

Therapeutic cannabis in France

Market Insights Series

*Stakeholders' opinion
and expectations*

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Smart Pharma collected and analyzed insights from 17 interviewees to highlight stakeholders' opinion and expectations re. the therapeutic cannabis in France

Project introduction

Context

- An experimentation on the relevance and feasibility of allowing therapeutic cannabis in France started in March 2021 with its first patient...
- ... and will end on June 30, 2025, after which cannabis-based drugs should be approved and marketed

Objectives

- The objectives of this study are to understand:
 - The main stakeholders' position and vision of the French therapeutic cannabis market until 2030
 - The main "customers¹" expectations in terms of product, services and reputation
 - The most efficient way of communicating to generate prescribers and/or patients' preference

Methodology











- Smart Pharma Consulting collected insights through interviews with:
 - 11 physicians (in and out of the experimentation)
 - 1 expert patient
 - 1 leading member of a PAG²
 - 2 retail pharmacists (involved in the experimentation)
 - 2 representatives from pharmaceutical companies involved in the market

Therapeutic cannabis is a plant-based product used in an experimentation in France for patients that are refractory to available therapies, or insufficiently relieved by them, in five indications

Therapeutic cannabis introduction

Context

- Therapeutic cannabis is extracted from the **Cannabis sativa plant** and must contain the entire spectrum of the plant
- A cannabis plant includes several chemicals, including **~70 cannabinoids**, the most well-known being cannabidiol (CBD) and tetrahydrocannabinol (THC)
- The **CBD:THC ratio** compares the amount of CBD vs. the amount of THC per dose
- The availability of various CBD:THC ratios allows to provide the **clinical benefits needed for each patient**, depending on the **indication and symptom targeted** (e.g., pain, nausea, insomnia)
- As of April **2024**, the available products in the experimentation were:

Galenic forms	Type of ratio	CBD:THC ratio	Supplier	Marketing company
Oil (oral)	CBD-dominant	2.0% : 0.1%	▪ Little Green Pharma 	▪ Intsel Chimos 
		5.0% : 0.1%		
		5.0% : 0.3%	▪ Panaxia 	▪ Boiron 
	Balanced	2.5% : 0.2%	▪ Panaxia 	▪ Neuraxpharm 
	THC-dominant	0.0% : 2.5%	▪ Panaxia 	▪ Neuraxpharm 
Dried flowers (inhalation)	THC-dominant ¹	1.0% : 20.0%	▪ Aurora 	▪ Ethypharm 

Sources: ANSM (Apr. 2024)

¹At the beginning of the experimentation, all the ratios were available in dried flowers, all commercialized by Aurora / Ethypharm

The experimentation demonstrated the feasibility of allowing therapeutic cannabis in France, and confirmed the medical efficacy and tolerability of this treatment in the studied indications

Experimentation in a nutshell – Intermediate outcomes (Sep. 2023)

Objective

- Assessment of the feasibility¹ of allowing therapeutic cannabis: prescription, dispensing, products’ supply and patients’ monitoring

Population

- **2,540** patients, distributed per therapeutic indication as follows:
 - Refractory **neuropathic pain** (54%)
 - Painful **spasticity** in **CNS**² diseases, incl. multiple sclerosis (16%)
 - **Palliative** care (12%)
 - Refractory & severe **epilepsy** (10%)
 - Intractable **oncology** symptoms (8%)

Methodology

- Drugs based on **cannabis extracts**, which contain the entire spectrum of the plant, in **oral** (oil) or **inhaled** (dried flowers) form
- Experimentation follow-up by a **Committee of 16 experts**³ (CST⁴)
- **Medical and patient-reported outcomes’ follow-up** through a national **register** (ReCann)
- **Pharmacovigilance and addicto-vigilance reports**

Results

- The **prescription and dispensing journeys** are **effective and secure**
- **The efficacy data are encouraging:**
 - **Neuropathic pain:** number of patients enduring “insufferable pain” reduced from 79% to 29% after three months⁵
 - Painful **spasticity** in **CNS** diseases: significant improvement⁶
 - **Palliative** care and **oncology:** positive effects on pain, nausea, sleep disorders
 - **Epilepsy:** significant reduction of seizure frequency and improvement of patients’ general condition (e.g., less agitated)
- **Few severe side effects** have been reported
- **No unexpected pharmaco- and addicto-vigilance data**

Conclusions

- The **feasibility** of the **prescription and dispensing journeys** of therapeutic cannabis is validated, even though the “retail-hospital” coordination is still underdeveloped
- The experimentation showed a significant **efficacy after three months** of treatment, and **maintained over time** in patients that are refractory to other available therapies

