Session 10

Global Cannabis Update

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MCIA

CANNABIS

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Session 1

Global Cannabis Update

March 2024

Deepak Anand

ASDA Consultancy Services

Worldwide momentum of medical cannabis legalization over the last decade but important countries have yet to implement effective access.

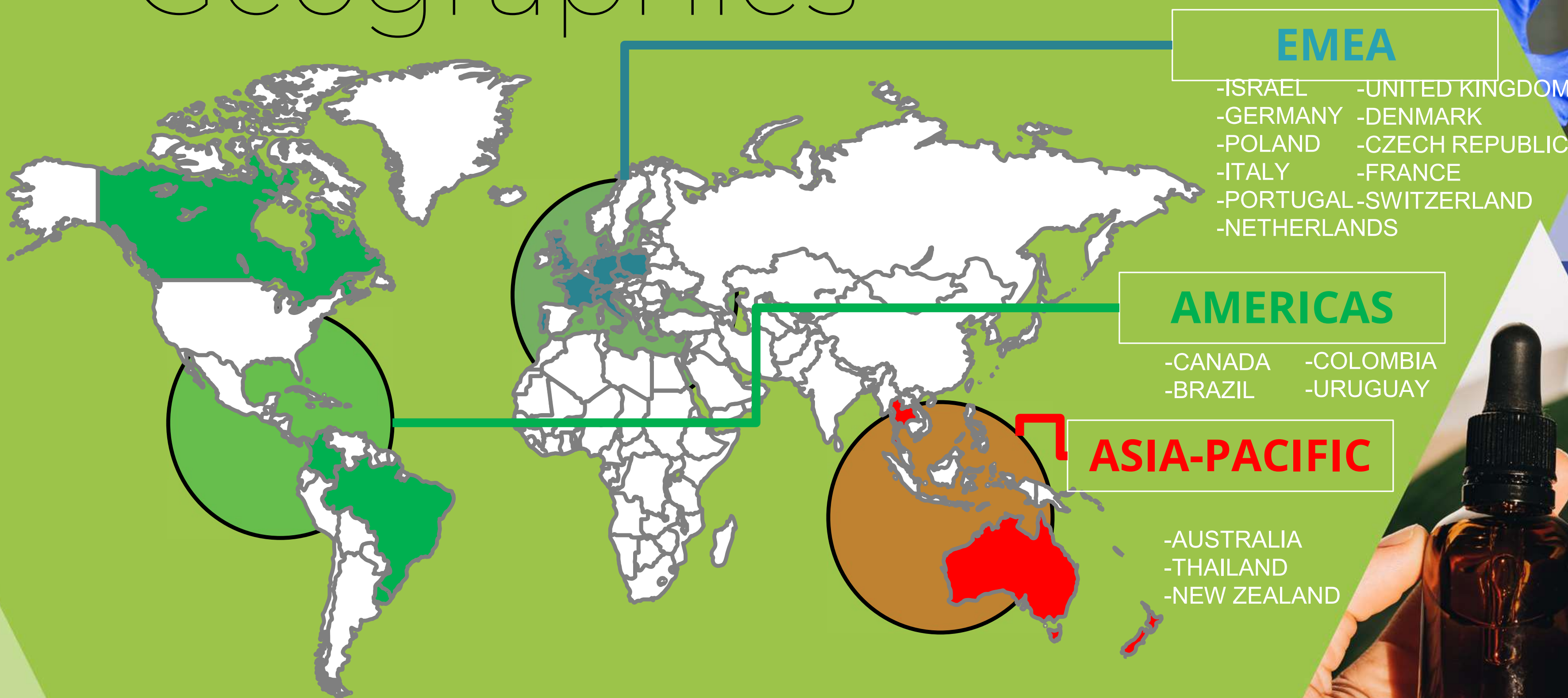
Legalization date of medical cannabis (cultivation/access) in key international geographies

2003	…	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	Upcoming	
Netherlands			Israel	Cz. Rep		Colombia	Macedonia	Germany	Greece	Brazil	Ecuador	Switzerland	Morocco	Albania	Ukraine	Spain	Philippines
			Finland	Italy		Croatia	Australia	Denmark	UK	Ireland		France					
				Canada		Brazil	Norway	Poland	Malta	Lithuania		Panama					
				Uruguay		Uganda		Luxembourg	Portugal	N Zeeland							
								Chipre	Thailand	Peru							
								Argentina	Jamaica	S. Africa							
								Sweden	S Korea								

Recreational legalization has been limited to the Americas, but Europe is starting to catch up: Switzerland and the Netherlands lead the way, Germany to follow.

Legalization date of recreational cannabis (cultivation/access) in key international geographies

Key Medical Cannabis Geographies



EMEA

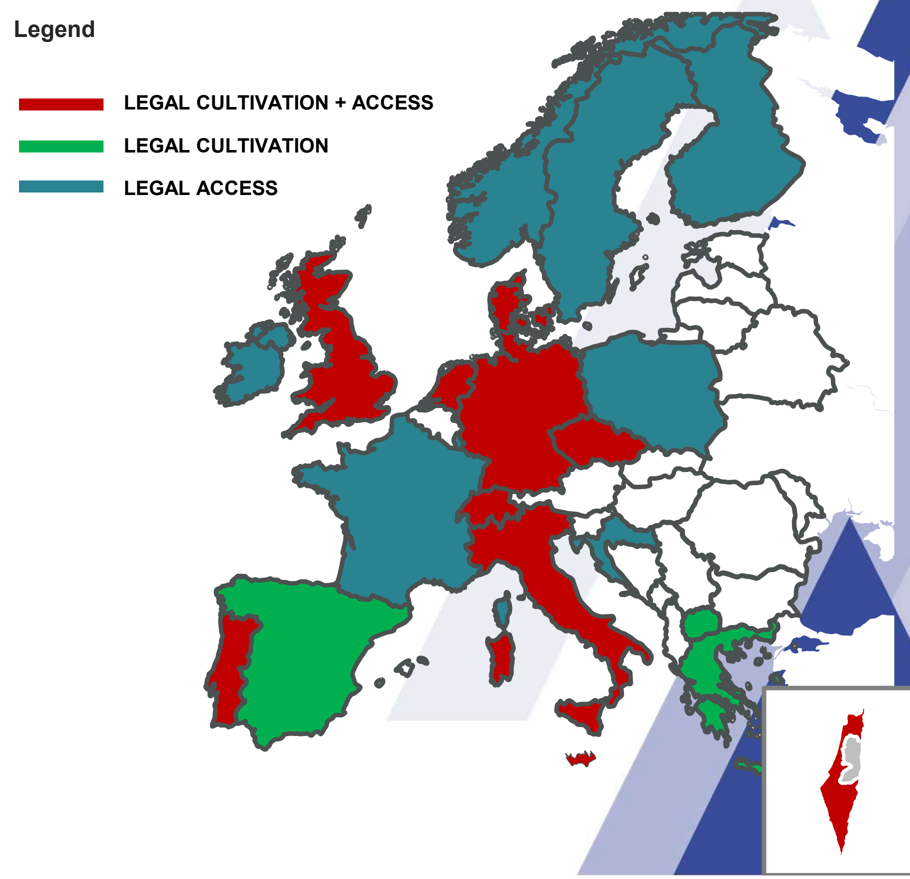
MEDICAL MARKETS

Europe, Middle East & Africa

In Europe, medicinal cannabis access schemes have existed in most countries for years and attention is shifting to allow recreational access.

- Most European countries have **allowed access to cannabinoid therapies**. However, there are major differences in openness of each national system and patient access remains patchy:
  - Some countries like **Germany and Poland have a relatively free-market** approach to distribution of medicinal cannabis - coupled with lenient prescribing guidelines have allowed the market to flourish.
  - Other countries like Finland, Sweden, Norway or Croatia only allow access to medical cannabis product on a **case-by-case compassionate** basis, severely limiting the potential patient base.
    - However, some countries which used to require additional case-by-case authorization to access medical cannabis products, like **Switzerland, have recently eased rules.**
  - Production and/or supplied is **often tendered by relevant authorities**, such is the case for cultivation in Germany or Cyprus (3 cultivators), or supply into France, Luxembourg and Italy.
  - Other countries such as Portugal, Denmark and Spain do not impose limits on the number of players that can be licensed to produce cannabis products if they meet all standards.
  - Mandatory **product registration is required in Poland** and Ireland to market medical cannabis products to the countries' pharmacies. France has announced that it will impose a similar system at the end of the current experiment running until the end of 2024.
  - Further regulatory action is expected in France at the end of the current medical experimentation in 2024, as well as Spain and Greece.

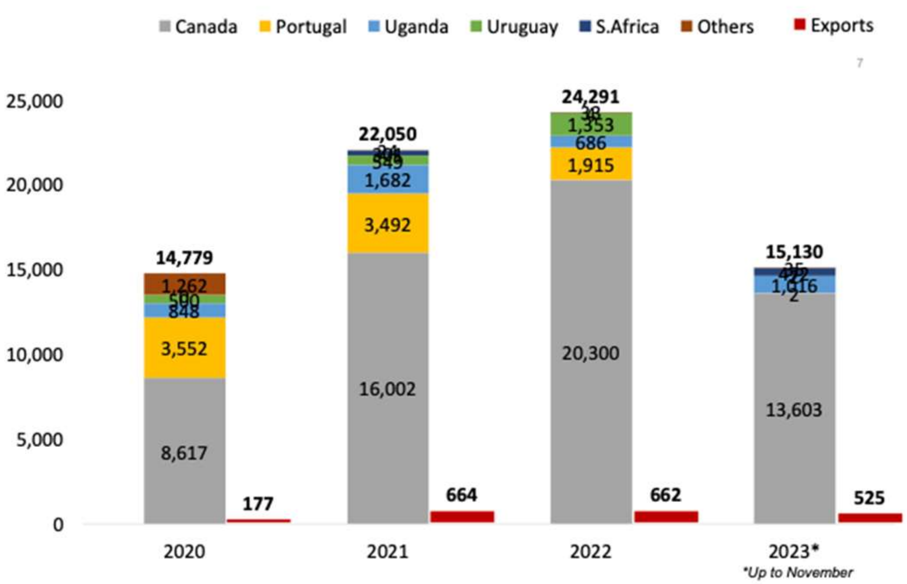
Legalization status of medical cannabis in Europe



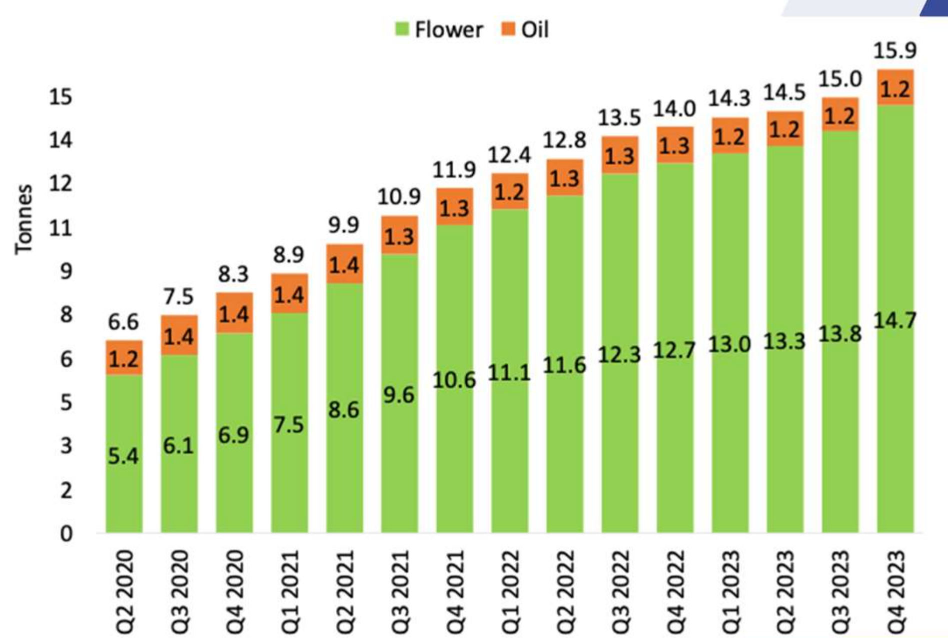
Israel (I)

- Despite dozens of licensed cultivators in the country, the Israeli market has been **increasingly supplied by imports** since they were first allowed in 2019.
- Israel **recognises EU-GMP** as well as third-party standards (e.g. CUMCS-GAP), which coupled with the most lenient quality standards for cannabis flower has opened the market to a variety of producers from all around the globe, primarily from Canada. Prospects of becoming a cannabis export powerhouse have not materialised as exportation remains limited.
- As of February 2024, an investigation was launched on suspicion of **price dumping** of 8 Canadian producers that exported to Israel at an average of U$2.3/gr during 2023. This move follows the petition of local industry stakeholders to limited importation, seen as the culprit for a wave of insolvencies during the year.

