapy, nor any other therapies had not shown any virtual result, and plaintiff thought, that only medical cannabis flowers could bring him relief, and he would not suffer from any other side effects. Plaintiff also claimed that he could not benefit from physiotherapy because of severe pain, hence this therapy was terminated, and concerning surgery, he found that it was connected with severe risks and could not guarantee that it could be useful for him. The defendant, in reverse, claimed that the plaintiff had not done any physiotherapy within the last years, and the medicine-based treatment was in fact not exhausted, and finally, the defendant claimed that the disease was not so severe, and there was no evidence of the plaintiff’s words that he may face a risk of an irreparable damage to his health. The Social Court of Ulm dismissed the plaintiff’s lawsuit in its judgment of August 8, 2017, finding that the plaintiff did not justify that the demands of the provision of Art. 31 (6) of the Fifth Book of Social Code of 1988 were fulfilled properly. The plaintiff, according to the view of the court, did not prove, that there is no omnipresently-recognized medical service that was available for him, or could not be applied in distinct cases according to a justified view of the treating physician, taking into consideration the possible side effects and the plaintiff’s health condition. According to social benefit records, the plaintiff was prescribed anti-pain medicines for five times in 2010-2017 for the defendant’s costs, and no physiotherapy was conducted during this time fragmenton. Physiotherapy, according to the medical service’s conclusion, should be viewed as an omnipresently recognized medical service, accompanied with the exercise which the plaintiff could perform himself. There was also no reason to believe, that the physician had arrived to a conclusion that the existing medical services could not be applied: plaintiff’s family physician only denoted, that the alternative means of medical treatment did not provide sufficient pain control in a case of a severe orthopedic disease. From this conclusion, it would be unknown what side effects could be anticipated from the alternative means of treatment, and the mere claim of the plaintiff that physiotherapy only declined his symptoms could not be enough for proof. Nevertheless, the plaintiff filed an appeal, where he set out a number of medicines he tried to consume without such effect as that he could lead his everyday life or work as an actor, and that these medicines did not relieve him from severe pain, and caused major side effects, and he also denoted that he could continue physiotherapy only in case the pain is alleviated. The plaintiff also said, that he did not observe any other medicines but medical cannabis, and confessed that he had used it before by a private recipe, and managed to improve his
health. Plaintiff also held that he dreamed of continuing to be engaged into his profession of an actor. The defendant found, that the plaintiff did not use the therapy on a regular basis before, having received five recipes – three in 2012 and two in 2016, two of which being not pain-relief medicines, and in order to have a substantial effect, the medicines need to be consumed on a long and regular basis. The court reckoned up the rules, under which the patients suffering from severe illnesses may be supplied with medical cannabis, and found, that it was not the case plaintiff could account on. The court held, that according to the explanatory note of the law, medical cannabis could be supplied to the patient only in strictly limited cases; since, its supply was developed as a substitution of an omnipresently recognized medical service, which corresponds to the medical standards, which is either unavailable, or is unjustified in distinct cases, the court found that it should use the term «serious disease» in the sense of S 35 (c) (2), sentence 1 of the Fifth Book of the Social Code. Whereas the chronical pain syndrome, caused by spondylolisthesis and other ailments of the plaintiff qualifies to be a serious condition, the fact that the plaintiff received so few recipes in years casts doubt relating to the seriousness of the plaintiff’s condition. What is more, plaintiff could not have a right to order the medical cannabis-based products, since there is no recipe of the supplier of state medical insurance (and the first-ever receipt for an insured company would require the approval by a medical insurance company). To be realized, the order should require an obligatory medical receipt, and it is not enough to have a private receipt. Upon such conclusions the court ruled to dismiss the plaintiff’s appeal [8].