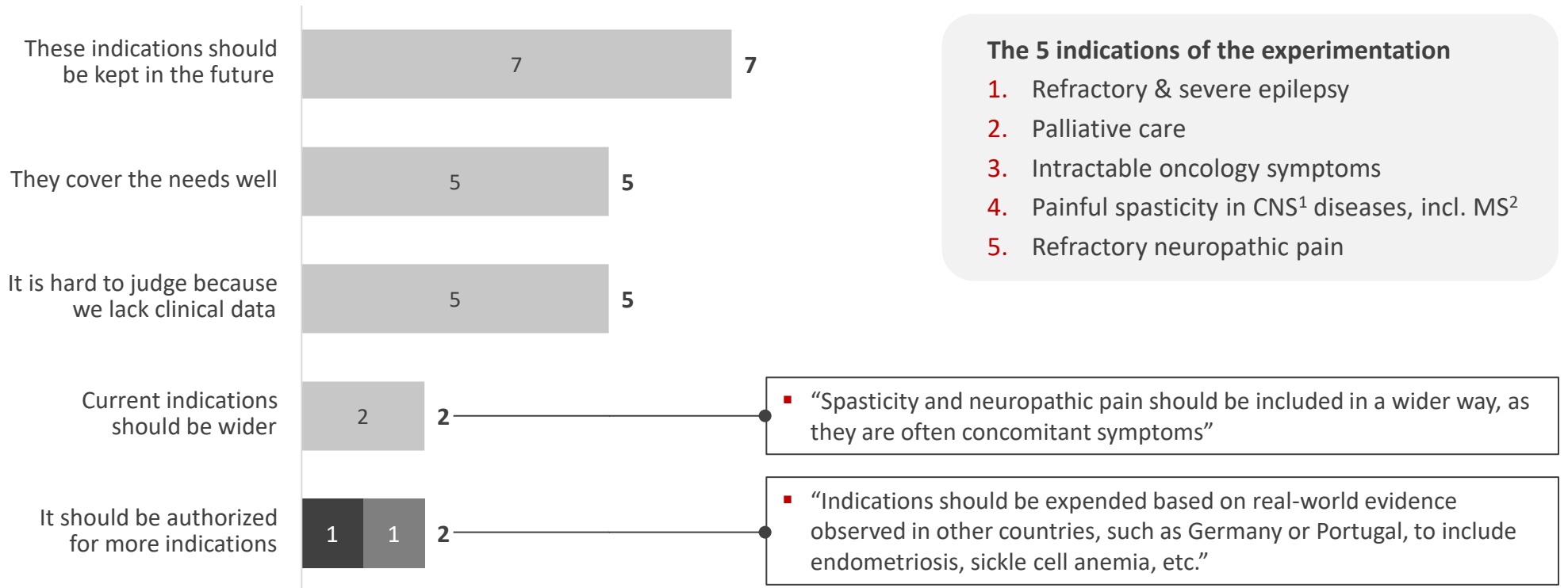
Sources: ANSM & IQVIA (Sep. 2023) – Smart Pharma Consulting analyses

¹ Efficacy data was also gathered and evaluated – ² Central Nervous System – ³ Physicians, pharmacists, patients and Patient Advocacy Groups – ⁴ Comité de Suivi Temporaire – ⁵ And up to 12 months – ⁶ Measured by the “Numerating rating spasticity scale”

Only a few physicians want to see some indications expanded and specified, most physicians agree on the need to keep them as they are in the future

Opinion on the experimentation – Indications

“What are your opinion and recommendation regarding the indications chosen for the experimentation?”