Imports (source of import) and exports of medical cannabis to Israel



Volumes of cannabis authorized to be dispensed to active patients in Israel

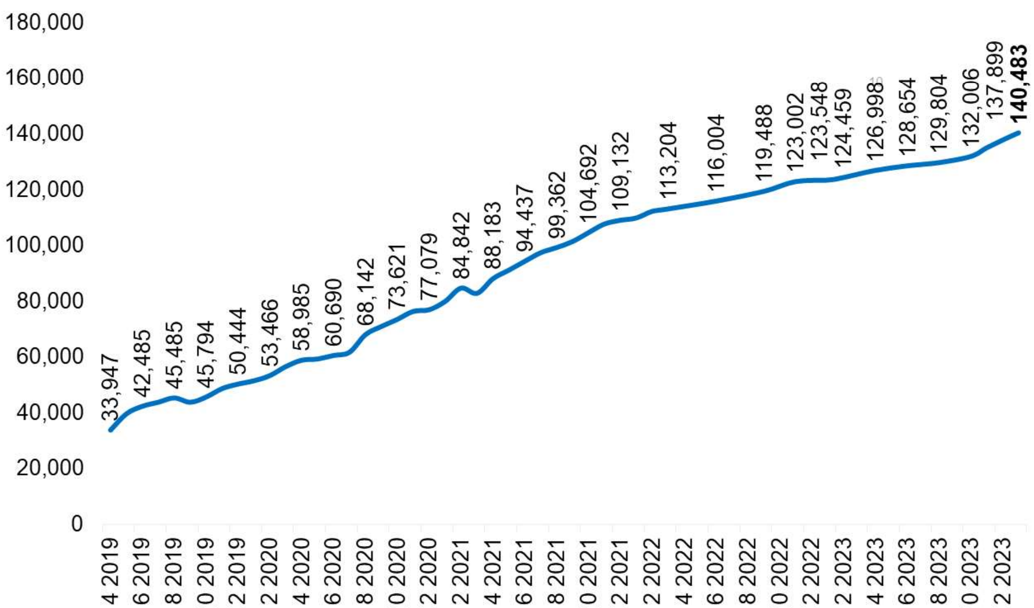


Source: Cannabis Magazine. Medical Cannabis Unit, Ministry of Health.

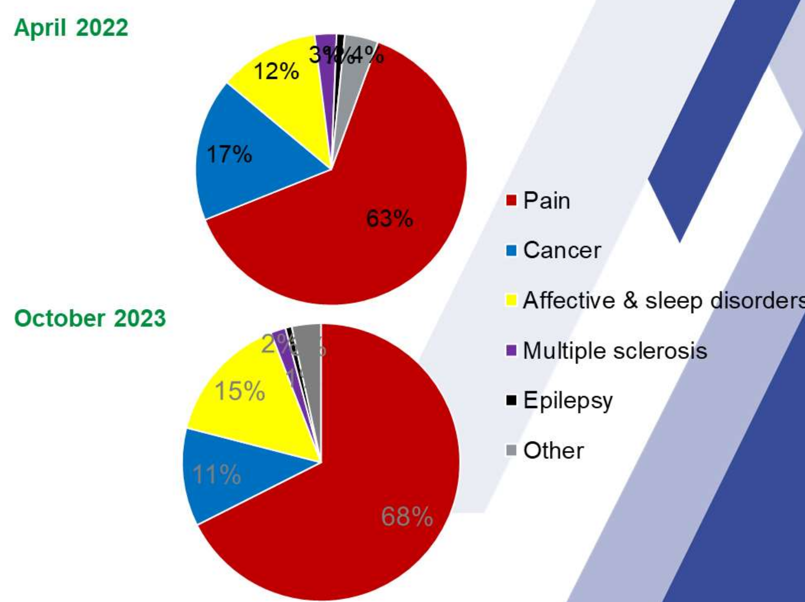
Israel (II)

- Israel was **one of the first countries to allow access** to patients of medicinal cannabis products since the end of the 1990's. Successive reforms in 2012 and 2019 allowed patient penetration to expand considerably and opened the domestic market to imports.
- In **January 2024** began the roll-out of regulations to ease regulatory burden on suppliers, allow cannabis as first line of treatment and permit OTC CBD sales in the country. **1.52% of the Israeli population** is accessing medical cannabis products as of the beginning of 2024, primarily for the treatment of pain, but increasingly for sleep and mood regulation.
- Since the beginning of the **war** with Hamas over **8,000 new patients have joined the market,** with a spike for Trauma and PTSD, despite the Minister of Health warning that cannabis is still to be considered as a 'last resort'. However, conditions on deliveries and prescriptions have accommodated displaced patients due to the confrontations.

Active patient licenses to access medical cannabis products in Israel



Main indication of active patients in Israel

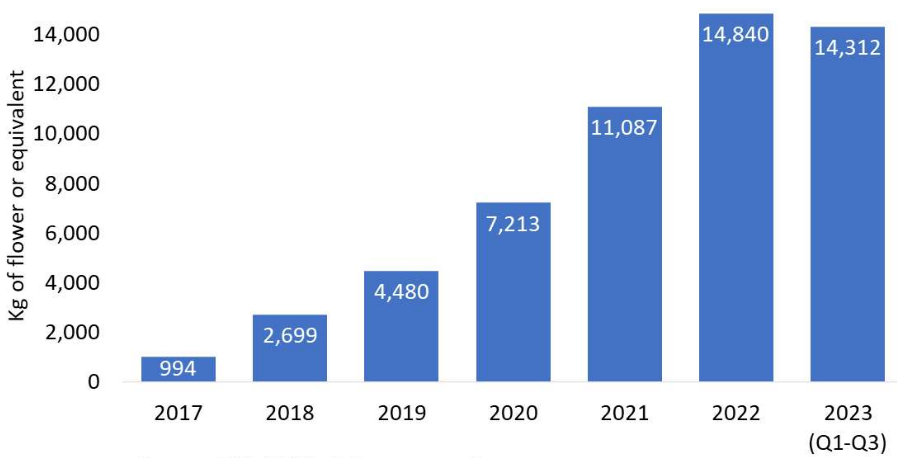


Source: Medical Cannabis Unit, Ministry of Health.

Germany (I)

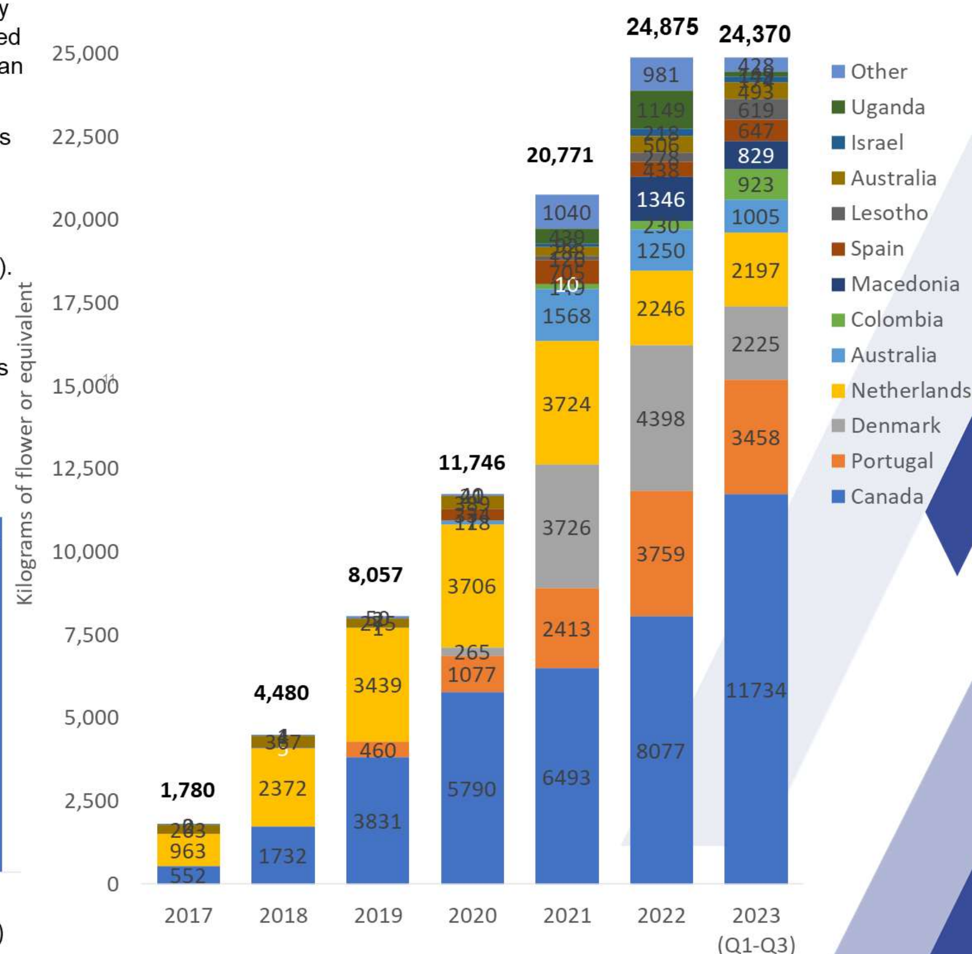
- Germany became the first country to **import cannabis** in the tonnes to supply its burgeoning domestic market. Initial importation from the **Netherlands** paved the way for Canadian, Danish, Australian, Portuguese, Colombian, Macedonian and Spanish producers entering the German market.
- Requirement of **EU-GMP** certification as well as stringent quality requirements in line with European Pharmacopoeia have limited the nº of players that can enter the market and kept wholesale prices relatively high.
- **Domestic licensed production of 2.6 tonnes** per annum is conducted by 3 licensed cultivators that won the tender in 2020 (Tilray, Aurora and Demecan). Upcoming legislative reform will liberalise production removing limits for domestic suppliers.
- The German market remains **highly dynamic** with new producers and strains hitting the shelves of German pharmacies every few weeks.

Pharmacy purchases of cannabis (flower + extracts)



Source: BfArM (Medicines agency)

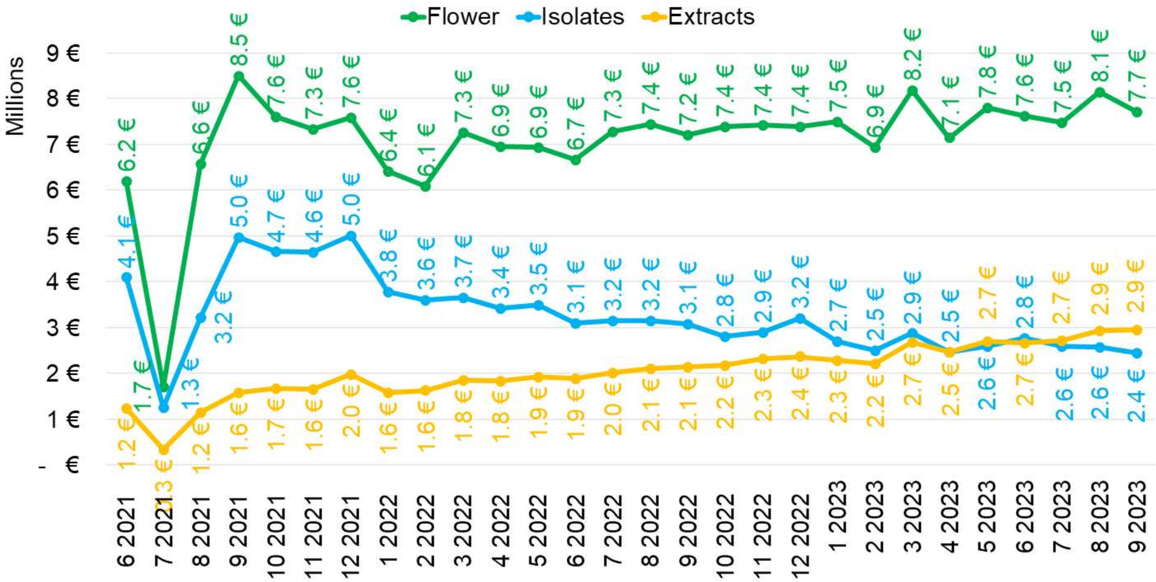
Source of imports to the German market (flower + extracts)



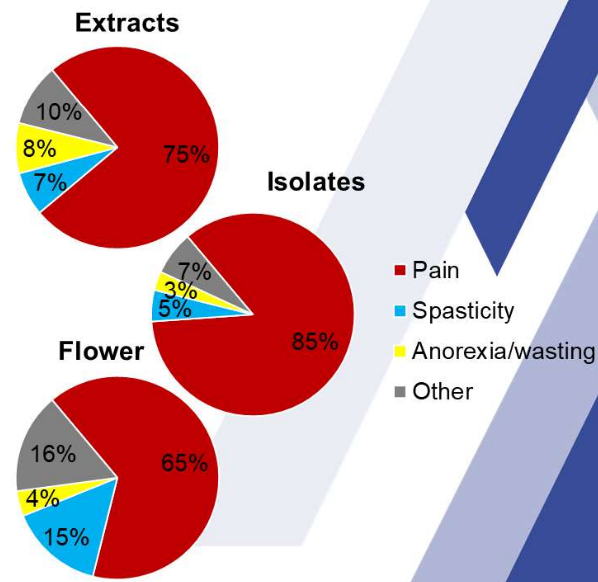
Germany (II)

- Patients can apply for reimbursement of their medical cannabis products, and it is estimated that **40-60% of patients manage to get reimbursement** approved.
- Despite flower remaining the dominant format, extracts are on the rise, given that reimbursement is more often granted for pharma-like formats such as extracts and isolated cannabinoids (dronabinol/CBD). In Q2 2023 **full-spectrum extracts surpassed isolates** (mostly dronabinol) in reimbursed sales for the first time.
- Flower dominates the non-reimbursed market, which has seen a lot of development in anticipation of the recreational reform. **Reimbursed prices sit at €4.26/gr** plus a 90-100% surcharge depending on the size of the prescription. Flower **prices in the private market range from €3/gr to €15gr** depending on supplier and pharmacy.
- **Dozens of wholesalers** compete for a piece of the German market, but only a handful of them are distributing significant volumes, with players competing in both price and quality of product regarding cannabinoid content and organoleptic qualities.