In the judgment of the Land Social Court of Baden-Württemberg of October 1, 2018, the plaintiff was a young man suffering from a number of chronic mental illnesses, which had quite a serious disabling impact on him. In 2010-2011, the plaintiff underwent an outpatient treatment at an outpatient psychiatric clinics, and his condition later compelled him to terminate his studies at a university, where he was obliged to take semester-long holidays, and since 2017, the plaintiff also underwent therapy conducted by a psychologist. In early 2018, plaintiff turned to approve the therapy based upon the flowers of medical cannabis, also submitting a general practitioners certificate, who approved the given therapy. Plaintiff actually confessed to having used cannabis-based treatment before, which seemed to have a positive impact on his health condition. Then, the plaintiff was notified by the defendant, a state medical insurance fund, that the medical services of the said company would conduct a medical examination of him. According to the conclusions of the medical service, the plaintiff’s condition, from one hand, could be described as a severe one, but on the other hand, he didn’t undergo a specialized psychiatric treatment before, and medicine-based therapy was also not applied before as well. So, the plaintiff was denied a cannabis-based treatment. However plaintiff did not give up and underwent specialized psychiatric treatment in Summer 2018, where escitalopram was used as a primary medicine, which
unfortunately caused multiple side effects, and thus the medicine was later changed to sertraline, which also cause side effects; hence, the psychiatrists recommended a therapy based upon medical cannabis. The plaintiff was again examined by the defendant’s medical service, and the examining physician agreed that at that time, there already was a justified evaluation of the treating physician that alternative means of therapy were not admissible, according to the side effects. So, plaintiff applied to the Social Court of Mannheim, pleading to provide him the flowers of medical cannabis, claiming that he feared he would be unable to continue his studies, also underlining that he had already taken a one more semester-long holiday at the university, and could not take an another period of holidays, since he would be otherwise expelled. However, the court dismissed his claim, finding that the plaintiff had no proper recipe from the supplier of state medical insurance. Plaintiff appealed, claiming that the actual conditions were fulfilled, providing an obligatory medical recipe of Bedrocan from a neurologist and a psychiatrist dated late August 2018. As plaintiff confessed to having used cannabis for treatment, no side effects of its use were found, and the physician has confirmed its positive effect, and at the same time, when plaintiff used antidepressants, there were multiple side effects, which was acknowledged by a new physician’s certificate dated late August 2018. The court upheld the plaintiff’s appeal. Under Art. 31 (6) of the Fifth Book of the Social Code of 1988, insured people suffering from severe conditions have a right to be supplied with medical cannabis or extracts of a standardized quality and the supply of medicines with acting ingredients of dronabidol or nabilon, in case omni-presently means of therapeutic treatment is either not available, or cannot be applied according to a justified explanation of the treating physician, or there is a relatively close perspective that such therapy could have a substantially positive effects on the course of the ailment or the symptoms. The court outlined, that the explanatory note to the law provided that it is not necessary that the person should not suffer from side-effects of the therapy the person is undergoing before the alternative in medical cannabis-based therapy will be approved. The provision of Art. 31 (6) (1) (b) clarifies that the absence of alternative means of treatment may be presumed, in case the physician comes to a justified conclusion that such means (if they exist) should not be applied after weighing the anticipated side-effects and taking into account the health condition of the insured person. Hence, here the evaluation of the treating physician is necessitated, which should consider a) the individual circumstances of the insured person, b) earlier therapies; c) concrete side effects of a standard therapy and possible side effects of the therapy based upon medical cannabis. Under the facts of the case, plaintiff had already underwent a behavioral therapy, which was unsuccessful. The first certificate of the physician was, according to the court’s estimation, written in a relatively abstract way in order to justify the absence of a standard therapy, but after that the plaintiff underwent psychiatric treatment and the certificates of the neurologist and the psychiatrists outlined considerable
side effects from the use of escitalopram and sertraline without any positive effect. At the same time, cannabis-based treatment showed its efficiency, since the plaintiff’s concentration, and was able to cope with the university tasks at home, and this treatment had a positive impact on his other diseases. The physician’s point of view also stuck to the point that the doctor did not observe clomipramine-based therapy as suitable owing to multiple side-effects, since plaintiff was already suffering from conditions the side-effects would arise, and so the use of this medicine would apparently decline the plaintiff’s condition even more seriously, and hence the physician did not recommend this medicine as a basis of therapy. The court found, that a medical insurance company has the right to decline a certain license only in concrete and justified cases, and if there is a justified view of a contracted physician, then it is not necessary to try theoretically any alternative of treatment. The court also agreed, that there is a relatively close prospect of a considerable positive impact on the patient’s health, and hence found for the plaintiff, ordering the defendant to provide the plaintiff with the flowers of medical cannabis in accordance to the medical recipe [11].

