

Post marketing surveillance of cannabis-based preparations

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Introduction

Throughout history, cannabis has been used as an analgesic and sedative. Today is the most widely cultivated, most trafficked and most exploitable narcotic drug in the world. The major and most researched phytocannabinoids are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). THC has psychoactive effects, while CBD does not affect perception and consciousness.

In February 2016, the Law on Control of narcotic drugs and Psychotropic substances was amended and the use of cannabis and cannabis preparations for medicinal purposes were allowed by the provision of Law in the Republic of North Macedonia. This regulatory framework permits access to unregistered cannabis extracts for medicinal use, manufactured by licensed pharmaceutical companies. Therefore, borderline products, as well as prescribed preparations for medicinal use, oil solutions with different proportions of CBD and THC approved by the Agency for drugs and medical devices, become available on the market. Consequently, the number of consumers using cannabis and cannabis-based products for medicinal purposes is increasing constantly. Pharmacists, as most available healthcare professionals (HCP) play a pivotal role in providing, advising and giving the pharmacy care for patient when dispensing cannabis-based products.

Hence, the aim of our study was the evaluation of knowledge, attitudes and experiences of consumers as well as community pharmacists when dispensing cannabis and

cannabis-based preparations for medical use in the Republic of North Macedonia.

Materials and methods

In a period of three months, survey questionnaires for medical use of cannabis and cannabis-based preparation with multiple choice answers scored from 1-5 by Likert scale (19 questions for pharmacists and 15 questions for users) were prepared and distributed among the mentioned target groups randomly selected on the territory of the Republic of North Macedonia.

The survey questions distributed among community pharmacist provided the demographic information (age, education and occupation), evidence for the number of consumers asking information related to cannabis and cannabis-based products, types of available products, frequency of prescriptions for a certain indication, number of dispensed products on a weekly base as well as dosing approaches. The questionnaire also contained questions for the level of pharmacist knowledge on this topic, their awareness for the necessity for further education, as well as the obstacles they are facing when dispensing this type of products.

On the other hand, the questionnaire intended for consumers of cannabis-based preparations provided the demographic information (gender, age and place of residence). In addition, the survey contained questions for the reason for treatment initiation with cannabis preparations and sources used to provide appropriate

information in decision making process, the diagnosis, the most prominent symptoms to be treated, frequently used dosage form of this products, and whether they are provided from the pharmacy. This study is also focused on the perception of the consumer regarding the quality of obtained information from the community pharmacist and other HCP.

Results and discussion

The overall survey in this study included a total of 277 respondents from all over the territory of the Republic of North Macedonia (133 community pharmacists and 144 consumers of different cannabis preparations).

Both pharmacists and patients increasingly believe in cannabis-based preparations and they are often a therapy of choice for certain medical conditions. Pharmacists mainly indicate that the number of patients who are interested in these kinds of preparations is increasing weekly and that many of them decide to take the preparation by their recommendation.

The most common way of users obtaining cannabis preparations from a pharmacy is recommended or prescribed by doctor (83%), while only 17% provide them in other ways. 77% of the evaluated pharmacist responded that between 1 to 10 patients ask for cannabis-based preparations on a weekly basis and 57% of them decide to take this preparation after consulting with the pharmacist. Consumers with different medical condition, especially those with cancer (30%) and chronic pain (13%), use cannabis products more often, due to the increased public perception for cannabis. 40% of the users in evaluated group were over 50 years old. According to the results obtained by respondents, the most common way of defining the dosage regime (52%) was according to the instructions in the patient information leaflet, which is officially approved by the regulatory body and only 8% of the users take the preparations according to their perception.

Consumers are most often informed about cannabis-based preparations by their doctors (31%) or friends (22%), 20% of respondents obtain information from pharmacists at a community pharmacy, and only 6% of respondents receive information by attending seminars. The prize of the available products on the market are the most common reason for discontinuing the use of these preparations (44%). On the other hand, only 2% of the respondents believe that use of preparations has no effect. More than 43% of the consumers were counseled by the pharmacists for the method of application and additional 8% of the patients were informed that usage of cannabis is not appropriate for their condition. The results of the conducted survey confirmed that 51% of the consumers knew the exact preparation they want to provide from

pharmacy contrary to the 49% that ask for recommendation. The most commonly reported side effects by the pharmacists from the use of cannabis-based preparations are increased sleepiness (32%), lack of effectiveness (lack of reduction of pain (19%)), as well as increased nausea and vomiting (10%). Additionally, other effects, such as low blood pressure, tachycardia, anxiety, depression, panic attacks or hallucinations were also reported.

The general attitude of the community pharmacists involved in this survey is that education on cannabis and cannabis-based preparations is needed. About 18% of the pharmacist identified the need for further education related to the indications of preparations containing different ratio of THC and CBD, potential side effects of their use and interactions with other drugs, while 14% confirmed the need for additional education related to the way of administration or dosing recommendations. The obtained results showed that pharmacists provide information for consumers in terms of dosage and method of administration (31%), product selection (29%), followed by giving advice for possible interactions with other therapy (20%) and expected adverse reactions (20%).

Conclusion

Both pharmacists and patients increasingly believe in the cannabis-based preparations and they even are offered as therapy of choice for certain medical conditions. Many consumers use cannabis-based preparations outside the approved indications accepted and recommended by the scientific communities and regulatory bodies. The users of cannabis products receive necessary information by the HCP; however, the role of community pharmacist is essential in arising the awareness of indicated, rational and safe use of these preparations. Therefore, there is inevitable need for further education of the HCP, that will be actively involved in the process of consumer cancelling for the risks and benefits of using cannabis for medical purposes.

References

- Lucas, P., 2012. It can't hurt to ask; a patient-centered quality of service assessment of health canada's medical cannabis policy and program. *Harm. Reduct. J.* 9(2). <https://doi.org/10.1186/1477-7517-9-2>
- Sexton, M., Cuttler, C., Finnell, J.S., Mischley, L.K., 2016. A Cross-Sectional Survey of Medical Cannabis Users: Patterns of Use and Perceived Efficacy. *Cannabis Cannabinoid Res.* 1(1):131-138. <https://doi.org/10.1089/can.2016.0007>
- Vigil, J.M., Stith, S.S., Adams, I.M., Reeve, A.P., 2017. Associations between medical cannabis and prescription opioid use in chronic pain patients: A preliminary cohort study. *PLoS ONE* 12(11): e0187795. <https://doi.org/10.1371/journal.pone.0187795>