Insured sales of medical cannabis in Germany



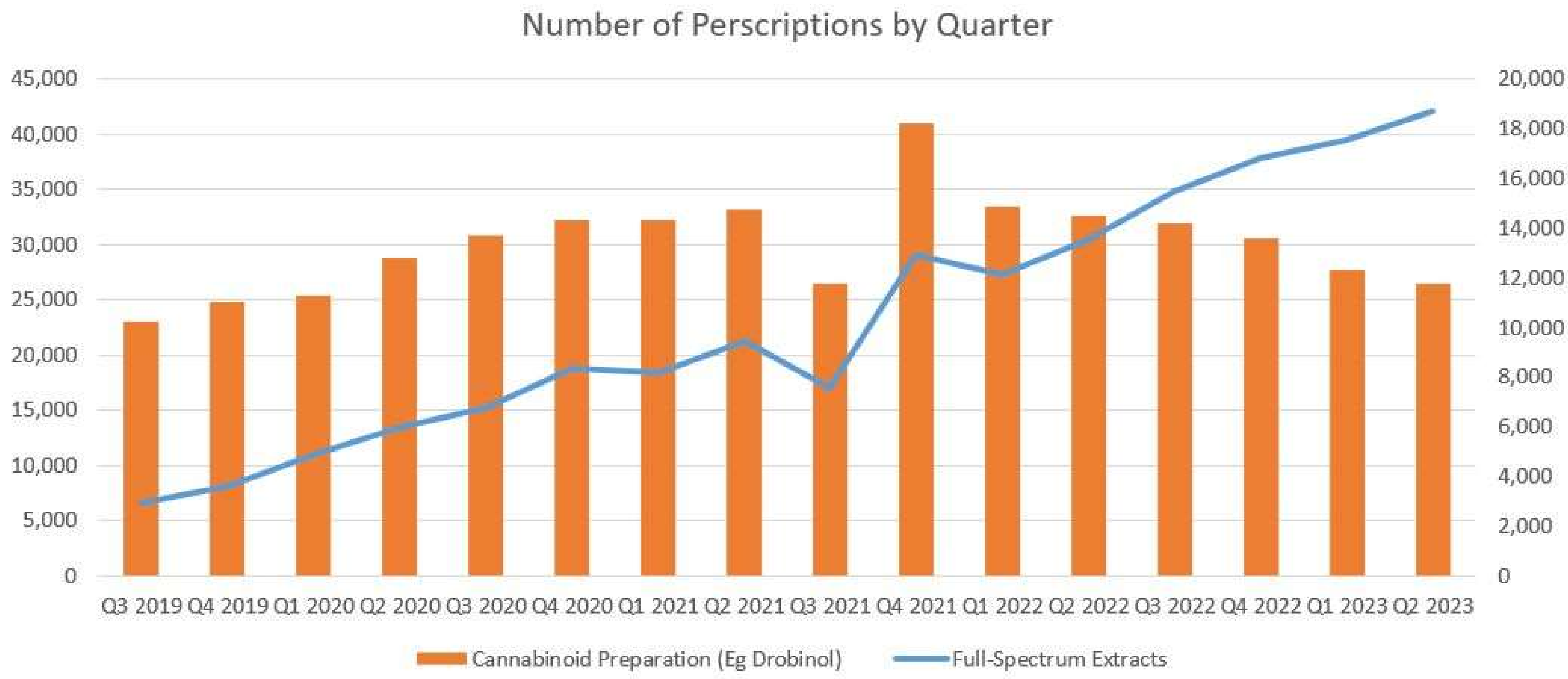
Indications of cannabis patients in Germany



Source: GkV-Gamsi (National Association of Statutory Health Insurance Funds). Preliminary results of the survey accompanying the prescription of medical cannabis in Germany

Germany (II)

- German insured cannabis sales have officially exceeded annual sales of 200m EUR (€ 203,892,770 Trailing 12 months [TTM]). We estimate the total German market, including private/self-pay, to be €305,000,000;
- 2023 Q2 Cannabis flower sales €21,105,980 versus Full Spectrum Extracts (FSE) €7,813,750;
- FSE now makes up 14.6% of the medical cannabis market and has a TTM growth rate of 47.4% (vs. Flower at 13.9%).

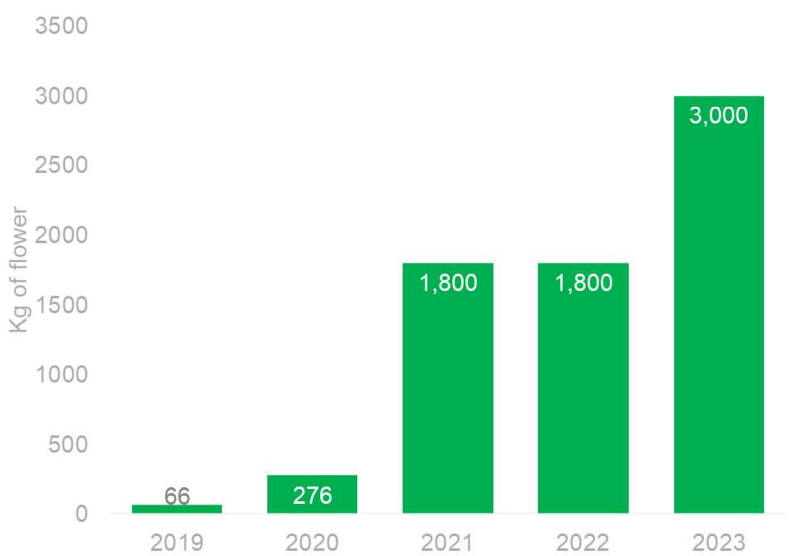


Source: GkV-Gamsi (National Association of Statutory Health Insurance Funds). Preliminary results of the survey accompanying the prescription of medical cannabis in Germany

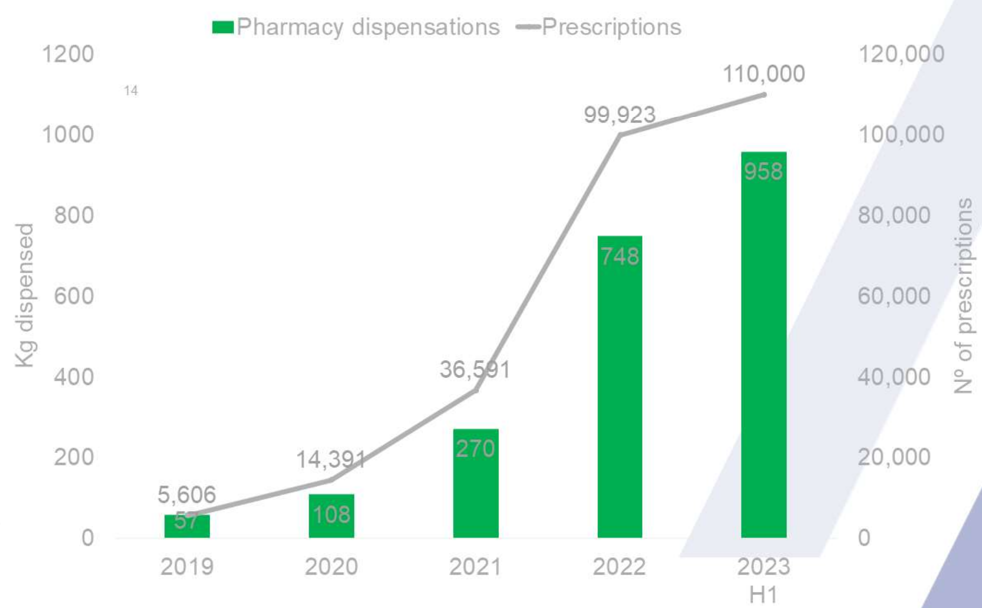
Poland

- Poland **liberalised its medical cannabis scheme in 2017** allowing all GPs to prescribe as well as importation in bulk and distribution through multiple suppliers. Since 2022, experiments in **governmental-approved facilities to cultivate** cannabis for the local market are underway, but it is uncertain when they will come online.
- **Mandatory product registration** which can take up to 18 months severely limits the number of players in the market: for now, only a few Canadian and Portuguese flower strains are available to Polish patients, and since 2022, also extracts produced in North Macedonia. Producers are using the same registration to bring multiple strains to market.
- Expansion in the prescriber base given the development of private clinics in the country means that the **number of patients and prescriptions is poised to continue increasing**, particularly as the supply situation is normalised with more players registering their products in the Slavic country.

Import permits of medical cannabis to Poland



Nº of kg dispensed and prescriptions issued

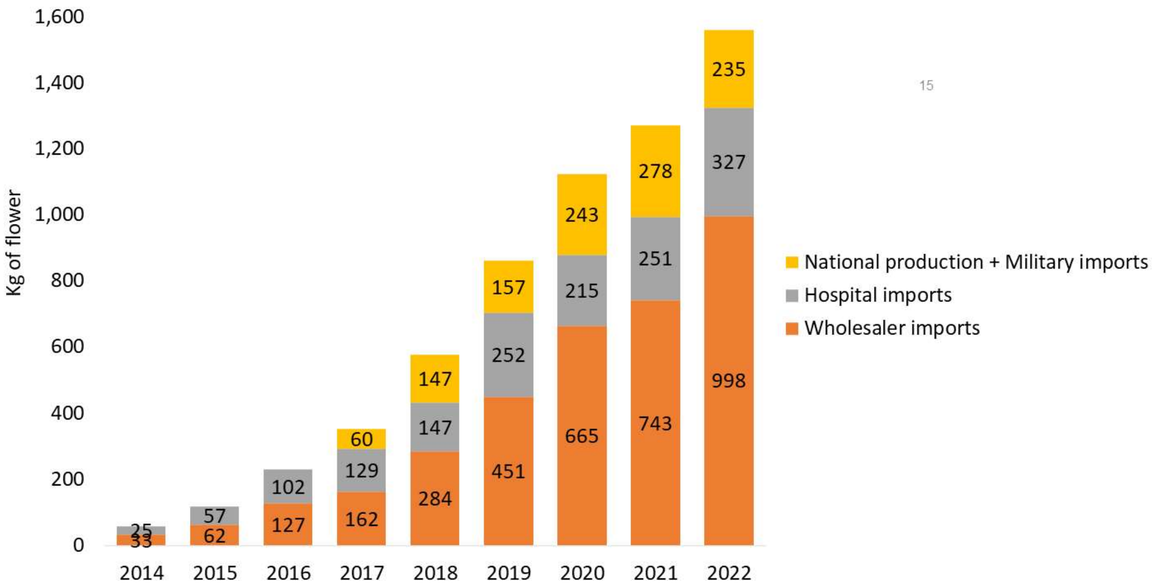


Source: M Zdrowia (Ministry of Health)

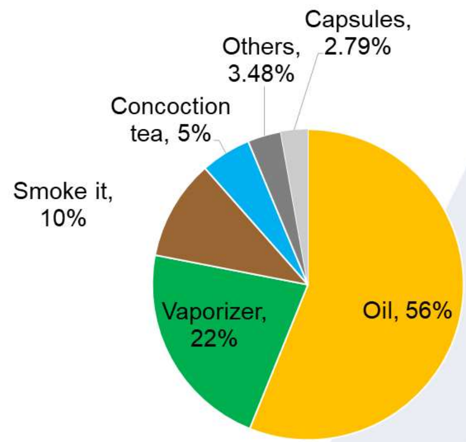
Italy

- Italy legalised medical cannabis in **2013 thus becoming one of the oldest** European markets. However, its tight approach towards supply, highly controlled by the State, has kept the market limited as over 50% of the patients declare having had their treatment stopped due to a lack of availability of products.
- The **Italian military** handles the only licensed national production in their lab in Firenze, but a tender to diversify production sources was opened in 2022 with multiple companies developing their projects. Other sources of imports include a contract with the government of the Netherlands as well as supply tenders awarded by the government.
- Since 2022 standardised full-spectrum extracts are distributed through the **6 licensed pharmaceutical raw materials** providers. As of 2023, **medicinal extracts** by Tilray and Avextra are available to patients, and in the case of Emilia Romagna and Lombardia fully reimbursed by the public system.

Medical cannabis supplied to the pharmacies in Italy



Self-reported means of administration of medical cannabis

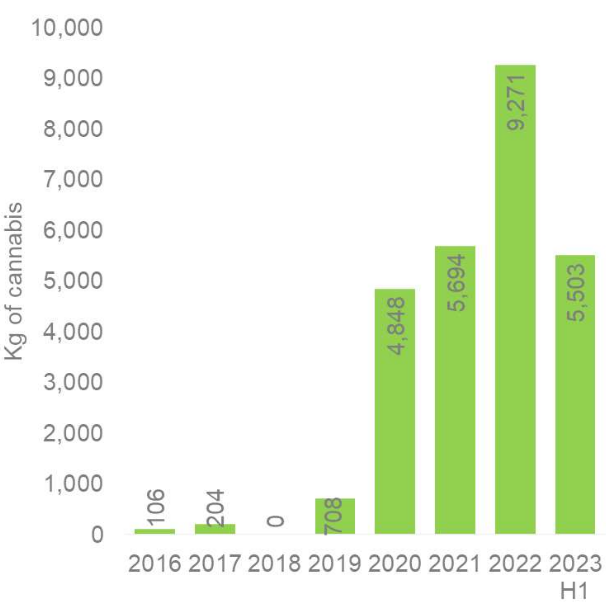


Source: Ministerio della Salute (Health Ministry), Comitato Pazienti Cannabis Medica (2022) Questionario Pazienti Cannabis Medica Italia (n=287).