In the judgment of the Land Social Court of Baden-Württemberg of March 30, 2021, the plaintiff litigated for the supply of a medical cannabis-based medicine named «Drobinadol». The plaintiff, aged 59, had a 50 per cent disability rate since 2011, primarily suffering from chronic neurotic pain and hepatitis; he applied to the defendant in July 2018, augmenting an inquiry from a general practitioner. The defendant applied for a medical service corollary, which was ready in late August, 2018, upon which, it was concluded, that the plaintiff did not fulfill the provisions of Art. 31 (6) of the Fifth Book of Social Code of 1988. It was not available to stipulate that the plaintiff’s condition was a severe one in the sense of the law, and the general practitioner also did not provide any medical records as to the plaintiff’s treatment; it was hallmarked, that plaintiff did not undergo any therapeutic treatment for years, and the plaintiff’s complaints relating to back pain were not anyhow documented by appropriate records of treatment, rehabilitation and other medical assistance, no data relating to rehabilitation and physiotherapy were also provided. Hence, it was concluded, that the diagnosis «neuropathic pain» was not tenable to be conceived, as it was not anyhow approved, and that unspecified back pain would be more appropriate to be treated according to national recommendations on medical assistance in relation to the diagnosis «Unspecified back pain». Hence, the defendant declined the plaintiff’s application for medical cannabis, which is given by recipe. The plaintiff objected and represented medical records, upon which he underwent physiotherapy in 2017, according to him having spondylolisthesis, suspected L5 vertebra spondilosis, L5/S1 vertebra chondrosis and other orthopedic ailments, augmenting disability medical records, certificates of an orthopedic physician relating to the use of a special vertebral orthosis and other medical records in confirmation of his condition. After that, the defendant had agreed to provide a new corollary of the medi-
cal service, but it was again negative. The medicinal order was not used, as there were no medicinal cheques, and the medical records also did not show how did the plaintiff undergo anti-hepatitis treatment, if he actually underwent it. The last time the plaintiff underwent physiotherapy, according to the record, was 2010, that is almost nine years before he applied for cannabis-based medicines. There was also no record of applying a medicinal therapy, recommended for neuropathic pain, and no record of how does the plaintiff conceive pain (as a condition), and since plaintiff suffered from depression, and applied for a psychiatrist in 2012, and a new application to this physician was necessitated. The record also revealed that the plaintiff had actually used cannabis for treatment before, and it seemed to have a negative impact on plaintiff, who had been diagnosed with psychological and behavioral disorders. It was also unclear, what impact hepatitis had on the plaintiff’s pain, and there also was no proof on how does a cannabis-based therapy impact on the course of the disease with an ongoing hepatitis and a complementary ailment. Vice versa, there was evidence, that cannabis had a negative impact on the course of the disease. In April 2019, plaintiff lodged a lawsuit to the Social Court of Freiburg, which adjudicated the case on November 28, 2019, dismissing the plaintiff’s lawsuit. The court found, that the provisions of Art. 31 (6) of the Fifth Book of Social Code of 1988 were not fulfilled: the plaintiff’s back pain could be treated by medicinal therapy and by physiotherapy, and the physician’s, who wrote the certificates for the plaintiff did not provide a justified evaluation, of why, considering the possible side effects and the plaintiff’s state of health, an omnipresently recognized medical service may not be applied in this case. The plaintiff appealed against this decision in early February 2020, augmenting his appeal claim by producing medical records, which approved that medicinal and balneophysical therapies were rendered insufficient. The court of appeal heard three expert-witnesses, which were plaintiff’s physicians, and they stated the following:

Witness 1: the plaintiff was treated by this physician in 2018–2019, and was, according to his view, suffering from a severe pain syndrome, a multi-modal approach to anti-pain therapy was rendered to be insufficient. The plaintiff used drobinadol (as found later, by private recipes) the plaintiff said that there was a considerable positive impact on his health, and the plaintiff did not overuse the dosage. The physician also found, that the back pain was a chronic condition, and that the plaintiff had a mild depression.

Witness 2: the plaintiff was treated in 2010, 2017 and 2018. In 2010, plaintiff underwent a physiotherapy with a follow-up in 2017. In 2018, he was prescribed ibuprofen and in 2017, he received a stabilizing back orthosis.

Witness 3: the plaintiff was treated by him since 2011. Plaintiff once underwent treatment from hepatitis in 2012 with some success, and the same dates, plaintiff suffered from depression. In 2017, the said doctor treated him from intense back pain, albeit one of the medicines had an adverse impact on the plaintiff. In 2018, the plaintiff was directed to an anti-pain therapy. Neither
anti-pain medicines, nor physiotherapy had a considerable impact on the plaintiff. The physician also said, that the plaintiff confessed to have used cannabinoids. However, there was no real risk on dependence or abuse.

