Augur associates

Summary - White Paper

"Cannabis for therapeutic purposes in France: which regulation for the patients?"

- **Summary**

This side-note accompanies the white paper addressed to more than 350 French decision-makers. An increasing number of countries are now regulating the use of cannabis for therapeutic purposes and global and European institutions are making progress on the subject - the French finally seem ready for such a reform. This document compiles the expertise of many French and foreign actors, as well as decades of experience in Europe and the rest of the world. This will make it possible to imagine a concrete and contextualised regulation, with recommendations at every stage, in order to avoid preconceived ideas on the subject and the problems encountered abroad, which could affect patients' access to treatment.

- **Context and scope**

To date, some 45 countries worldwide (21 of them in Europe) provide legal access to cannabis-based treatment for therapeutic purposes. While the World Health Organisation (WHO) Expert Committee on Drug Dependence has recommended to reclassify cannabis and its derivatives, and that the European Parliament has adopted a motion for a resolution on the therapeutic use of cannabis, the conditions seem to be in place for French political decision-makers to meet expectations on the subject.

In France, it has been possible since 2013 to grant a "*marketing authorisation for medicinal products containing cannabis or its derivatives*". In view of the complexity of the subject, Minister of Health Agnès Buzyn decided to launch a debate in May 2018. A Temporary Specialised Scientific Committee (CSST) was subsequently created by the french National Agency for the Safety of Medicines and Health Products (ANSM) in September 2018 concerning the availability of therapeutic cannabis in France. This CSST gave a favourable preliminary opinion under certain conditions in December and final conclusions were given end of June. Implementation of an experiment phase will start at the beginning of 2020 for a period of 2 years.

While a recent survey by the French Observatory for Drugs and Drug Addiction (OFDT) in April 2019 showed that 91% of French people support the introduction of cannabis for therapeutic purposes, this white paper is intended to guide political decision-makers by giving them an overview of the various existing regulatory models that France could draw on to provide a specifically adapted political and regulatory response.

- **Main lessons from the White Paper**

<u>Unjustified fears</u>

Drafting this paper has highlighted many often unjustified fears when it comes to establish a regulated regime for therapeutic cannabis. The many foreign experiences show, for example, that such reform:

- do not lead to any increase in illicit cannabis use;

- do not lead to any increase in the number of road accidents caused by acute cannabis intoxication;
- has little effect on violent crimes against persons or property;
- it is neither the open door to decriminalization nor to the regulation of so-called "recreational" use;
- is centered around a product that does not carry more health risks than other commonly used drugs.

Positive effects of the regulation

→ The legal regulation of therapeutic cannabis in France is a necessity that responds to an urgent and growing demand from patients who are often in distress and are currently turning to the illegal market. Between 2 million and 21 million patients (depending on the pathologies considered) could benefit from such regulation in France.

→ Beyond the therapeutic challenges, this reform represents a major economic opportunity to highlight French agricultural and industrial agronomic know-how, and to create potential jobs that cannot be relocated while generating substantial tax revenues.

Risks of maintaining the status quo

→ While promoting the sustainability and development of the black market, the current situation is delaying the structuring of the cannabis industry in France and depriving many patients of products within a safe and monitored treatment.

- **Recommendations at each step of the regulation process**

(a) Regulatory Agency

→ *Integrate a specialized regulatory agency attached to the french health agency (ANSM).*

The purpose of this agency would be to control the cultivation, harvesting, processing, quality, storage, packaging and distribution to entities designated to distribute therapeutic cannabis to patients (pharmacies, hospitals, etc.). This agency should also be able to supervise the granting of licences for production and sale, and ensure control of the harvest, from production to distribution.

(b) Varieties and products

→ *Allow the use of a large number of varieties for better treatments.*

Many cultivars are now available to offer a wide variety of possible treatments for patients. As cannabis is not a single remedy but a whole family of drugs due to the diversity of its active ingredients, the greater the diversity of molecule spectra, the greater the chance that a spectrum corresponds to a specific medical condition.

→ *Authorize all forms of products available, including flower buds.*

Foreign experiences show that the vast majority of countries allowing the medical use of cannabis allow the use of the plant in its entirety, including its dried flowers or products derived from it.

(c) Production

→ *Establish a national production system that is balanced between private initiative, compassionate policy and state regulation.*

The model proposed in this White Paper is based on a balance between private initiative, public regulation and the non-market dimension with a regulated business model, involving private producers licensed by the State.

(d) Import/export

→ Rely on imports while favouring growing domestic production.

If it is recommended to favour national or even local production for the supply of the French market, however national demand in the short term will not be met immediately. To overcome this problem and provide patients with the safe cannabis they need as soon as possible, several options are available for importing standardized, pharmaceutical-grade therapeutic cannabis, particularly for research and the first years of experimentation. This is the choice of our neighbouring countries.

(e) Distribution

→ Integrate a diversified distribution system allowing barrier-free access for the patient through a dual offer: city pharmacy and online ordering.

The network of city pharmacies will allow patients access to their treatment while benefiting from the advice of a health professional. Secure online ordering should also be considered for patients who cannot travel themselves.

(f) Prescription

→ Provide accessibility and a complete offer of the treatments existing today.

The solution that seems to offer the best guarantees of safe accessibility to the product for patients would be a prescription by the general medical practitioner. Cannabis should also be considered as a fully integrated component of pharmacopoeia rather than a treatment of last resort, and may constitute a great potential for substitution in the face of increasing consumption of benzodiazepines or opioids.

The prescription must take into account:

- a redefinition of illicit use in the Public Health Code: the exception to this definition must be based on a medical prescription;
- an "authorization to transport" cannabis products;
- an evolution of the driving code to consider the influence of products on driving and no longer a predetermined THC rate.

(g) Reimbursement

→ Guarantee coverage by Social Security, with the possible assistance of mutual health insurance companies.

It seems fundamental to enable patients to be relieved in an equitable way to guarantee coverage by Social Security, with the possible assistance of mutual health insurance companies, including for medical devices such as medical grade vaporisator for the flower buds.

(h) Support for stakeholders

→ Integrate government support for the training of all stakeholders (general public, patients, health personnel).

Support and training of the general public, patients, as well as health and medical personnel are essential. Indeed, in countries regulating therapeutic cannabis, one of the main obstacles for patients is the lack of information for prescribing physicians.

Pharmacists are often health referees, and they also must be able to respond to patients who want reliable information on these treatments, as must the medical staff, especially nurses.

(i) Scientific research

→ *Enable the implementation of an ambitious private and public research plan as of today.*

Scientific research plays a key role in improving the understanding of cannabis products. In order to encourage financial actors to take risks in equity and quasi-equity capital, as well as to encourage the emergence of French Weed Tech, it is necessary to consider the intervention of the Public Investment Bank in direct investment or "funds of funds", channels for professional investment funds, channels for individuals wishing to invest and support companies directly, and support for public and private research in dedicated laboratories.