Portugal

- One of the first European countries to legalize cannabis production, Portugal began commercial cannabis operations through the supply of cannabis raw materials to GW Pharma in the UK to produce cannabis-based pharmaceuticals.
- In recent years, dozens of production projects have emerged placing Portugal as **the second largest international supplier** only behind Canada, with many international companies such as Tilray establishing their European operations in the country.
- Being a EU members has allowed Portugal to become a **hub for European distribution**, with players receiving biomass from the global south and reexporting it to Israel or Germany. Portugal has a small domestic market with only one registered product (high THC flower by Tilray).

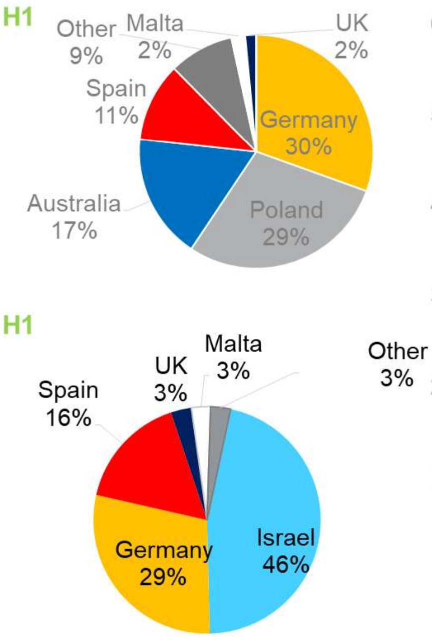
Medical cannabis exports from Portugal



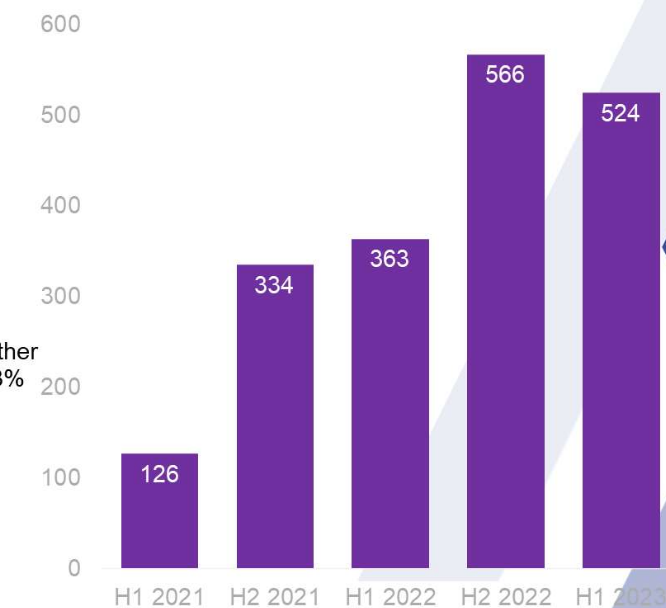
Share of exports destination

2023 H1

2022 H1



Nº of prescribed medical cannabis items in Portugal

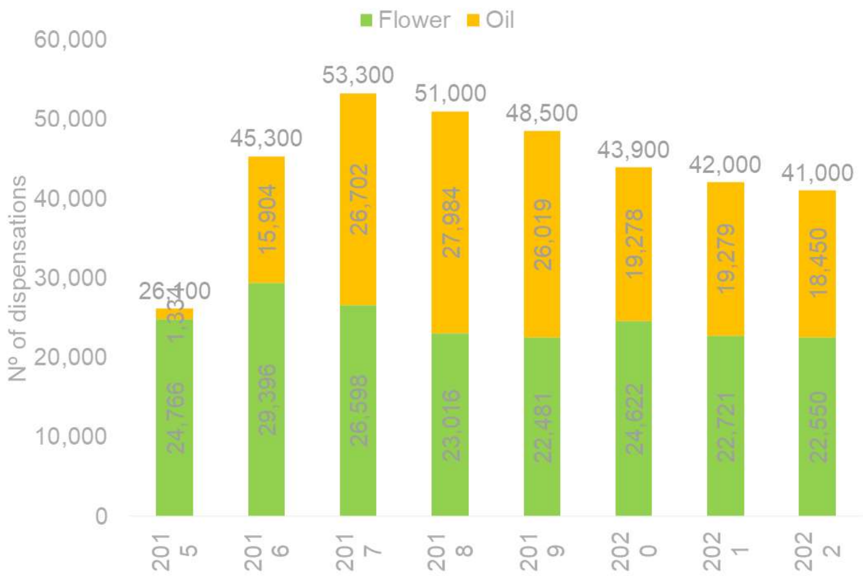


Source: INFARMED (Medicine Agency)

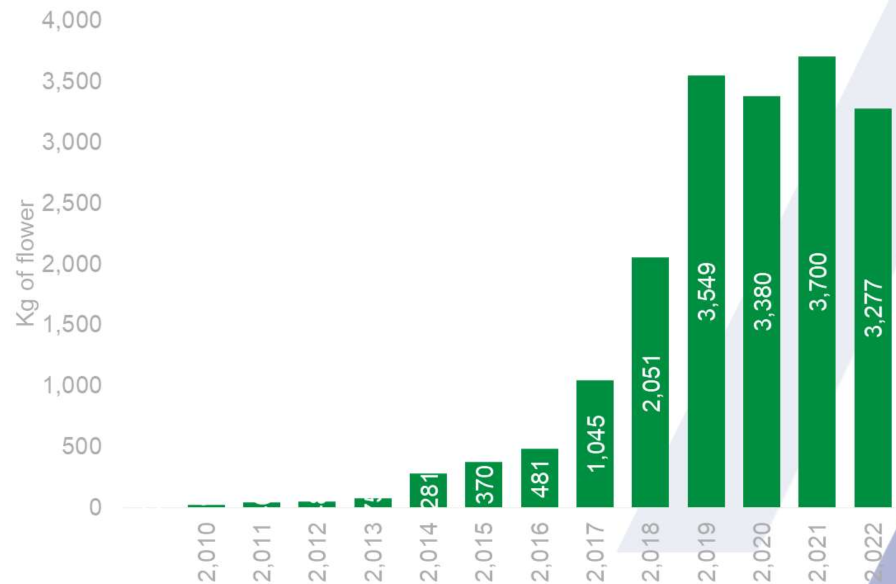
Netherlands

- The European pioneer in progressive cannabis policies, the Netherlands has allowed coffee-shops to flourish since the 70s and was the **first to legalise medical cannabis in 2003**.
- The **medical cannabis supply chain is tightly controlled** by the government: only a handful of pharmacies are involved in the production of oils as a magistral product for the domestic market and products for export by the only licensed producer Bedrocan are acquired by the Office of Medical Cannabis who commercialises them internationally.
- The cancellation of reimbursement in 2017 as well as the tolerant approach towards recreational cannabis has led the medical market of the country to falter. According to an official survey up to 25% of coffee shop users consider themselves to be medicinal users.

Medical cannabis dispensations in the Netherlands



Exports of medical cannabis from the Netherlands

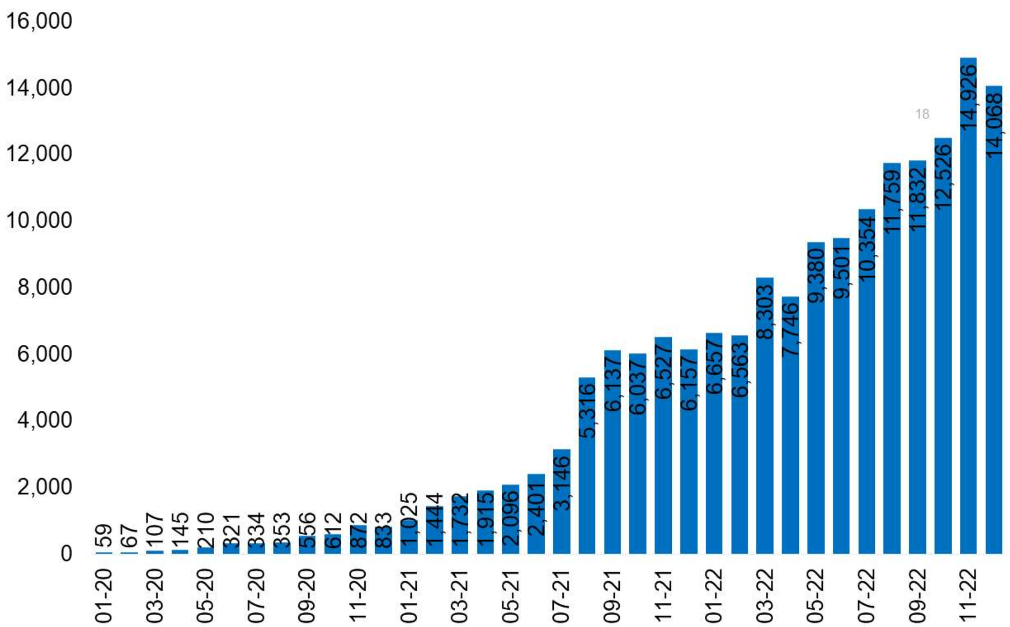


Source: Cannabisbureau (Office of Medical Cannabis), Stichting Farmaceutische Kengetallen (Foundation for Pharmaceutical Statistics).

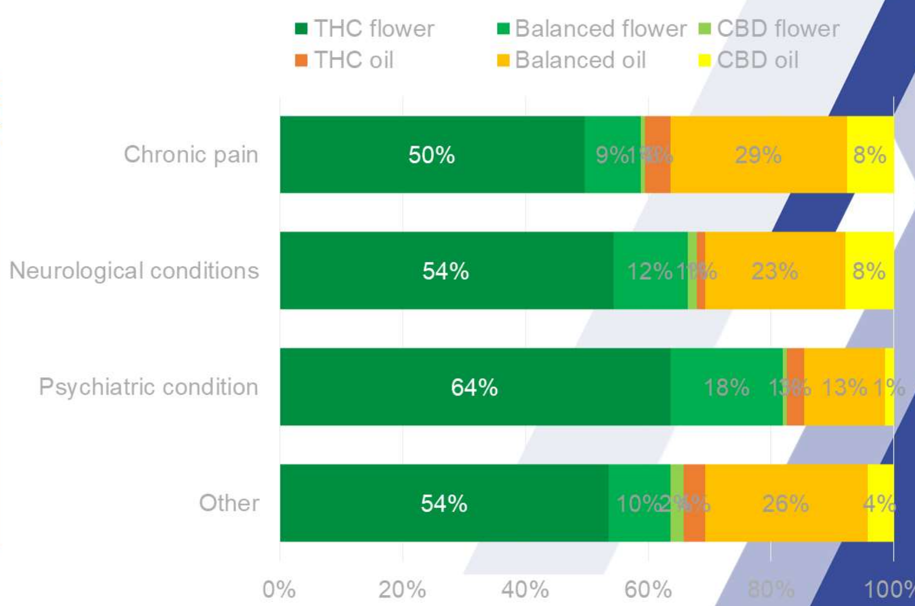
United Kingdom

- Despite possessing the largest quota for cannabis trade by the INCB, due to GW Pharma licensed pharmaceuticals being produced in the country, the UK medical cannabis scheme remains a **small albeit fast-growing market**, with the main hindrance being the **lack of NHS support** with only a handful of prescriptions being written through public healthcare.
- Private prescriptions by registered specialists represent the largest share of the British market, which has seen the proliferation of **private clinics**, often linked to wholesalers, as the primary means to obtain medical cannabis prescriptions by patients. In October 2023 electronic prescriptions were allowed in the country.
- Initially supplied through named-patient importations, imports in bulk were authorised in 2020 easing the supply situation for patients. The focus on oils of the initial prescriptions has evolved into a **thriving flower market**, while other formats such as **vapes, and capsules** are becoming increasingly available in the country.