The court of appeals found, that the plaintiff indeed suffered from considerable vertebral ailments, because of which he received a disability group. Whether or not such disease should be rendered as a «severe» one, in reference to Art. 31 (6) of the Fifth Book of the Social Code of 1988, the Court decided to leave the issue open. The information provided by the physicians was occasionally controversial, especially in terms of the diagnosis of a chronic neuropathic pain, which was, upon one of the physician’s conclusions, changed to a chronic pain syndrome. The plaintiff was also diagnosed with hepatitis, which was, seemingly, successfully treated in 2012, and depression, which was treated in 2012, again diagnosed in 2018, but was not anyhow treated. According to Art. 31 (6) (2), the lack of standardized therapy, as a legal provision’s demand, is fulfilled when a certain «classic» therapy either is not available, or it is proved, that the insured person cannot tolerate it. The medical service corollary provided, that a chronic pain syndrome in the back could be treated by a multitude of different medicinal therapies, and the same conclusion was drawn in relation to the depression. The court stated, that legal provisions in terms of a justified evaluation of the physician who could prove why alternative methods of treatment cannot be used, were not fulfilled, as there was no such evaluation was provided. The certificate of the treating physician also rose doubts: for instance, the court found it strange, that the diagnosis (chronic neuropathic pain) was later changed, the physician did not pay attention that the plaintiff had undergone a specialized psychiatric treatment, and it was not checked whether the plaintiff actually had any counterindications to medical cannabis, and the physician, acting as an expert-witness in the case, confessed to have no knowledge relating to the earlier negative impact of the plaintiff’s use of cannabinoids. The further record revealed that the plaintiff underwent treatment irregularly, and did not undergo physiotherapy since 2010. So, the court found that the legislative demands of Art. 31 (6) of the Fifth Book of the Social Code of 1988 were not fulfilled, and rejected the appeal [13].