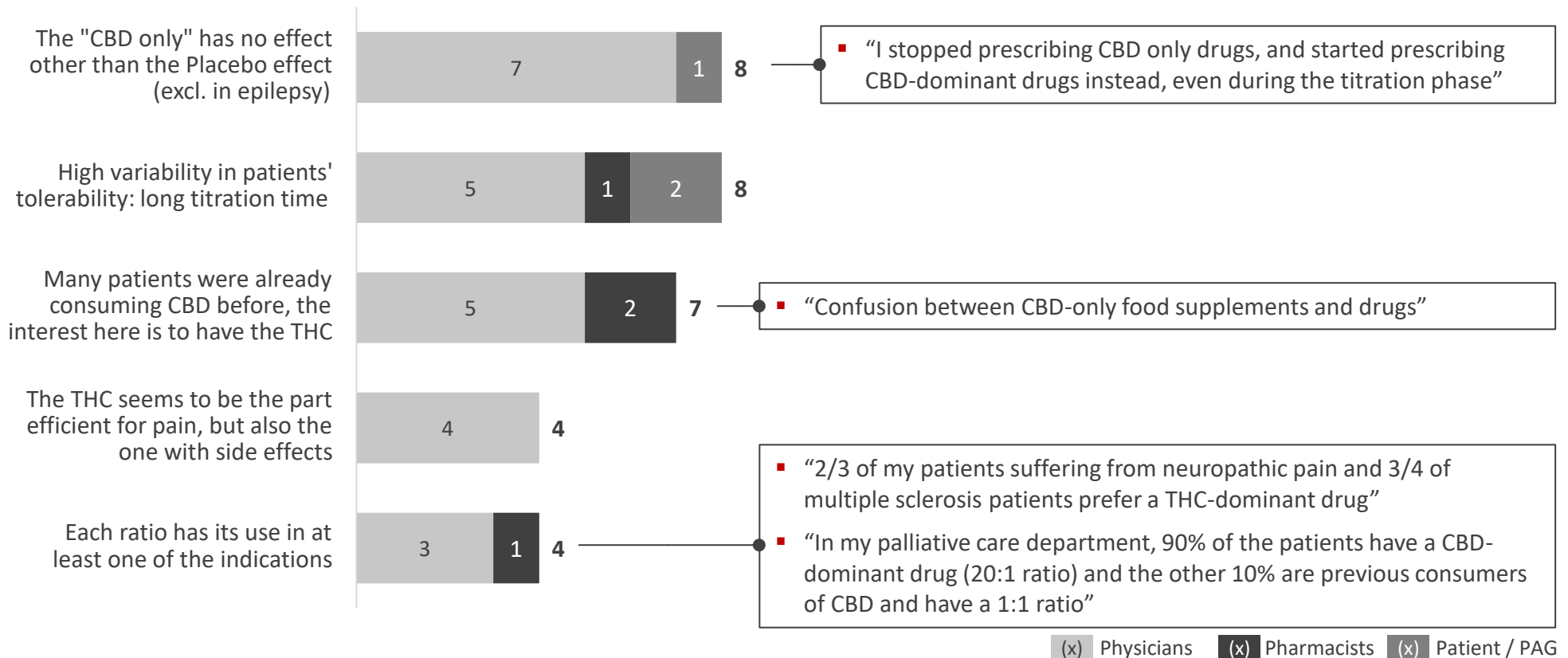
Sources: Interviews with 11 physicians, 2 retail pharmacists, 1 patient and 1 member of a PAG (Nov. 2024) – Smart Pharma Consulting analyses

¹ Central Nervous System – ² Multiple sclerosis

Most physicians see the “CBD only” ratio as not effective on pain, but use all ratios during the long titration time needed

Opinion on the experimentation – CBD:THC ratios

“What are your opinion and recommendation regarding the CBD:THC ratio?”