Privately prescribed medical cannabis items in England (monthly)



Types of product prescribed under Twenty21 access scheme

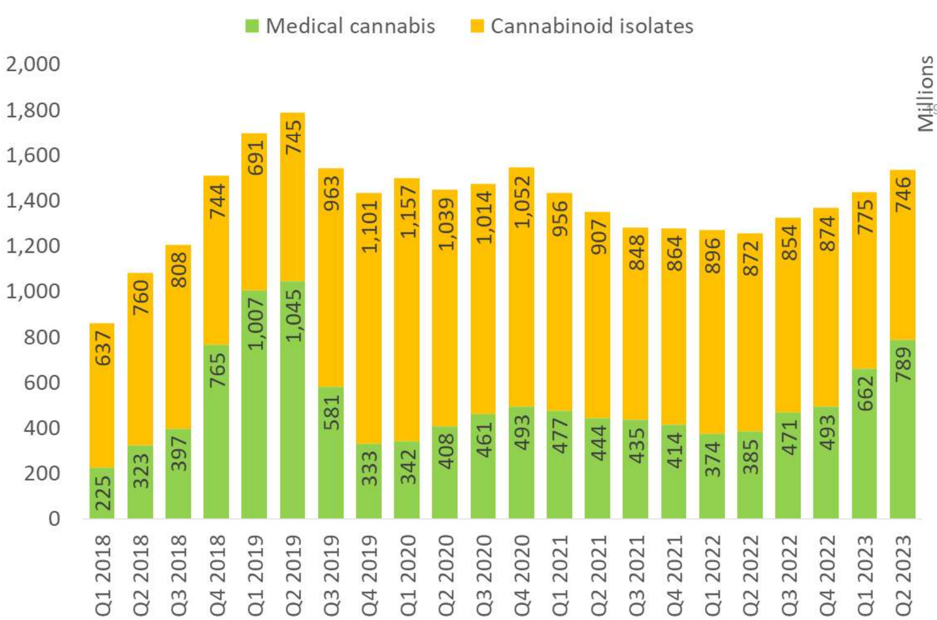


Source: NHS Business Services Authority, BusinessCan. Drug Science.

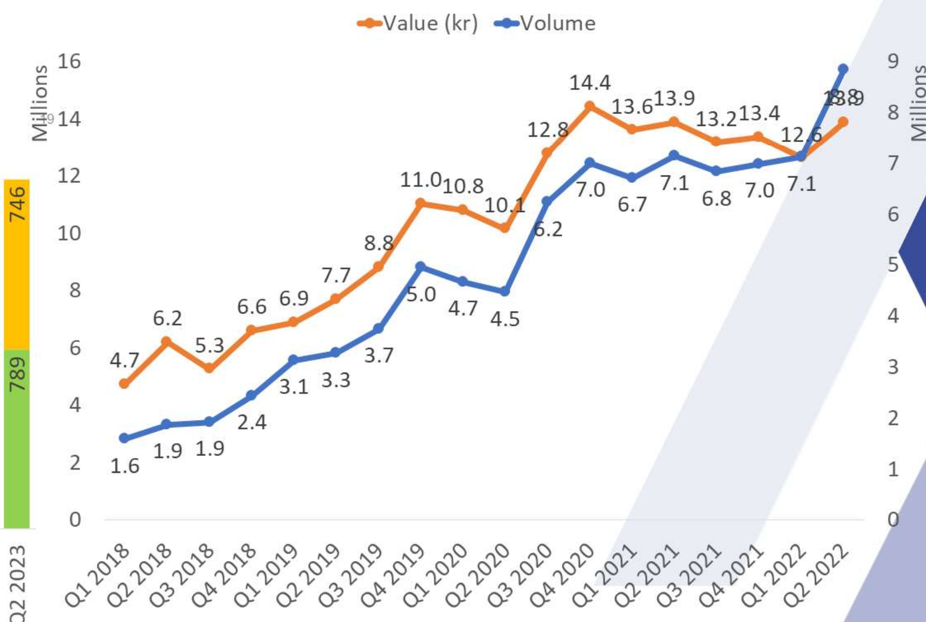
Denmark

- Danish pilot project to access unlicensed cannabis medicines was launched in 2018 through the supply of imported **flowers, oils and isolates** (dronabinol/CBD).
- The discontinuation of Canadian extracts due to the downfall of Cantrust in 2019 brought a reduction in dispensations of which the **scheme only started to recover in 2023**.
- A hub for **medical cannabis cultivation** has developed around the town of Odense, with international companies such as Aurora and Little Green Pharma stablishing their European production facilities as well as local producers such as Schroll Pharma which are increasingly supplying the German market.

Nº of active patients



Volume and value of dispensed products (medical cannabis + isolates)

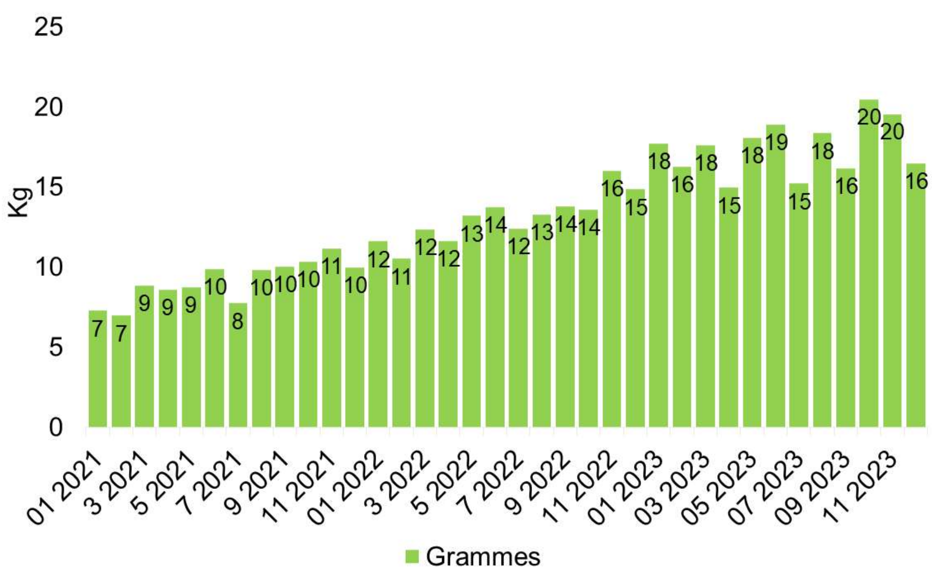


Source: E-Sundhed (Danish Health Data Agency)

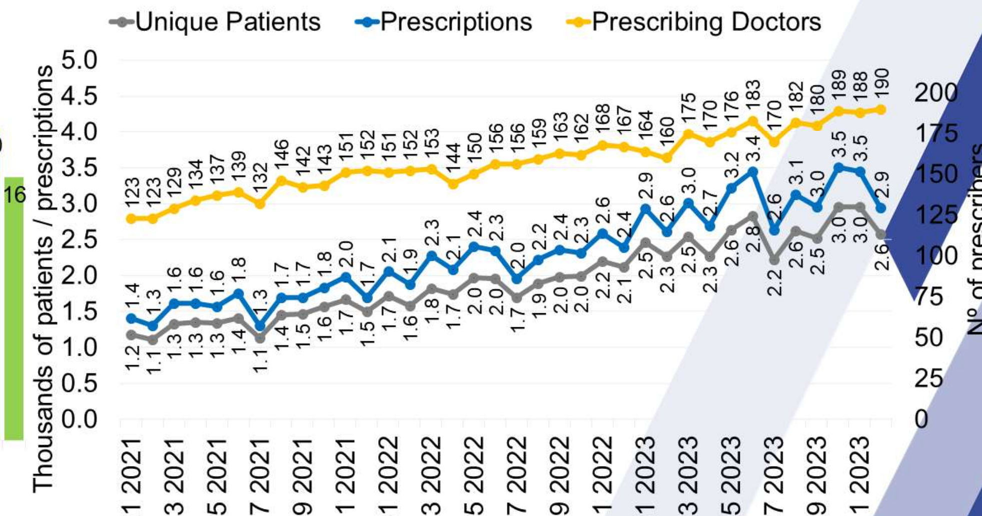
Czech Republic

- In **2013 the Czech Republic was one of the first** European countries to legalise medical cannabis through the allowance of imports of cannabis flower and the tender for domestic production which was awarded to Czech company Elkoplast.
- Domestic production has remained limited while imports, primarily from Canada through Germany, account for the majority of dispensed products to clients. Under 160kg were dispensed to patients in 2022, while in the first 9 months of **2023 over 150kg** have already been supplied to the patients.
- **Product availability** in the market has improved thanks to new market entries and the **allowance of extracts** in the market, but the government plans to license more domestic suppliers to ensure domestic supply .

Medical cannabis flower dispensed in Czechia (monthly)



Number of prescriptions, patients and prescribing doctors in Czechia

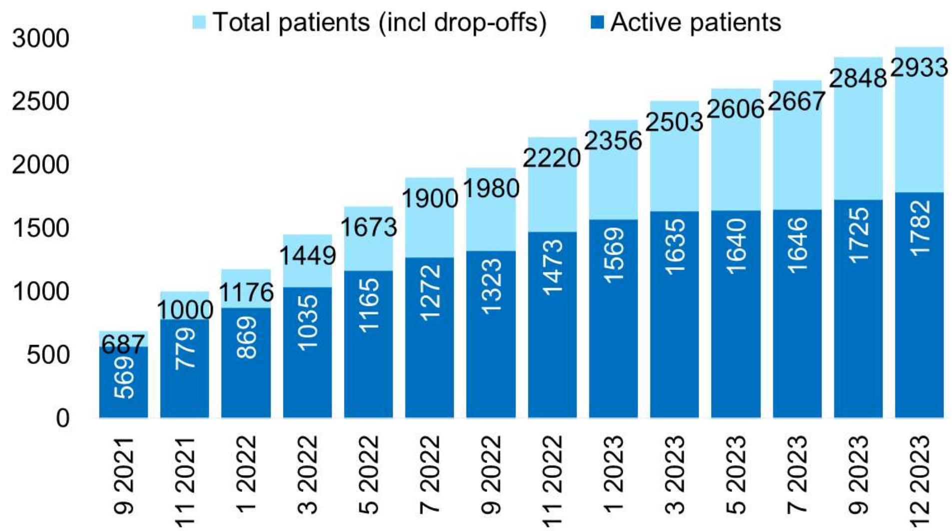


Source: SAKL (State Institute for Drug Control / State Agency for Medical Cannabis)

France

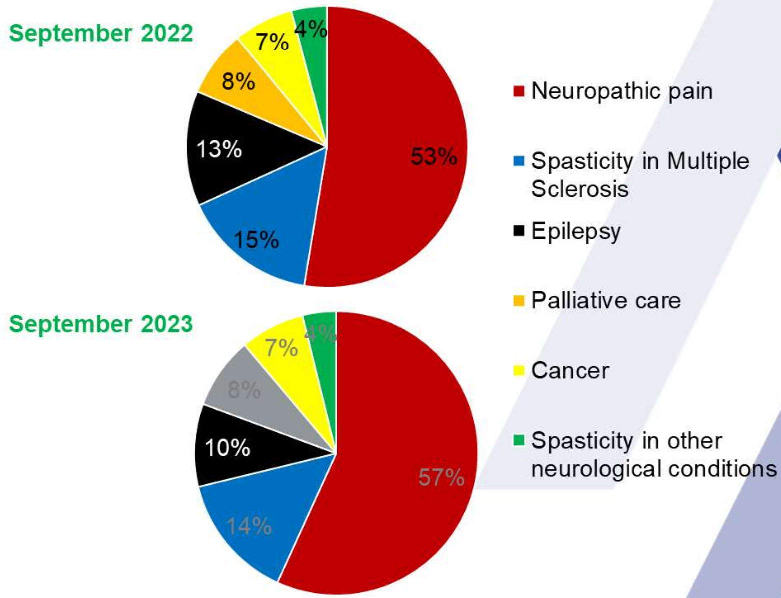
- In 2021 France launched its **experimentation on medical cannabis use** for a duration of 3 years with a maximum of up to **3,000 patients** enrolled in the scheme. Only physicians and pharmacists that have undergone an official course can prescribe and dispense medical cannabis products to patients.
- Supply to the experimentation has been allocated through a **tender** awarded to Aurora, Tilray, Panaxia and Little Green Pharma to supply oils and flowers of different concentrations, which has been renewed in 2023 through new tenders for the remainder of the experimentation.
- Lobbying by French groups has managed to change the position of the government including in the social security budget an **allocation of €10M** to continue the experimentation until the end of 2024, when it is expected that general medical legalisation will take place by granting a special marketing authorisation for specific products with a duration of 5 years.
- However, doubts about the future legal medical market in the country remain, particularly regarding the **extent of reimbursement** or the **inclusion of flowers**. In February 2024, patients that were treated with flower received a communication about **stopping their current treatment with flower** and transitioning to oils.