In the judgment of the Land Social Court of Baden-Württemberg of March 22, 2022, the plaintiff, aged 37, was suffering from attention deficiency syndrome and hyperactivity since his childhood. He also confessed to have terminated using Ritalin back in his childhood as had used cannabis for twenty-five years for treatment, and asked the defendant to reimburse the costs of treatment by means of cannabis flower, claiming he needed to treat his mental condition and a mild depression, and without a cannabis-based therapy, he could not cope with his everyday life, claiming that the said therapy would considerably alleviate his symptoms; plaintiff also claimed that he was suffering from attention deficiency syndrome since he was 7 years old, and he was compelled to consume Ritaline, after which he had developed a disgust towards tablets. He also provided a certificate, according to which, in May
2019, he had no psychotic symptoms or any other contraindications, and the cannabis-based therapy was supported from a neurological point of view. Plaintiff claimed he benefitted from this therapy, but the main problem that this therapy was not legitimate itself. So he applied to the defendant, and in late May 2020, the defendant ordered the medical service to prepare a report, in which the demands of the plaintiff had been dismissed in terms of the costs, and the report hallmarked that the attention deficiency syndrome in children, adolescents and adults should not be treated by a cannabis-based therapy, and there is no prospects that this kind of therapy would have a positive effect on the course of the disease or its symptoms, and therefore, the plaintiff had to be referred to other available means of psychopharmacological and psychotherapeutical therapy, based upon the recommendations. So, the plaintiff’s plea was dismissed by the defendant’s decision of June 3, 2020 and in December 2020, the plaintiff lodged a lawsuit to the Social Court of Mannheim. Plaintiff justified the claim that he was suffering from attention deficiency syndrome and a mild depression, which is a serious condition, which requires medicinal and psychotherapeutical treatment and could bring to severe and deplorable consequences, such as diminishing the lifespan and the quality of life, and the plaintiff claimed he could not cope with his everyday life without such therapy. A doctor, who treated the plaintiff, being released from confidentiality, testified as an expert-witness. He told that he treated the plaintiff for a year, finding that without therapy, plaintiff would be nervous and frustrated, the expertise results were not somewhat anomalous due to the fact that plaintiff had used cannabis before, and that other treatment means such as psychotherapy and behavioral therapy were available. The Social Court of Mannheim rendered its judgment on November 11, 2021, where the court dismissed the plaintiff’s lawsuit. The court found that the main reason for supplying medical cannabis to a patient is that this patient suffers from a serious disease, and a «serious disease» should mean a medical condition which endangers the life or quality of life in a long prospect because of the degree of the severity of the health impairment caused by the illness. The court did not find, that the disease plaintiff was suffering from was either a disease which is endangering life or has got a major influence in a long prospect. The court also found the plaintiff’s assertions doubtful in regard with his claim that he could not lead an everyday life without his self-treatment by means of cannabis, and according to the testimony of the physician heard as an expert-witness, there were several unused means of treatment (psychotherapy and behavioral therapy). The plaintiff decided to impugn the said judgment to the Land Social Court of Baden-Württemberg outlining that medicinal therapy is inapplicable in his case due to the fact he had developed a phobia of tablets or a certain psychologic disorder, claiming that he was under a close attention of his treating physician, who only recommended psychotherapy and behavioral therapy as an augmented means of treatment, reiterating that he was suffering from attention deficiency syndrome from childhood and other means of therapy were
applied without effect. The defendant asked to dismiss the appeal, referring a precise conclusion that in the plaintiff’s case, a medical cannabis-based therapy is strongly non-recommended. The Court outlined the legal requirements for receiving the flowers of medical cannabis, and the plaintiff’s situation did not satisfy these conditions. Firstly, the plaintiff did not manage to prove that he suffered from a serious disease, which the court chose to overview in the sense of Art. 35c (2), sentence 1 of the Fifth Book of Social Code of 1988, and the court arrived to a conclusion that a serious disease is a health impairment which is distinct from the others by its severity, and it is an ailment, which endangers the life or which constantly impairs the quality of life; the court also hallmarked that the rarity of the disease does not provide the ground to say that it is a serious disease. The ailment suffered by the plaintiff neither endangered his life, nor had a long impact of the quality of life of the plaintiff in a long-term prospect; the allegation in terms of the seriousness of the disease does not spring out of the diagnosis itself, the decisive factor is the level of impairments caused by the disease. The physician of the plaintiff, being an expert-witness in the case before the trial court, outlined that the plaintiff’s behavior was quite calm and adequate, and the certificate of 2019 also did not provide for the conclusion that the illness was serious; the depression, which was mild, was not proved to reach such a level of severity to be considered as serious, which was not proved by any physician. In terms of alternatives of treatment, the report of the medical service dated May 28, 2020 stated that there are different medicines for the treatment of attention deficiency syndrome are available, and in neither of the physician’s reports relating to plaintiff it was said that there were no treatment alternatives. The treating physician actually mentioned that the plaintiff had developed a phobia of tablets, but the court found that it was insufficient in the view of Art. 31 (6) (1) (b) of the Fifth Book of the Social Code of 1988, for which it is necessary to provide a justified estimation of the contracted physician that the standard therapy could not be applied, taking into consideration of the possible side effects and the health condition of the insured person. According to such views, the court ruled to dismiss the plaintiff’s appeal [14].