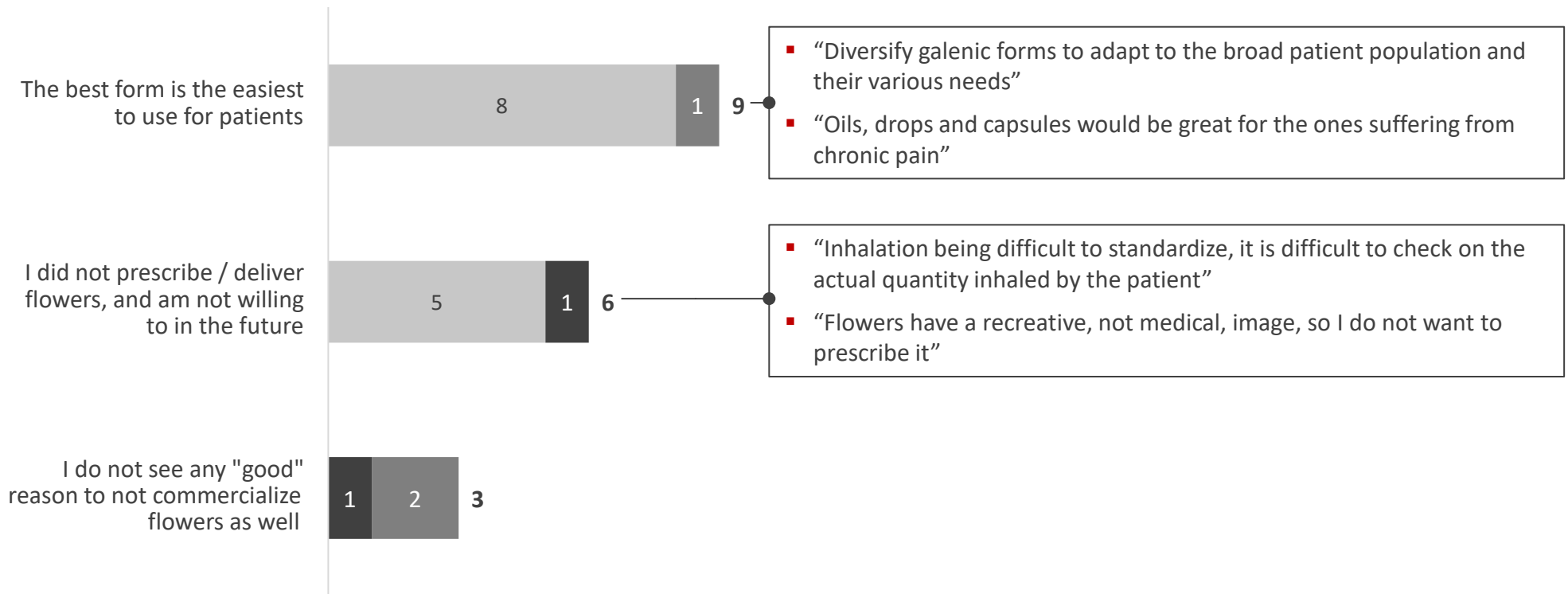


Sources: Interviews with 11 physicians, 2 retail pharmacists, 1 patient and 1 member of a PAG (Nov. 2024) – Smart Pharma Consulting analyses

Stakeholders agree on the need to have several forms to adapt to each patient's needs, but many physicians are not comfortable with prescribing flowers

Opinion on the experimentation – Galenic forms

“What are your opinion and recommendation regarding the available forms (i.e., oils and flowers)?”



(x) Physicians (x) Pharmacists (x) Patient / PAG

Sources: Interviews with 11 physicians, 2 retail pharmacists, 1 patient and 1 member of a PAG (Nov. 2024) – Smart Pharma Consulting analyses

Although HCPs agree on the need to be trained for the specificities of therapeutic cannabis, they expect a short, useful and practical information support

Opinion on the experimentation – HCPs’ training

“What are your opinion and recommendation regarding the mandatory training of the experimentation?”

Training for physicians

- “Physicians should be trained, but not particularly for cannabis vs. other drugs” (10)
- “The training can be mandatory, but it must be shortened” (7)
- “The time needed for the current training was a real obstacle for physicians” (5)
- “Physicians will censor themselves if they feel like not being informed enough, and will look for all necessary information by themselves: the training should be available, but optional” (3)



- **A 15 minutes training with all key aspects and regular updates:**
 - Likely side effects
 - Drug interactions
 - Misuse risks and detection
 - Existing ratios and their use for each indication
 - Switch (between forms) management and consequences

Training for retail pharmacists

- “Retail pharmacists need an information booklet, especially if new galenic forms enter the market” (4)
- “Pharmacists’ education and experience dispensing opioids means they only need a quick hands-on training for therapeutic cannabis” (4)



- **A 15 minutes training with all key aspects and regular updates would be perfect:**
 - Likely side effects
 - Drug interactions
 - Misuse risks and detection

(X) Number of quotes

Sources: Interviews with 11 physicians, 2 retail pharmacists, 1 patient and 1 member of a PAG (Nov. 2024) – Smart Pharma Consulting analyses

Even though the experimentation goal was not to prove therapeutic cannabis efficacy, physicians recognized its relatively good to very good efficacy, depending on the indication

Opinion on the experimentation – Efficacy

“What is your opinion regarding the efficacy of therapeutic cannabis as shown in the experimentation?” (physicians only¹)

Refractory & severe epilepsy

- “Results are good in two syndromes only (Lennox-Gastaut and Dravet syndromes), not in epilepsy as a general disease” (2)
- “It is quite a revolution for epileptic patients” (1)
- “Low tolerability rate” (1)

Palliative care

- “Very good efficacy” (3)
- “Patients are hopeful and have been expecting it” (2)
- “Very good results for symptoms other than pain, such as anxiety, sleeplessness and appetite loss” (2)
- “Not statistically meaningful” (1)

Intractable oncology symptoms

- “Few results, but relatively good result on pain” (2)
- “Very good results for symptoms other than pain, such as anxiety, sleeplessness and appetite loss” (2)
- “Patients are very hopeful, as most of them suffer from long-lasting pain” (1)

Painful spasticity in CNS² diseases

- “Good efficacy on spasticity-related pain and neuropathic pain” (5)
- “It is quite a revolution for multiple sclerosis patients” (2)

Refractory neuropathic pain

- “Very good efficacy” (6)
- “Pleasantly surprised, as we did not get results from any (or few) clinical studies about this indication” (1)

11 respondents

(X) Number of quotes

Sources: Interviews with 11 physicians (Nov. 2024) – Smart Pharma Consulting analyses

¹ Physicians may have an opinion about indications they do not treat, as they all received the preliminary results from the experimentation – ² Central Nervous System

The experimentation was reassuring for physicians, as real-world data showed no unexpected nor severe side effects that should not be a barrier to future prescription

Opinion on the experimentation – Tolerability

“What is your opinion regarding the tolerability of therapeutic cannabis as shown in the experimentation?”