Active patients enrolled in the French medical cannabis experimentation



Source: ANSM (Medicines Agency)

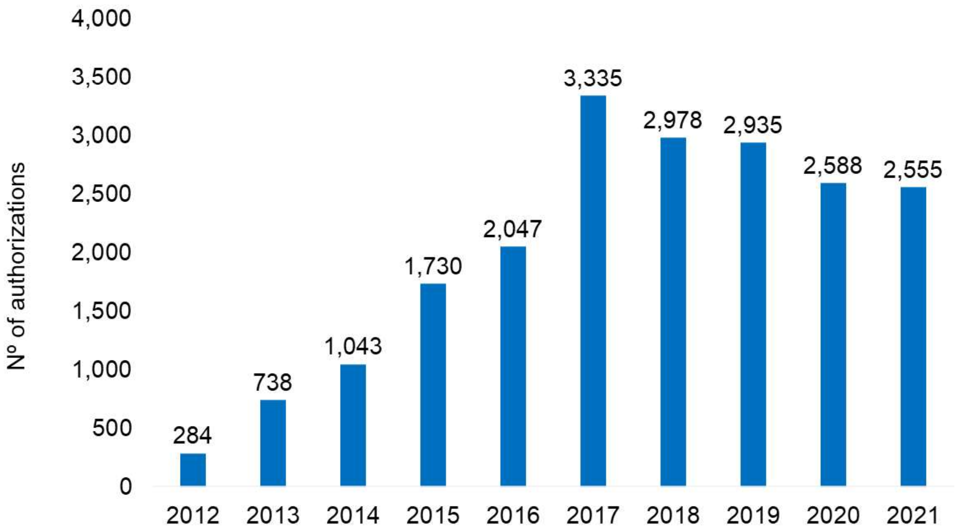
Main indication of active patients in the French experimentation



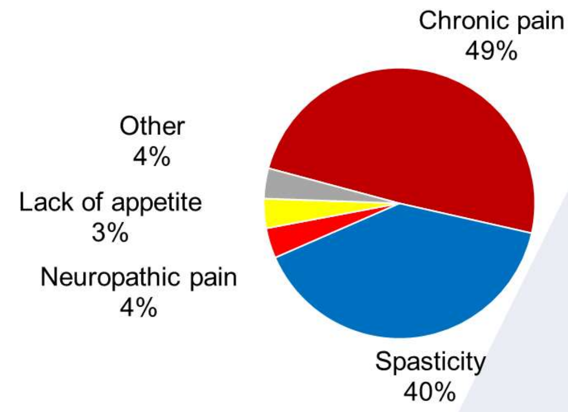
Switzerland

- Since 2012 patients have been able to access unlicensed medical cannabis products with a special authorisation granted by the Federal Office of Public Health (2022). A reform of the system in place since August 2022 allows patients to be **prescribed medical cannabis without an additional FOPH authorization** being required.
- Most of the prescriptions have been filled for **magistral preparations** with isolated cannabinoids (e.g. dronabinol), however cannabis extracts produced at the pharmacy are also available and since 2023 imported flower products are also available through the pharmacies.
- Thanks to its 1% THC limit on hemp products Switzerland has seen the development of a **vibrant CBD market** focused on the flower and other smokable products which are treated under tobacco legislation. Switzerland is home to many indoor producers of CBD flowers which are now seeking licenses to produce medical cannabis as well.

Patient authorizations to use medical cannabis in Switzerland



Main indication of patients using medical cannabis in Switzerland (2014)



Source: Swiss Ministry of Health, Prohibition Partners, Medical use of cannabis in Switzerland: Analysis of approved exceptional licences.

EMEA

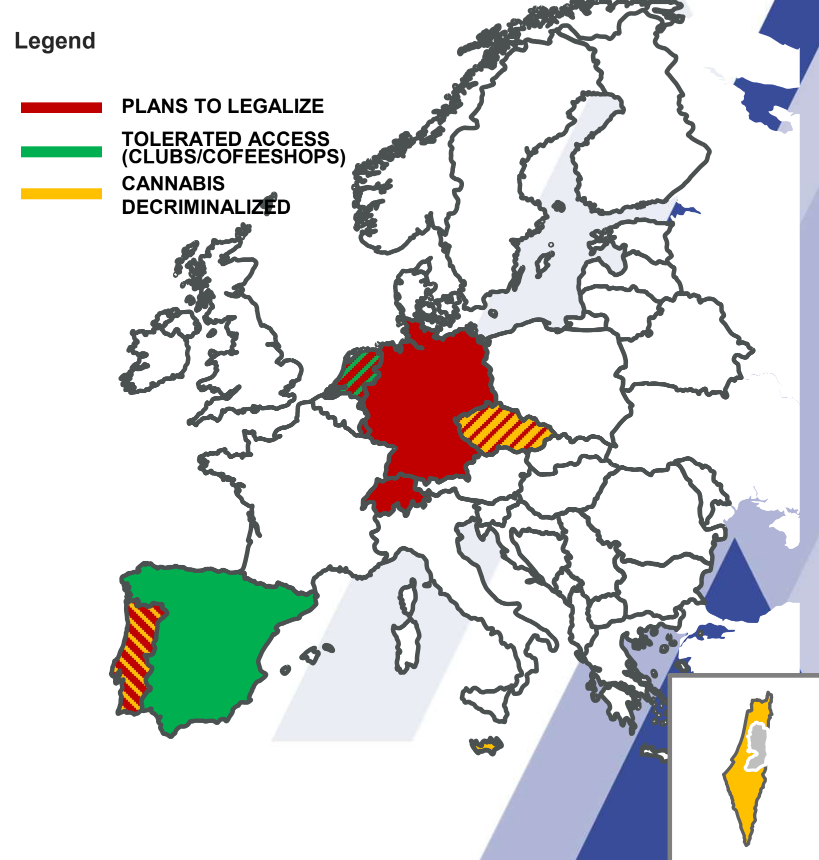
RECREATIONAL MARKETS

Europe, Middle East and Africa

Debate on cannabis legalisation in Europe is heating up: following German plans to allow recreational access, other countries are likely to follow suit.

- The cultural shift in favor of cannabis is starting to influence legislators and provoking a **wave of drug policy reforms** that is sweeping the European continent:
- **Malta** has joined the **Netherlands, the Czech Republic and Portugal** in enabling the private, domestic production and use of cannabis. Other countries such as Italy and Germany are likely to follow suit.
- The lack of examples of legalization in Europe as well as uncertain regulation at the international level are the main deterrents, but it is likely to change after **German legalization**.
- The Netherlands and Spain have illegal but tolerated recreational cannabis markets:
    - **Coffee-shops** in the Netherlands have existed since the 70s, but production and supply has been illegal (backdoor policy) until the experiment launching in December 2023.
    - **Spanish social clubs** operate based on the right of association of their members, which can purchase cannabis products for their private use.
- The first **European recreational schemes** are expected to roll out in the coming quarters:
    - In **Germany, limited legalization** will involve decriminalization and social clubs in the first phase, but the second phase consisting of commercial supply chain is in jeopardy by bad electoral polls of the current government which is running out of time before 2025 elections.
        - A 2021 study conservatively estimated the potential demand for cannabis in the German market at more than 200 tons.
    - In the **Netherlands, the supply chain experiment** has been announced to commence in December 2023 in 10 municipalities plus the East district of Amsterdam.
    - Multiple **pilot projects** are underway in different **Swiss cities and cantons**, with the first legal recreational commercial sales happening in January 2023.
    - **Malta** decriminalized cannabis in 2022, allowing private citizens to grow up to 4 plants at home and licensing the first 2 non-profit clubs in October 2023.
    - **Luxembourg** announced more concrete plans to legalize during 2023, including the public control of dispensaries in the Duchy.

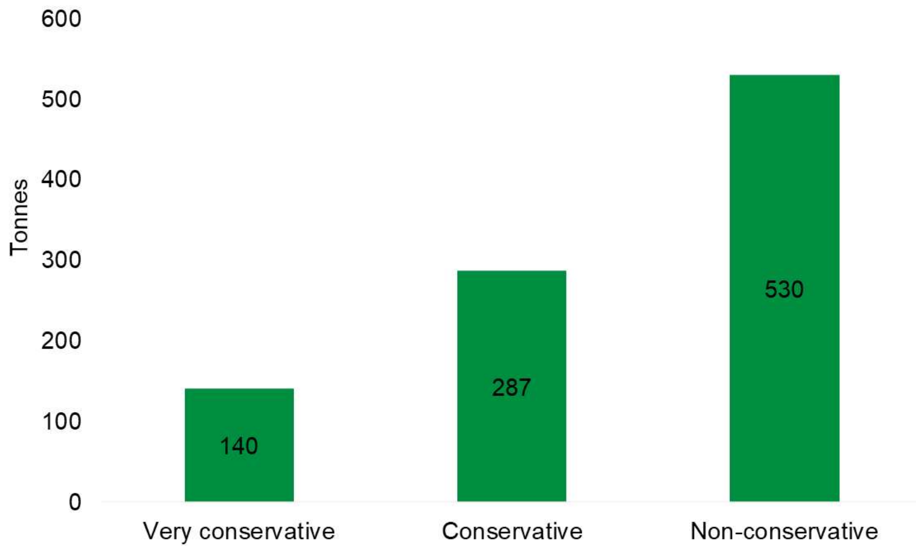
Legalization status of recreational cannabis in Europe



Germany

- The Social-democrat, Green and Liberal parties that compose the German federal government won the 2021 election with a program to legalize recreational cannabis. In March 2023, the government announced a revised **plan of legalisation consisting of two phases**, with decriminalization of **consumption and home-growing** in the first phase, and **commercial supply chain** in the second. The second phase is uncertain to move ahead due to conservative opposition and difficulties by the current government to get a majority.
- The draft of the first phase has currently been approved by the lower house of Parliament, but still requires to pass a vote in the upper chamber, that cannot veto legalization but might impose a delay on the date of entry into force of the law, currently planned for **April 1st**.
- Up to **3,000 clubs** are expected to be created in Germany over the first few years of limited legalisation. However, harsh rules involving over 200 meters from schools and youth facilities, a ban on on-site consumption and limits on use of revenues generated from the cultivation will limit the potential of these cannabis clubs.

Estimated demand of a German legal market



Key elements of German recreational project (first phase)

Adults will be able to lawfully possess and carry up to 25gr of cannabis for their personal consumption, grow up to 3 plants at home and acquire 50 grams a month from their cultivation association.

Cannabis will be grown by Cultivation associations of up to 500 members that receive a permit of the state with a duration of 7 years. Residential areas won't be able to house an association. Members will need to tend to the grow and non-member employees are not allowed.

Cultivation associations will be financed by membership fees and will not be able to charge for the supplies. Deliveries are forbidden except for seeds and clones.

Source: Fiscal Implications of Cannabis Legalisation in Germany: an update (2021). FAQ Cannabisgesetz (2023)

Switzerland

On 25 September 2020, the Swiss Parliament amended the Narcotics Act to provide a legal basis for conducting **scientific pilot tests on recreational cannabis** limited in the space and time, ensuring compliance with international narcotic convention treaties.

Projects must be limited to a particular commune and can be submitted by the canton, universities or research agencies.

Swiss cannabis growers for experimentation require authorization from pharmaceutical regulator FOPH and must comply with the same Good Agricultural Harvesting Practices (**GACP**) as pharmaceuticals.

- Products supplied under pilot projects must possess **organic certification**. In September 2022 cannabis sales in the Basel were not able to commence due to the finding of pesticidal residues.
- However, importation from abroad or the use of non-organic agricultural products will be possible if it is not possible to obtain the products in another way.

Pilot projects that have commenced or been announced include:

- In **Basel,** the Weedcare project, supplied by Pure Holdings, conducted the first legal recreational sales in Europe in January 2023. 370 adults
- **Lausanne** project "Cann-L" plans to launch before the end of 2023 with the opening of a dispensary in the city center serving up to 1,200 users.
- In the canton of **Geneva,** a Cannabinoteque will open in December 2023 supplying cannabis to 1,000 users.
- Zürican in **Zurich** will provide 2,100 participants through 21 dispensaries.
- **Basel-Country**, in collaboration with German company Sanity Group, will open '**Grashaus'** dispensaries to supply 3,950 users.
- In **Bern, Bienne and Lucerne** the SCRIPT project will be monitored by universities to study the effects of recreational on 1,091 participants.

Source: Federal Office of Public Health (2023)

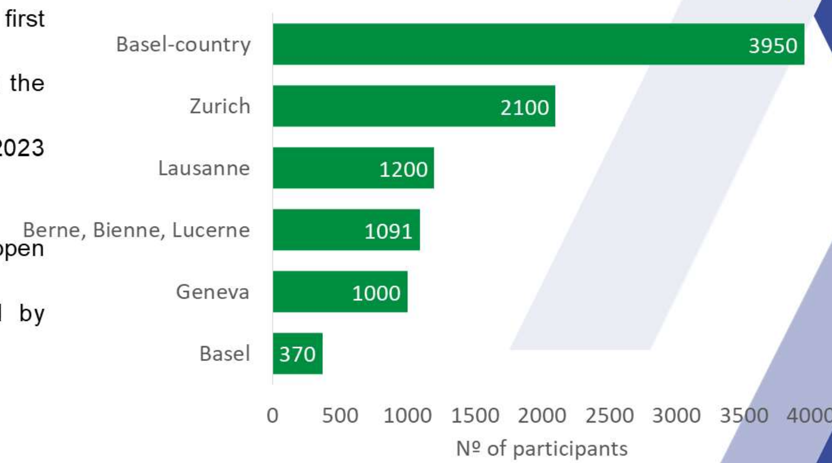
Key elements of Swiss recreational pilot projects

A maximum of 5,000 regular users per project will be able to purchase a maximum of 10g per purchase for private use.

Only GACP-collected cannabis, organic and grown in Switzerland of up to 20% THC will be used in the experiment.

Depending on the project, pharmacies, social clubs, and dispensaries can be used to dispense cannabis products.

Max nº of users that can be enrolled in Swiss recreational pilot projects



Netherlands

- In December 2023, an experiment was launched to legalize the coffeeshop supply chain, which have been operating on a “backdoor policy” since the inception of the model in the 1970s.
  - The goal of the experimentation is to pursue the goals of harm reduction and combat against illegal trafficking that led to the tolerance of the coffee-shops in the first place.
- All coffee shops in the municipalities of **Tilburg and Breda** are participating in the experiment and obtaining supply from the 2 only licensed growers currently enrolled in the experiment, with others still building facilities.
  - During the start-up phase of the experiment, expected to last 6 months, coffee shops are allowed to keep supplying from other sources, but they will need to transition to 100% legal sales in the next phase.
  - 5 new growers are expected to join the experiment in the summer.
- In March 2024, the amount of stock that retailers can hold has been increased, following problems with the limited amount of stock allowed to be held by the coffee shops.
- Despite the announcement that the **East District of Amsterdam** would also participate in the experimentation, opposition by 5 out of 11 coffeeshops in the district has casted doubts on its participation, while other municipalities such as The Hague are discussing joining the experiment.