The case law of the Federal Social Court of Germany

In the judgment of the Federal Social Court of Germany, handed down on August 8, 2017 (Case No. S. 27 KR 698/17 ER), the court had to determine of whether the plaintiff was entitled to reimbursement of a medicine named «Cannabis Flos Bedrocan», upon which he also applied a recipe to the defendant, also augmenting a license (according to Art. 3 (2) of the Drug Act of October 9, 2012) to purchase the flowers of medical cannabis from the Federal Institute of Medicines and Medical Devices, as well as the physician’s certificate holding that the plaintiff was treated many years without considerable effect. The plaintiff was a senior, who suffered from polyarthritis, many various bone
deformities, spine conditions, Bechterev’s disease etc., and was insured by defendant. The plaintiff was known to have been suffering from polyarthritis and Bechterev’s disease since the 1980s. Plaintiff had a large family, and his wife was the only wage earner, while him being disabled, and plaintiff claimed that he could not afford self-financing of the medicines. A doctor’s certificate dated early 2017 stipulated, that the plaintiff’s condition was very chronic, considerably affecting the quality of life, and the medicines he would need to alleviate pain and other symptoms would necessitate using them in a very high dosage, also causing a multitude of side effects, such as bowel diseases, cramps and kidney stones. The record provided, that the plaintiff had already used the cannabinoids before, and that his condition had gradually improved after four years of using them. The defendant, however, refused to refund the costs of the medicine, finding that it was not clear from the medical record, of whether what exact medical and non-medical methods of treatments were used, and which of them were found to be unsuitable for treatment, also pointing out that the plaintiff has not been on any specific anti-rheumatologic treatment since 2005, and hence it should be concluded that it was unlikely, that plaintiff could not apply an omnipresently means of medical treatment, which corresponded to omnipresently-recognized standards. Plaintiff filed a lawsuit to the Dusseldorf Social Court, claiming that before applying the therapy, which involved medical cannabis he used different treatment, such as cortisone and non-steroid anti-inflammatory medicines in the first stages of his illness back in the 1980s and 1990s, also applying diclofenac in order to protect the stomach from possible side effects. He claimed that all the aforesaid treatment was either in vain or barely sufficient, after which the plaintiff used cannabis for treatment purposes. Next, he claimed that the could not afford any more medical cannabis, since it was very expensive, and hence the senior asked to oblige the defendant to cover «Cannabis Flos Bedrocan». The defendant pleaded to dismiss the claim, finding that the pain the plaintiff was constantly feeling and referring to was not sufficiently proved. Moreover, the defendant claimed, that other means of treatment were far not exhausted, since the plaintiff did not underwent specific anti-rheumatism treatment. The defendant also discarded the position of plaintiff’s doctor, finding that they were too generalized, and that it was unclear for which reason alternative therapy did not (if it did not) exist. The case reached the Federal Social Court, which, despite finding the plaintiff’s complaint admissible, decided to dismiss the complaint. The Court reiterated the law, that according Art. 31 (6) (1) of the Fifth Book of the Social Code of 1988, insured persons with a serious disease have a right to be supplied with medical cannabis in the form of watered-down flowers or extracts of standardized quality, and the supply of medicines with the acting substance of drobinadol and nabilon, if an omnipresently-recognized medical service, which corresponds to a medical standard is unavailable, or it cannot be used in separate cases according to a justified certificate of the treating physician, taking in account the anticipating side effects and taking into account the health
condition of the insured person, or when a relatively soon prospect of a positive treatment effect exists. The Court agreed, that the plaintiff, a disabled person, was suffering from severe diseases, since such diseases precluded the plaintiff to conduct everyday activity, and at the same time, the plaintiff’s diseases still could be treated while applying omnipresently-recognized medical treatment services, which corresponded by the medical standards, and such therapies, in fact, were actually referred to in the physician’s certificates. The Court found, that according to the presented documents, it could not be concluded, that the medical treatment services, which is omnipresently-recognized, could not be provided to the plaintiff according to the doctor’s evaluation. Moreover, the certificates by doctors did not provide for such evaluation. For instance, one doctor held in the medical record, that the plaintiff was treated by him since 2012, and only mentioned what medicines the plaintiff was given, and what were the side effects, and plaintiff actually did not undergo treatment by omnipresently-recognized methods; the doctor recommended a therapy based upon medical cannabis according to the complaints of the plaintiff, and there was no detailed justification for what reasons plaintiff could not benefit from ordinary treatment methods. Another doctor’s certificate also lacked justification necessitated by the law. There, the doctor mentioned that the plaintiff used diclofenac, as well as non-steroid anti-inflammation medicines, the side effect of which was diarrhea, and it was also mentioned that a further immunosuppressive therapy was necessary. The certificate further went to refer the success of cannabis therapy and claimed that a classic therapy would be less successful, but it was not mentioned of whether the classic therapy would be excluded for medical reasons.

In this article, I would like to represent the facts and the judgment of the Federal Social Court of Germany, handed down on November 10, 2022 (Case No. B 1 KR 9/22 R). Plaintiff, registered at the hospital sickness fund (the defendant) who suffered from fibromyalgia, pain syndrome and several other ailments, lodged an application through his caregiver to request the hospital sickness fund to take charge for the reimbursement of costs for the prescribed medical cannabis flowers and the prescribed therapy. The defendant asked the plaintiff to provide records concerning the medical cannabis medicine he was to be prescribed, as well as notified plaintiff of the necessity to be examined by the insurer’s medical service. Nevertheless, plaintiff provided all the requested documents, including a certificate of the treating physician ascertaining the facts on all preceding therapies. Though the insurer’s medical service has affirmed fibromyalgia, but denied the subsistence of a severe impairment, and found that plaintiff had been addicted to cannabis, and that not all treatment alternatives had already been applied. What is more, since plaintiff suffered from a behavioral disorder, and the treatment involving medical cannabis was contraindicated. Then, the man filed a lawsuit against the hospital sickness fund, but lost the lawsuit at first instance [10], lodging an appeal. The appeal was dismissed: the Land Social Court of Berlin in
its judgment of March 17, 2022 found, that there were alternative means of
treatment for the plaintiff in his situation, which meet the necessary medi-
cal standards [11]. Then, plaintiff lodged a complaint to the Federal Social
Court, which decided to dismiss the plaintiff’s complaint. The key findings of
the court are the following:

a) Plaintiff’s situation did not correspond to the norm of Art. 31 (6) (1) of
the Fifth Book of Social Code. There was no evidence, that plaintiff’s ailments
somehow were hazardous for his life. Plaintiff’s condition tolled to a moderate
disability in overall, including different ailments of internal organs, pain syn-
drome, sleep impairments and behavioral disorders; he had a caregiver, and
it could be concluded that his condition could gradually worsen, hence, there
might be a possibility that his condition would somehow qualify for a severe
disease, according to the conclusions of the appellate court (but still, the
appeal was dismissed). The Federal Social Court also denoted, that the mere
fact that plaintiff had consumed cannabis before was not a reason to reject
his request at all. Whether there is a contraindication to plaintiff for the use
of medical cannabis in case he consumed cannabis earlier, is a matter, which
has to be decided by the treating physician. In case the hospital sickness fund
had wrongfully refused to pay for the service the insured patient had desirer,
then the hospital sickness fund has to reimburse it, in case the patient man-
aged to provide the service himself or herself, but this was not the situation,
since plaintiff was not refused to be provided with medical cannabis, but was
refused in approving in a receipt for it.

b) When the receipt for prescribing medical cannabis is approved, than it
means, that a standard therapy, which corresponds to a set medical standard
is: a) either unavailable, or cannot be applied, in case there is evidence of this
fact according to the conclusions of the treating physician. The «unavailabil-
ity» of the procedure means, that: a) it is unavailable, because it does not exist:
b) there are risks for health of the insured person to undergo this therapy; c)
such therapy had been ineffective. According to the findings of the appellate
court, the Federal Social Court established that standard methods of treat-
ment were available for plaintiff’s ailments, which also included the treatment
of addiction and anti-depression medication. There was also no conclusions
made by the physician, that the standard ways of treatment were inappli-
cable in plaintiff’s situation. The process of approval of providing a patient
with medical cannabis for treatment purposes is fulfilled in a natural form,
when it is obtained from the treating physician on contract, who would pre-
scribe it for the costs of the hospital sickness fund. According to Art. 31 (6) (2)
of the Fifth Book of the Social Code, the approval should be equalized to the
assistance which the insured persons could receive as assistance in a natural
form from the hospital sickness fund, and since it is made only after a careful
examination of the circumstances for fulfillment of the provisions of the law,
it should be regarded as an approval of a service. According to the conclusions
of the appellate court, the plaintiff had no right to the approval of the receipt
of medical cannabis according to his condition, and the given conclusion was affirmed by the Federal Social Court.

c) The physician’s conclusions possess considerable weight. For instance, potentially hazardous outcomes of consuming medical cannabis; in case addiction and behavioral impairments are established, then the physician should claim, whether there is a complete contraindication to medical cannabis, or in terms of a specified amount of medical cannabis, used for the purposes of treatment. The physician should also indicate, what are the preventive measures for avoiding, or diminishing the hazardous consequences of consuming medical cannabis; the physician, who draws the conclusion, has to have a considerable expertise in this field of medicine, and it is not allowed to use the conclusions of other expert physicians. The prescription of the form of medical cannabis may be alternated upon the view of the treating physician. The Court concluded, that there was no complete conclusions of the physician in respect with the plaintiff’s case, for instance, there was no consideration of the plaintiff’s behavioral impairments in connection with consuming cannabis, and no measures to diminish the negative consequence of consuming medical cannabis were written in the physician’s conclusions. It was not disputed, that the plaintiff received both the notification on the necessity to provide the requested medical records, and received the answer with a refusal to approve the receipt in a timely manner. The Federal Social Court ruled to dismiss the plaintiff’s complaint [5].