■ “There were only 75 cases of serious side effects (5.9%) reported during the experimentation”

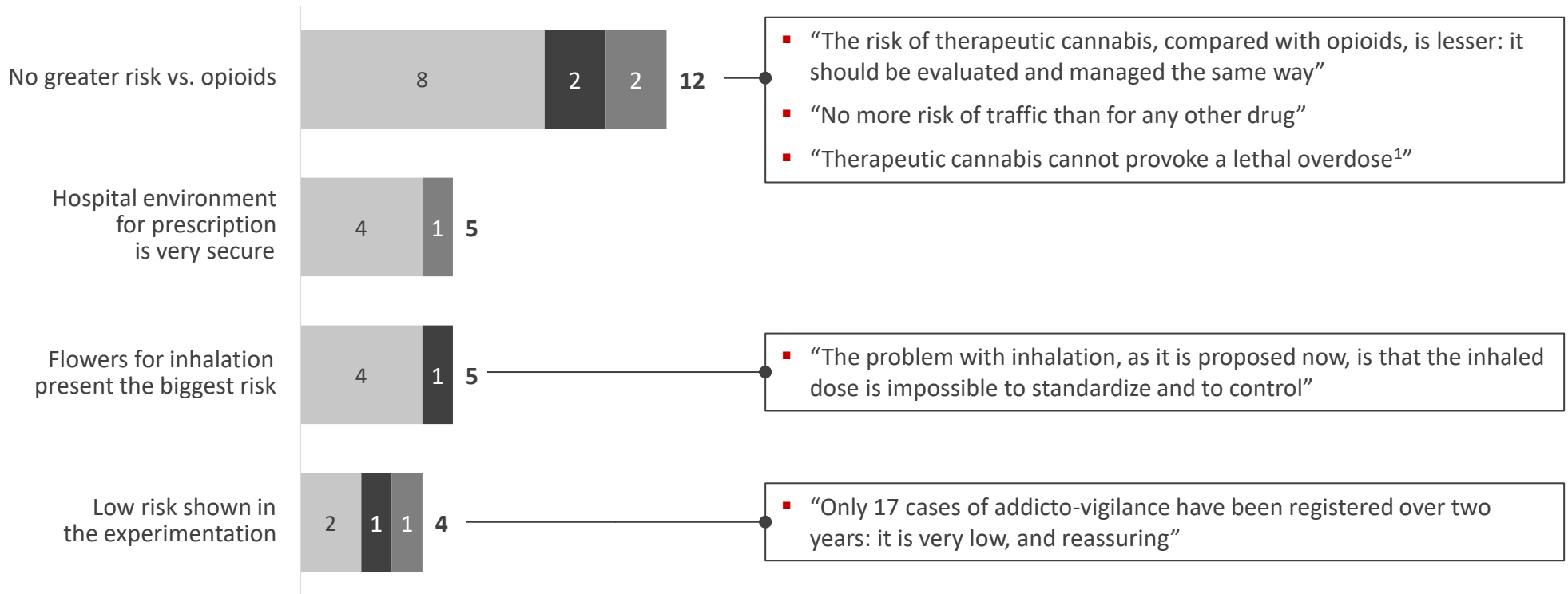
■ “Just like any other treatment: need to inform the patient about possible side effects”

Sources: Interviews with 11 physicians, 2 retail pharmacists, 1 patient and 1 member of a PAG (Nov. 2024) – Smart Pharma Consulting analyses

The experimentation confirmed that therapeutic cannabis does not present more misuse risks than other narcotics and opioids, which should reassure authorities

Opinion on the experimentation – Misuse risks

“What is your opinion regarding the misuse risks ?”



(x) Physicians (x) Pharmacists (x) Patient / PAG

Sources: Interviews with 11 physicians, 2 retail pharmacists, 1 patient and 1 member of a PAG (Nov. 2024) – Smart Pharma Consulting analyses

¹ The endocannabinoid system is not received on the brain stem, and thus, cannot cause lethal overdose (contrary to opioids, which can cause respiratory distress)