Nº of available items in Dutch coffeeshops by format (%)

Key elements of the Dutch supply chain experiment

There are no additional regulations on use beyond the tolerance policy of the Netherlands since the 70s

10 licensed growers can supply flowers, hashish, pre-rolls and edibles to coffee shops participating in the experiment.

All coffee shops in the municipalities in the study are to obtain their supplies only from licensed producers after the experiment begins.

Nº of coffee-shops in the participating municipalities of the experiment

Source: Government of the Netherlands (2023). Health Reform Monitor: Cannabis policy in The Netherlands: Rationale and design of an experiment with a controlled legal (‘closed’) cannabis supply chain (2023). RAND Corporation, Breuer&Intraval, Trimbos-instituut (2023) Study in support of the Controlled Cannabis Supply Chain Experiment: Pre-measurement report 2021

Americas

Medical & Recreational MARKETS

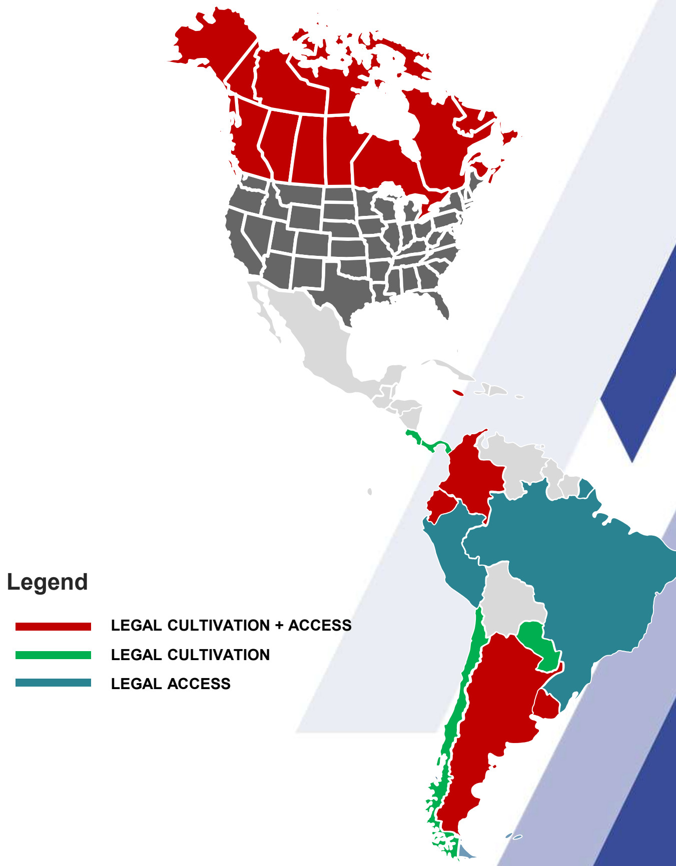
North America, South America

and the Caribbean

North America leads the way in cannabis reform, while medicinal cannabis is booming in LATAM.

- North America has **led the cannabis reform wave** sweeping the globe in the last decade, with **Canada** being one of the first countries to recognise the medicinal use of the plant at the end of the 1990s and the second to legalise the recreational use at the federal level.
    - The **US**, despite slow steps towards federal legalisation, is home to some of the most advanced policies in regard to cannabis in the world, particularly in the States that have legalized recreational cannabis.
        - Before Missouri and Maryland voted on legalising the recreational use in 2023, 48% of the US population lived in a state that has legalized recreational cannabis, with an additional 26% living in states that have recognized the medical use. [36]
- **Latin American** countries have traditionally been the source of raw materials for the black-market during decades, leading to huge problems with trafficking and criminal organisations that have led them to explore multiple modalities of drug policy reform.
    - **Uruguay** was the first country to legalise recreational cannabis in the world in 2013, with the aim of curtailing the economic capacity of drug-trafficking mafias.
    - **Colombia** emerged as a legal cultivation powerhouse following legalisation in 2017, with exports of primarily CBD extracts and since 2022 also flower.
    - **Brazil** has the largest domestic market in the region, entirely supplied by imports.
    - **Jamaica** has enacted medical cannabis legalisation and the first exports of Jamaican-grown cannabis hit the international market in 2021.
    - Despite the constitutional court mandate to reform cannabis policies in **Mexico**, the lack of concrete regulations has limited its market to the import and distribution of CBD products as food supplements.
    - Small medicinal markets are developing in **Ecuador and Peru**, which have begun licensing cultivators, despite importing all of the products for distribution.
    - **Argentina** has passed regulations concerning cannabis in 2023 as well as permitted the first medical cannabis products for dispensation in the pharmacies (primarily CBD oils).

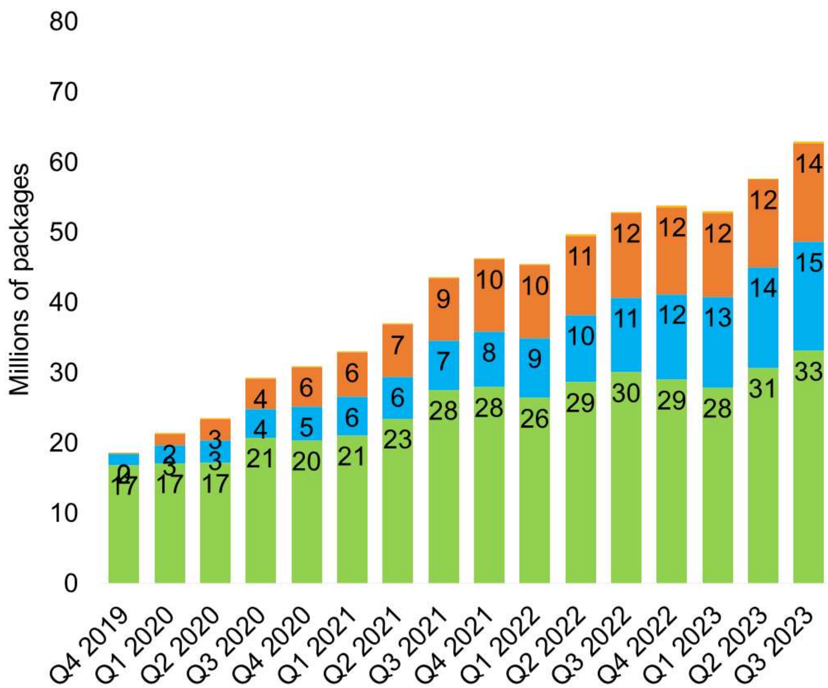
Legalization status of medical cannabis in America



Canada (I)

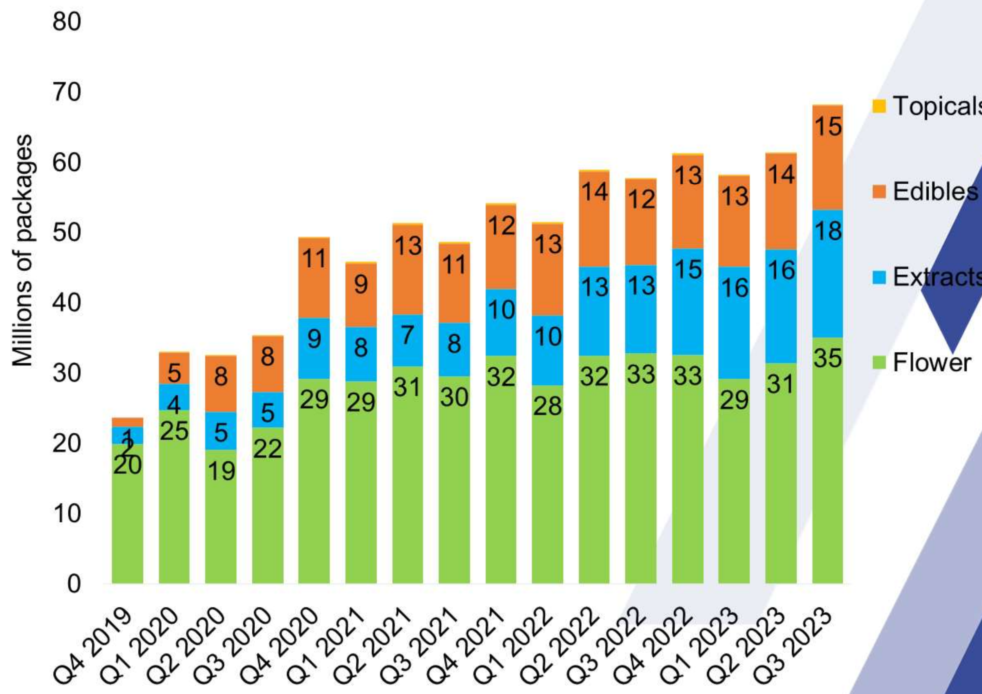
- Successive legal reforms in Canada have allowed the development of a **flourishing market** around cannabis: some patients were able to access medical cannabis on an exemption basis before, but full medical cannabis legalization was enacted in 2012, while recreational legalization was established in 2018.
- Due to being the **second country to legalize cannabis at the federal level**, Canada saw an **explosion in production capabilities** with dozens of LPs building indoors and greenhouses to supply the domestic market as well as for exportation. This led to **overproduction** and high levels of inventory, as well as facility closures and repurposing of facilities to other agricultural segments.

Legal cannabis sales in Canada (quarterly)



Source: *Health Canada.*

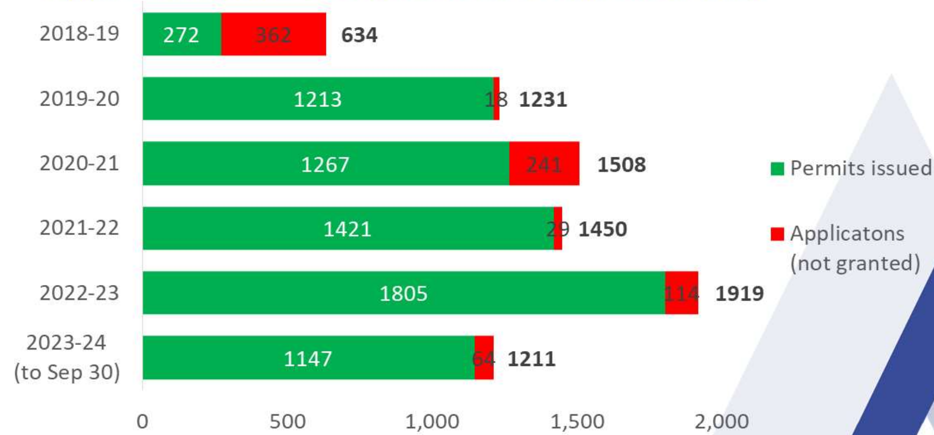
Packaged production of cannabis products in Canada (quarterly)



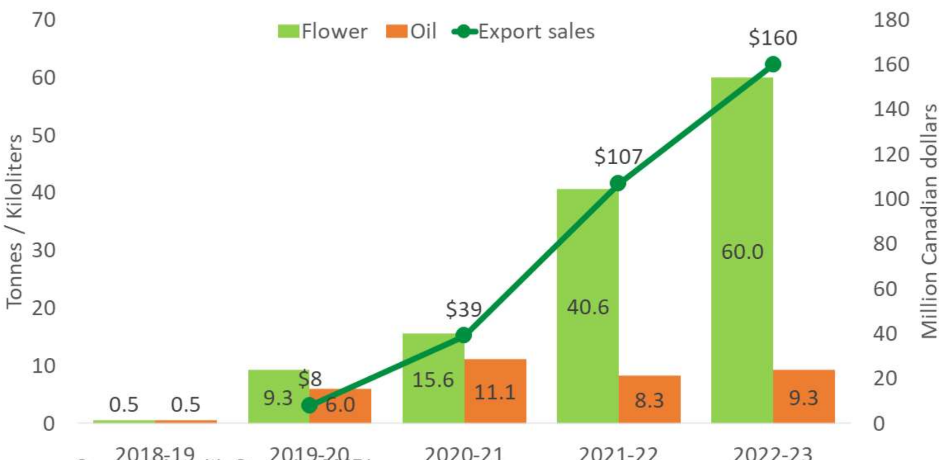
Canada (II)

- Despite a slower trend in international trade of cannabis than many predicted, Canada is today the **largest exporter of medical cannabis** in the world with a huge advantage over the next exporters.
- Health Canada recorded a **new record on Canadian export applications** of 1,919 in the 2022-23 fiscal year which also saw a 48% increase in flower sales jumping to 60 tonnes.
- This was driven primarily by the **good performance of the Australian market** which is almost entirely supplied by exports, with **26.4 tonnes of flower and 8,303 litres** of oil, followed **by Israel with 20.9 tonnes** exported and **Germany with 9.6 tonnes**. Minor quantities were exported to New Zealand, Portugal and other geographies.

