Académie nationale de Pharmacie

MEDICAL USE OF CANNABIS

The Academy of Pharmacy is concerned about the lack of rigor of the current experimentation.

The Academy expresses the greatest reservations concerning the conditions of the implementation by the National Agency for the Safety of Medicines and Health Products (ANSM) of the experimentation in the decree relating to experimentation with the medical use of cannabis in the form of a medicine[i]

An unjustified exemption procedure.

The decree relating to experimentation with the medical use of cannabis introduces an exemption procedure for obtaining marketing authorization which unjustifiably contravenes the regulatory requirements, safety and ethics in the field of medicines. The Academy points out that it is important not only to verify that a substance is effective, but also that its benefits outweigh its undesirable effects, taking into account the seriousness of the target disease. The Academy of Pharmacy recalls that certain pharmaceutical specialties based on tetrahydrocannabinol (THC) and/or cannabidiol (CBD), or even cannabinoids, may be of medical interest in specific therapeutic indications, when validated by double-blind randomized clinical trials. At the end of these studies, it is also necessary to take into account the medical service provided, evaluated by the Transparency Commission of the High Authority for Health (HAS) according to the effectiveness and usefulness of the medicines. However, with regard to the decree of October 16th 2020, which sets out "the specifications for cannabis-based medicines", these would be exempt from having to go through a randomized clinical trial, which alone is capable of assessing their risk/benefit ratio, as recalled in a recent tri-academic press release[ii]: "In a pandemic as well as in an ordinary situation, the rules for the critical evaluation of methods and results must apply".

A lack of scientific rigor

The plant *Cannabis sativa L.* and its extracts used for experimentation are not pure products, but mixtures of more than two hundred substances, whose quantities and proportions vary according to the methods of cultivation, harvesting and storage. In the absence of target concentrations of their main active ingredients, THC and CBD, these herbal mixtures cannot in any way guarantee the quality and safety required for a medicinal product, since only

ratios are mentioned, which are no longer even defined as they were to begin with, but are only given as an indication with the wording "concentrations greater than..." or "less than...", without any upper limit with regard to the undesirable effects of the components. As a reminder, in 1953, the plant with weak pharmacological effects at the time, but already recognized as the main cause of harm, was withdrawn from the French pharmacopoeia.

A need for transparency in evaluation and follow-up

The decree and orders specify that the information collected by prescribing doctors and pharmacists during the follow-up of the 3000 patients included in the experiment will be reported in a register the analysis of which will be entrusted to the director of the National Agency for the Safety of Medicines and Health Products (ANSM). **How will this analysis be carried out and controlled? Will the pharmacovigilance and addiction monitoring centers be included?**

The National Academy of Pharmacy:

- **Considers that the experiment cannot be subject to media or political pressure but must be based exclusively on recognized scientific criteria guaranteeing public health**.

- **Considers it essential to evaluate the risk/benefit ratio for each of the five groups of pathologies included in the experiment, taking into account the THC and CBD doses of the different preparations (oral, sublingual or inhaled forms)**

- **Recommends that the regional pharmacovigilance and addiction monitoring centers be involved both in collecting information and in the precise evaluation of any risks.**

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[i] Decree no. 2020-1230 of 7 October 2020 relating to experimentation with the medical use of cannabis - Order of 16 October 2020 setting the specifications of cannabis-based medicines used during the experimentation provided for in Article 43 of Law no. 2019-1446 of 24 December 2019 - Order of 29 October 2020 setting the technical terms and conditions of the national electronic register provided for in Article 4 of Decree no. 2020-1230 of 7 October 2020 relating to experimentation with the medical use of cannabis.

[ii] Opinion of the National Academy of Medicine, the National Academy of Pharmacy, the Academy of Sciences "Clinical trials during the Covid-19 pandemic: Therapeutic targets, methodological requirements, ethical imperatives"(29 May 2020)