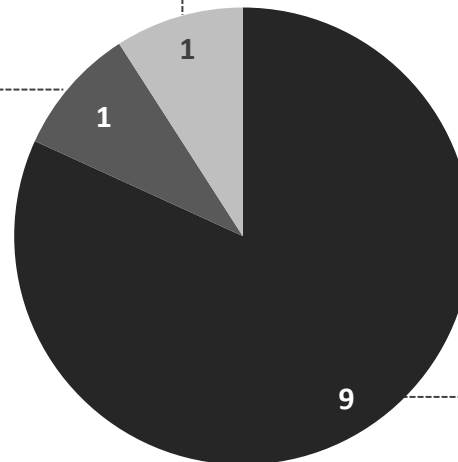
Most interviewed physicians think the titration prescriptions should be done by specialists, then renewed by general practitioners, and followed by regular meetings¹ with the specialist

Opinion on the prescription journey

“What is your opinion regarding the prescription journey for therapeutic cannabis?” (physicians only)

All physicians should be able to prescribe therapeutic cannabis
“It should be the same as opioids”

Only specialists should be able to prescribe therapeutic cannabis



11 respondents

Note: interviewed retail pharmacists and patient think that all physicians should be allowed to prescribe therapeutic cannabis, just like other opioids

Sources: Interviews with 11 physicians (Nov. 2024) – Smart Pharma Consulting analyses

¹ Annual (7) or every 6 months (2)

All stakeholders believe therapeutic cannabis should be dispensed in all pharmacies, in order to provide the best possible access to care for all patients

Opinion on the dispensing journey

“What is your opinion regarding the dispensing of therapeutic cannabis?”



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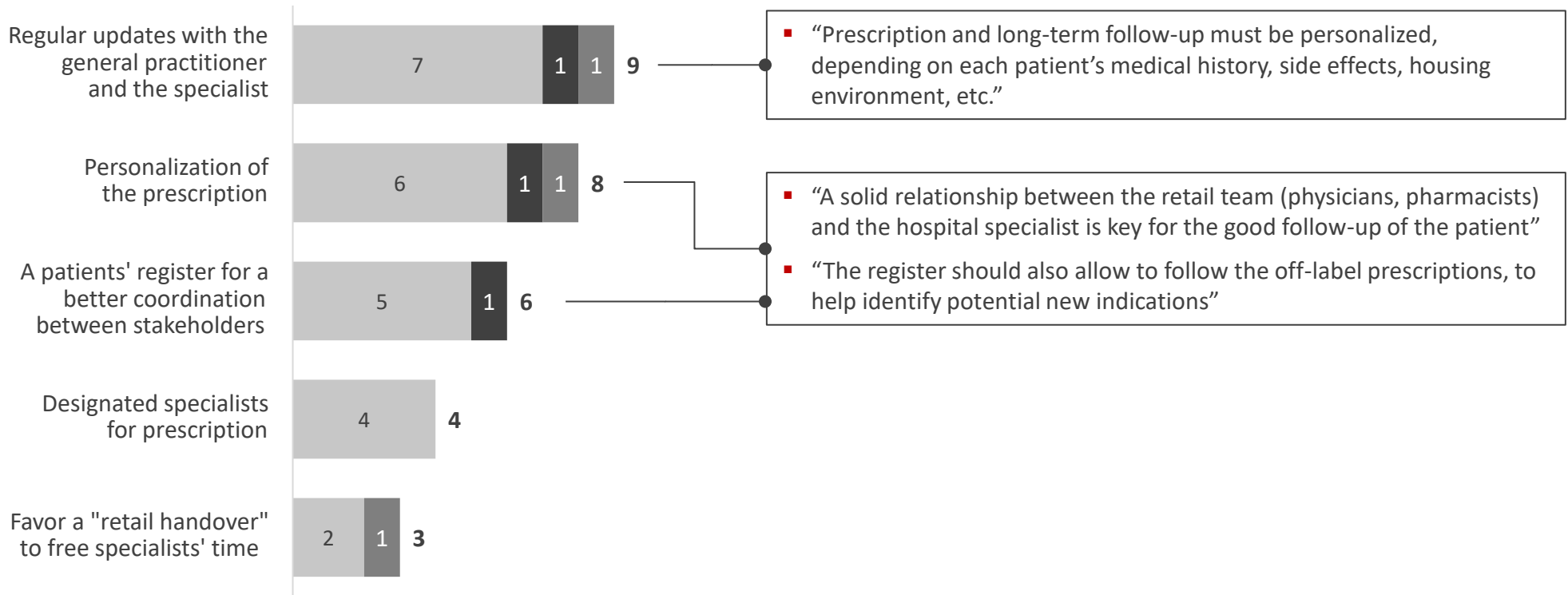
All retail and hospital pharmacies should be allowed to deliver therapeutic cannabis

- “Therapeutic cannabis should be dispensed like any other narcotic drug, which pharmacists know how to manage”
- “Retail pharmacies are necessary for a better access to care for each patient, especially in rural areas, it is ethically fundamental”

A triumvirate of the designated retail pharmacist, general practitioner and specialist is key to ensure an efficient follow-up of each patient

Vigilance points – Prescription

“What are the points of vigilance specific to the prescription of therapeutic cannabis?”