Conclusions

According to Art. 405 of the EU-Ukraine Association Agreement, Ukraine has taken the obligations to harmonize the domestic legislation in compliance with the EU regulatory acts, which is underlined in Appendix XXXVIII to the Agreement. Hence, the adoption of the draft law will amplify Ukraine’s guarantees in the sphere of European integration, the rights and freedoms, which are guaranteed by the Constitution of Ukraine, and will not create conditions for any discrimination. The adoption of the draft law will strengthen the guarantee of access to necessary medical services and medicinal products, involving those manufactured on basis on medical cannabis, its extracts and tinctures, which will also amplify the process of research in medical, industrial, scientific and scientific-technical fields of science. Apparently, we should take into consideration the experience gained in different European Union states. In this article, the author represented the experience of Germany, where a cannabis-based therapy was legalized in 2017. The administrative procedure is quite strict, since the patients need to provide medical certificates ascertaining that alternative means of treatment are either unavailable, or cannot be applied for certain reasons, for instance, having an adverse impact to the patient. The courts carefully review the issues of the severity of the disease and the existence of alternative means of treatment and their potential application, if possible.
For instance, the fact of a patient’s disability does not automatically render a cannabis-based therapy to be applicable, if alternative means of treatment exist and/or are not exhausted. The case law shows that it is quite difficult to prove that alternative means of medical treatment are insufficient, but it is possible. Moreover, the courts also take into consideration of how did the plaintiff undergo different means of treatment, how frequently such means were applied, and what impact on the plaintiff they made. These precautions are likely to be strong against drug addiction and abuse, especially against the background that some of the plaintiffs have confessed to having used cannabis for treatment in spite of its illegitimacy. To sum up, this administrative procedure is robust and allows to check the objective information about a concrete patient’s case according to the strict rules, provided in Art. 31 (6) of the Fifth Book of the Social Code of 1988.

1. Draft Law (Ukraine) «On regulation of the turnover of the cannabis plant in medical, industrial needs for creating conditions concerning broadening the access of the patients to necessary treatment of cancerous diseases and post-traumatic stress disorders because of the war». Register No. 7457, 10.06.2022. URL: <https://www.apteka.ua/article/638277>


4. VG Köln, Urteil vom 30.01.2018 – 7 K 7275/14
7. SG Aachen, Urteil vom 06.05.2019 – S 1 KR 174/19 ER
10. Bundessozialgericht, Urteil vom 08.08.2017, S 27 KR 698/17 ER
11. LSG Baden-Württemberg, Beschluss vom 01.10.2018 – L 11 KR 3114/18 ER-B.
12. LSG Baden-Württemberg, Urteil vom 22.03.2022 – L 11 KR 3804/21
14. LSG Berlin-Brandenburg, 17.03.2022 – L4KR230/19
Судові аспекти легалізації медичної коноплі
в Україні та досвід Німеччини

Проаналізовано проєкт Закону України № 7457 стосовно легалізації використання медичного канабісу для пацієнтів з важкими захворюваннями. Проведено дослідження Закону Федеральної Республіки Німеччини від 6 березня 2017 р., а також відповідної судової практики, зокрема справи Соціального суду землі Баден-Вюртемберг, а також справи Федерального верховного соціального суду. Крізь призму судової практики вивчено особливості застосування законодавства, яке регламентує отримання медичного канабісу пацієнтами, які страждають від важких захворювань. Встановлено, що ця адміністративна процедура є насправді достатньо складною для виконання й передбачає низку запобіжників: пацієнт має довести, що він чи вона справді страждає від важкого захворювання, а альтернативні методи лікування або не доступні, або неприйнятні в цьому конкретному випадку. Отже, якщо спір доходить до суду, пацієнт повинен виконати вимоги ст. 31 (6) П’ятої книги Соціального кодексу 1988 р. і на підставі медичної документації та висновків лікарів довести важкість стану свого здоров’я та відсутність альтернативних методів терапії чи їхню неефективність. Судова практика свідчить, що суди скрупультозно враховують ці докази, і пацієнтам доволі важко довести, що терапія, у якій використовується медичний канабіс, є єдиним доступним методом лікування. У статті на конкретних прикладах показано, як відбуваються спори у цій сфері права соціального забезпечення і чи завжди пацієнтам вдається довести необхідність терапії з застосуванням медичного канабісу.

Ключові слова: право соціального забезпечення, легалізація медичного канабісу, пацієнти з важкими захворюваннями, законопроекти.

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