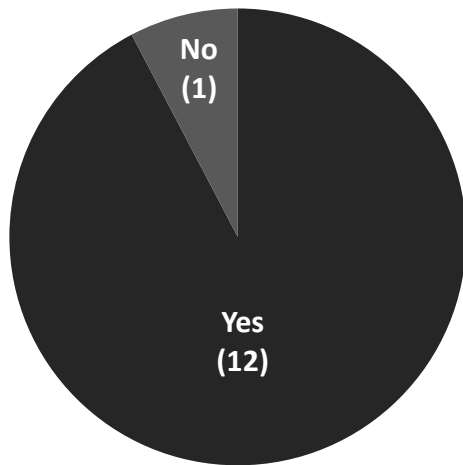
(x) Physicians (x) Pharmacists (x) Patient / PAG

Sources: Interviews with 11 physicians, 2 retail pharmacists, 1 patient and 1 member of a PAG (Nov. 2024) – Smart Pharma Consulting analyses

Most stakeholders agree on the necessity to obtain a reimbursement for therapeutic cannabis, even though the lack of clinical evidence is an obstacle they fear

Reimbursement policy

“Do you consider it essential for therapeutic cannabis to be reimbursed? Why? Under which conditions? At what rate?”



13 respondents

It is essential to reimburse the therapeutic cannabis

- “The indications are already relatively restrictive, considering that it is a drug of last resort for selected patients”
- “As a last resort drug, it should be included in the ALD 30¹ process, and thus, 100% reimbursed”
- “Medico-economic studies are key for the reimbursement: a study on the savings achieved due to the decrease in consumption of other drugs, for instance, may be key for a better reimbursement”
- “Without a reimbursement, we would have done all this experimentation for nothing”

It should not be reimbursed

- “There is not enough demonstration of therapeutic cannabis efficacy to date”

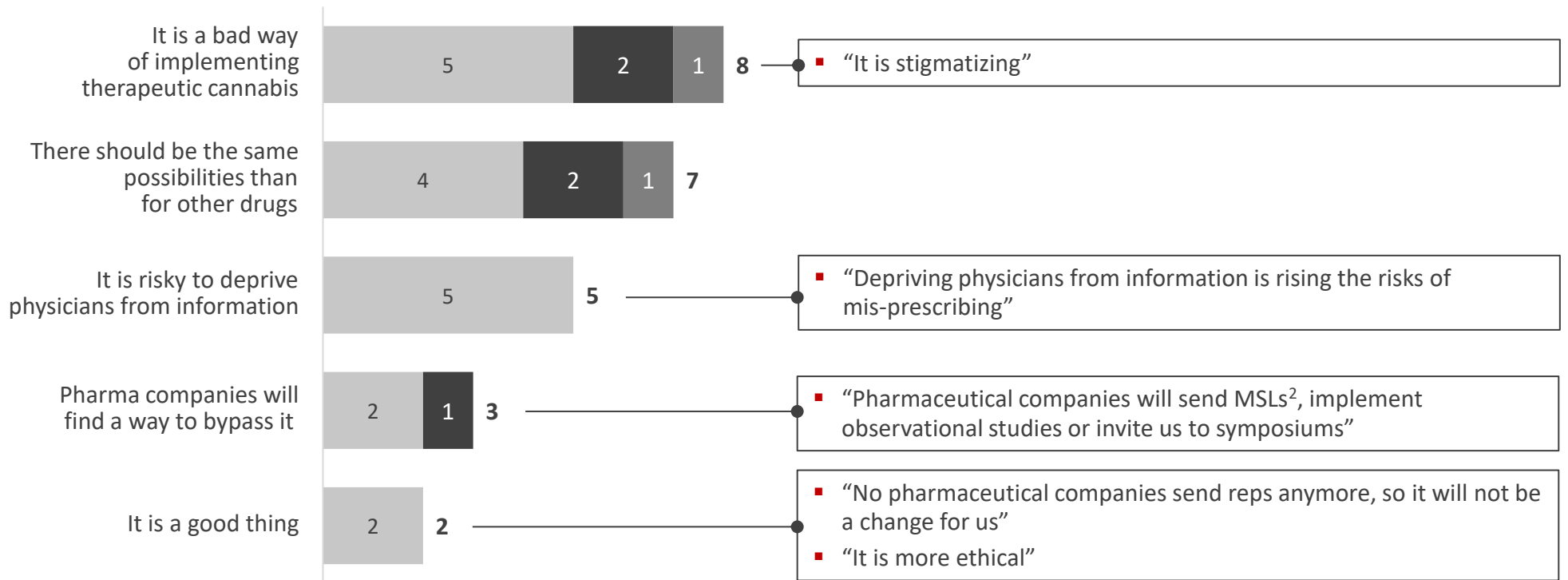
Sources: Interviews with 11 physicians, 2 retail pharmacists, 1 patient and 1 member of a PAG (Nov. 2024) – Smart Pharma Consulting analyses

¹ List of 30 ALDs (Affection Longue Durée: Long-lasting pathology) for which treatments are 100% reimbursed by the National Health Insurance Fund

HCPs and the interviewed PAG¹ do not understand the ban on communication, considering it is only a stigmatizing way of differentiating therapeutic cannabis from other drugs

Pharma companies' communication right

"Pharma companies commercializing therapeutic cannabis will probably not be allowed to communicate to HCPs. What is your opinion about this point?"







(x) Physicians (x) Pharmacists (x) Patient / PAG

Sources: Interviews with 11 physicians, 2 retail pharmacists, 1 patient and 1 member of a PAG (Nov. 2024) – Smart Pharma Consulting analyses

¹ Patient advocacy group – ² Medical Science Liaisons

HCPs are ready for the transition of the therapeutic cannabis into common law, provided that allocated resources and administrative policies do not restrain them

Expectations from key stakeholders

Stakeholders	Authorities	HCPs	Patients and PAGs ¹	Pharma companies
				
Expectations	1. Engage and accelerate the process to transition therapeutic cannabis into common law	1. Prepare physicians to be ready to prescribe therapeutic cannabis if conditions allow it	1. Use PAGs' lobbying power to accelerate the political decision-making process	1. Invest in research, through providing more clinical and real-world evidence
	2. Raise public awareness (e.g., de-demonization through fighting against the confusion between recreational and medical use)	2. Involve retail pharmacists in the patient journey to provide the best possible access to care	2. Capitalize on patient testimony, to combat fake news and the "toxicomania" image	2. Inform HCPs about products (e.g., titration phase, galenic forms, outcomes expected per ratio and per indication)
	3. Capitalize on the new medical know-how of French HCPs	3. Involve nurses in the therapeutic education of patients and of their families	3. Ensure that non-medical vindictive opinions do not slow down policy decisions	3. Innovate in new galenic forms (e.g., capsules, ovules, suppositories) and/or ratios

Sources: Interviews with 11 physicians, 2 retail pharmacists, 1 patient and 1 member of a PAG (Nov. 2024) – Smart Pharma Consulting analyses

Should the French therapeutic cannabis market open in 2025, pharmaceutical companies must carefully fulfill stakeholders' needs to gain market share

Key takeaways

1. After 4 years of experimentation, the marketing of therapeutic cannabis should be authorized by the Ministry of Labor, Health, Solidarity and Families by the end of 2025

2. The market may be restricted to the 5 current indications¹ with prescriptions limited to designated hospital specialists, even if the experimentation has shown that the renewal by office-based physicians was not an issue

3. All pharmacies (retail and hospital) should be allowed to deliver the drugs, which is the best way to provide an equal access to care to all patients



4. The market is divided between oils and dried flowers but new galenic forms (marketed in other countries) could be approved in the future

5. Several companies are expected to enter the French market, some of them being already involved in the experimentation, others present in CNS²

6. Physicians and pharmacists expect a strong involvement from market players to support them and their patients, while authorities will keep a close eye on pharma companies' communications and key initiatives

Sources: Interviews with 11 physicians, 2 retail pharmacists, 1 patient, 1 member of a PAG and 2 representatives from pharmaceutical companies involved in the market (Nov. 2024) – Smart Pharma Consulting analyses

¹ Refractory & severe epilepsy, palliative care, intractable oncology symptoms, painful spasticity in CNS² diseases (incl. multiple sclerosis) and refractory neuropathic pain – ² Central Nervous System

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Market Insights Series

- The Market Insights Series has in common to:
 - Be well-documented with recent facts and figures
 - Highlight key points to better understand the situations
 - Determine implications for key stakeholders
- Each issue is designed to be read in 15 minutes and not to exceed 24 pages

Therapeutic cannabis in France

Stakeholders' opinion and expectations

This position paper highlights stakeholders' opinion and expectations re. the therapeutic cannabis market in France:

- Track record of the experimentation launched since 2021 (opinion on the scope of indications, the CBD:THC ratios, galenic forms, HCPs' training, products' efficacy and tolerability, risk of misuses, patient journey, etc.)
- Stakeholders' assumptions on the market perspectives (e.g. reimbursement policy, pharma companies' communication right)
- Expectations from key stakeholders (incl. authorities, HCPs, patients, PAGs and pharma companies)

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Best regards

Jean-Michel Peny