Applications/permits to export medical cannabis or hemp

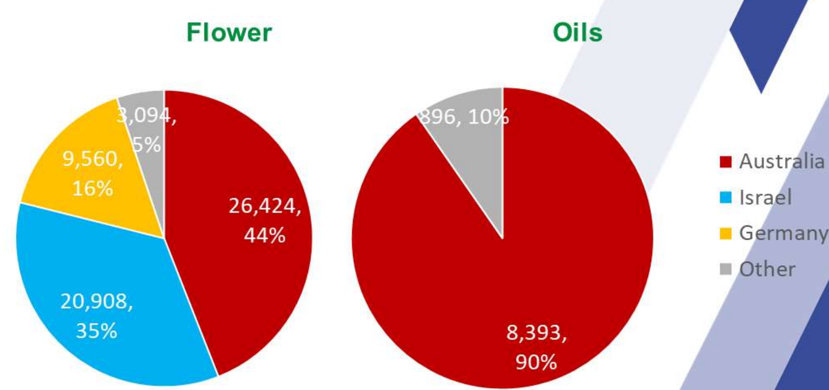


Exports of medical cannabis from Canada (fiscal years)



Source: Health Canada, MJBiz.

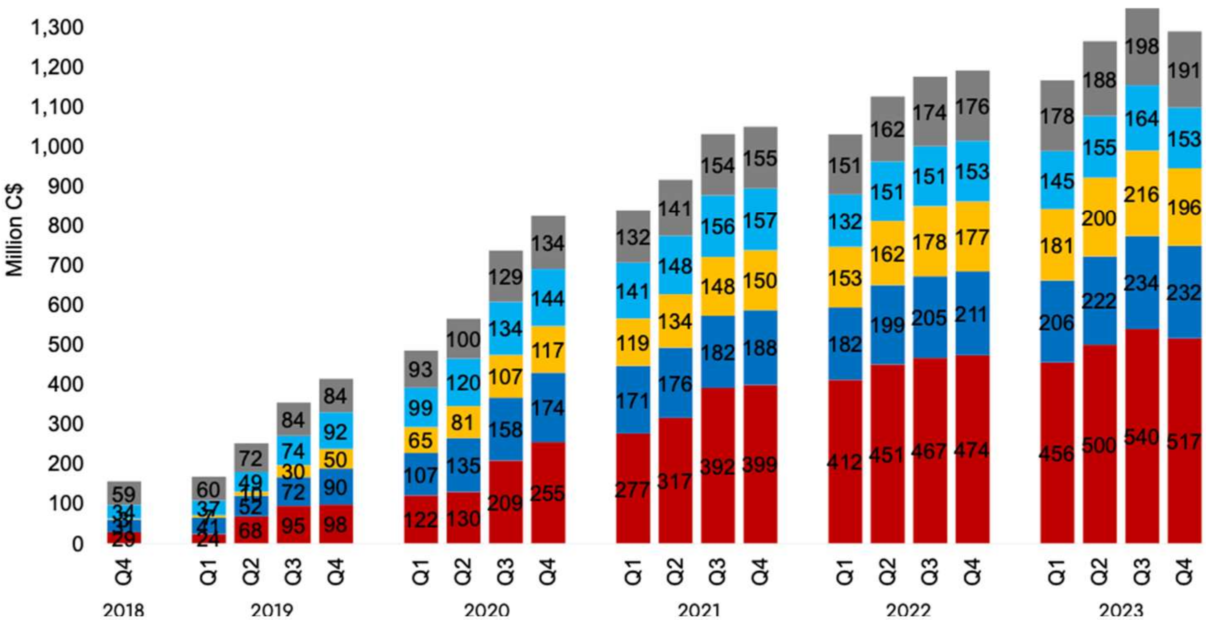
Destination of Canadian medical cannabis exports (2022-2023FY)



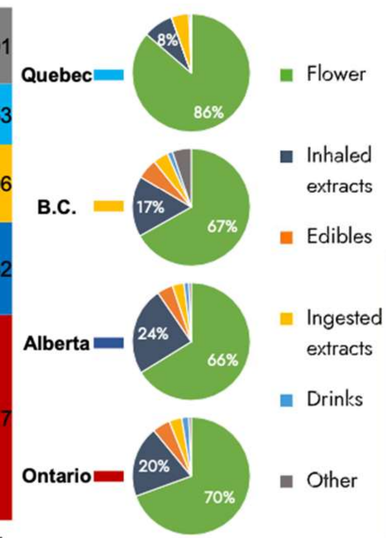
Canada (III)

- The Canadian market has kept growing throughout the 5 years since legalisation, but growth has been concentrated on traditional formats such as **flower** and innovative such as **vapes**. In recent quarters the surge of **pre-rolls** (included as flower in the stats) has reached almost 1/3 of all legal sales in the Canadian market.
- **Cannabis 2.0** products such as beverages and topicals have not managed to gain a large traction in the country 4 years after they became legally available. Strict rules on the allowed dosages of edibles have been quotes as one reason preventing their market penetration to increase.

Retail adult sales by province (quarterly) – C$M



Provincial category market share (%)

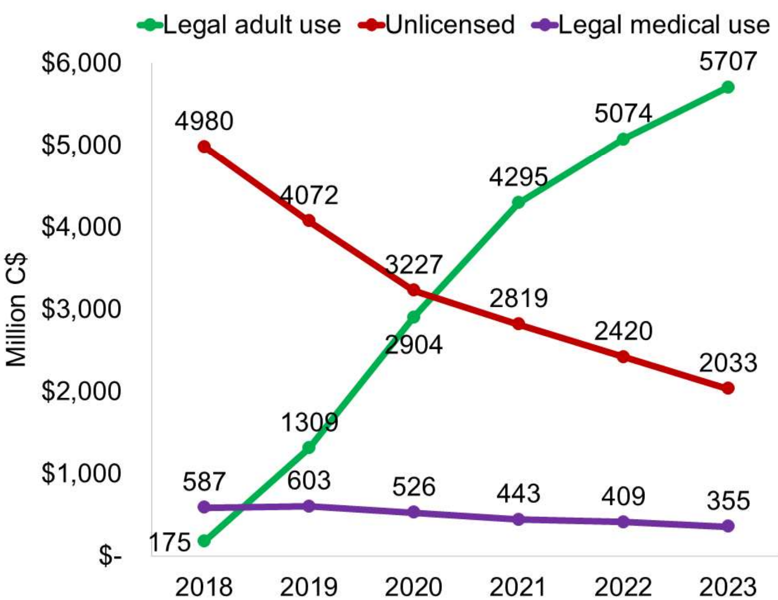


Source: Statistics Canada.

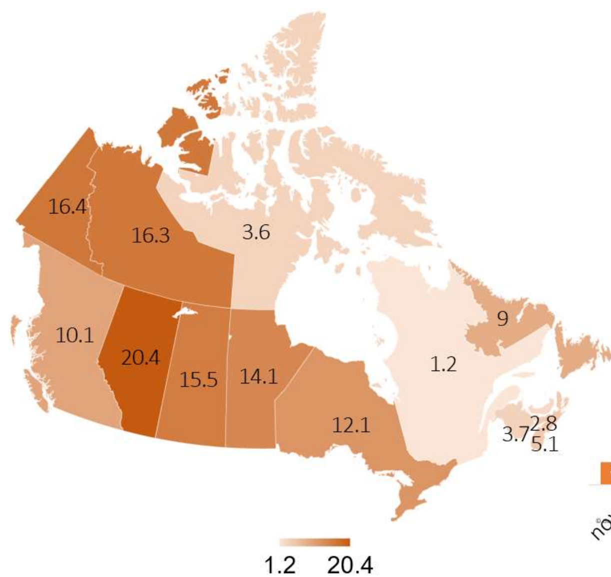
Canada (IV)

- Despite commentators pointing to the fact that the illicit market still exists in Canada, official stats show that **70% of the market is now legal**, while unlicensed sales are mostly led by friends and family and home-growing instead of criminal enterprises. This points to the success of the federal legalisation of adult-use cannabis in Canada.
- Market penetration has been highly correlated with density of retail fronts and rules on dispensary number and location awarded on a provincial basis, with great disparities being translated into lower volumes in certain provinces. There are currently over **3,000 specialized shops** selling cannabis products legally in Canada.

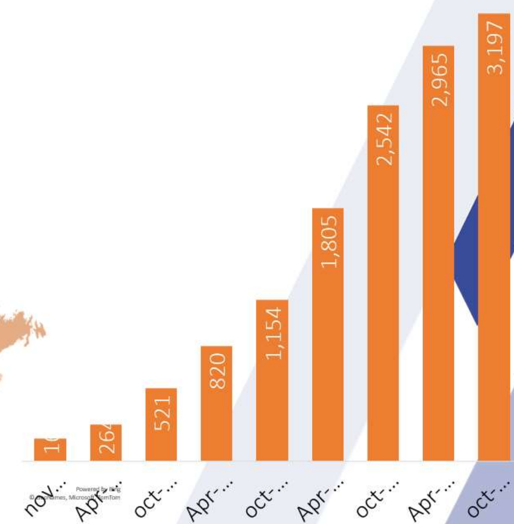
Household spending on cannabis products – C$M



Nº of stores per 100,000 population by province



Number of dispensaries over time

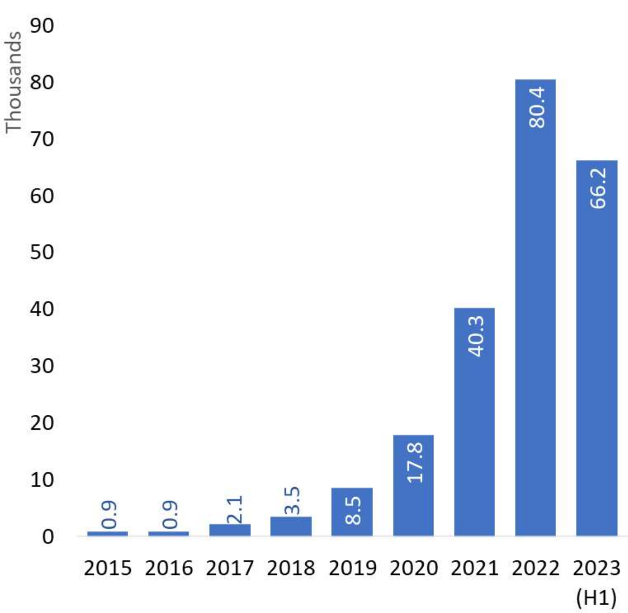


Source: Statistics Canada.

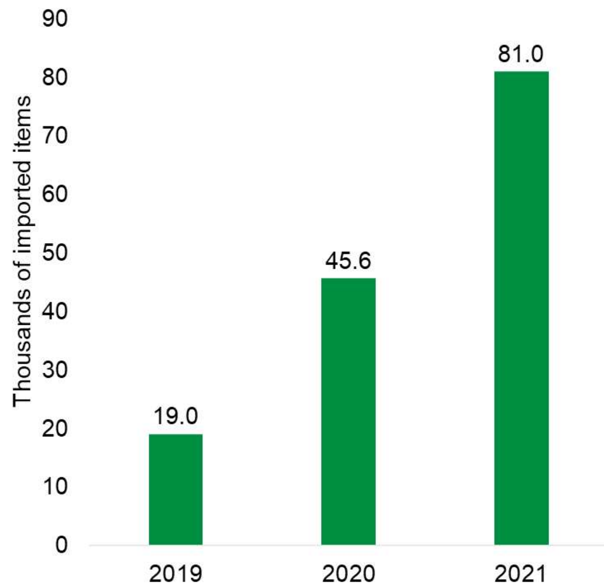
Brazil

- Cultivation of cannabis is forbidden in Brazil despite the existence of judicial exceptions allowing the private domestic cultivation for medicinal use. For this reason, the raw materials used to manufacture all the medical cannabis products accessed in the country are **imported**:
  - Patients can request a **special authorization** to medicinal regulator ANVISA to import cannabis products, which are shipped individually to a named patient. Special permits are overwhelmingly for CBD products, even though some THC authorisations exist as well. Primarily food-grade CBD oils, 87% of which come from the United States.
  - Brazilian pharmaceutical manufacturers import API to manufacture medical **products that are registered by ANVISA** to be sold at the pharmacies.
  - Additionally, patients can register in associations to jointly supply cannabis products to members. According to a study by Sao Paulo based consultancy KayaMind, there could be over **400,000 patients** accessing cannabis products in Brazil, including 114,000 doing so through associations.

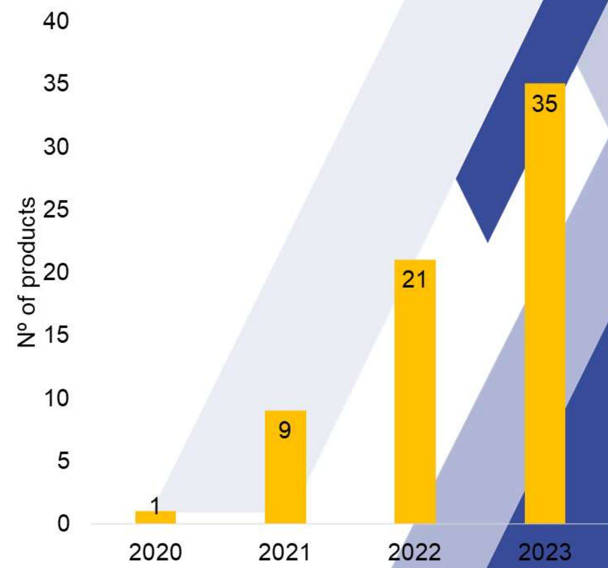
Patient authorizations to import cannabis products



Nº of imported medical cannabis items



Nº of products authorized for pharmacy sale

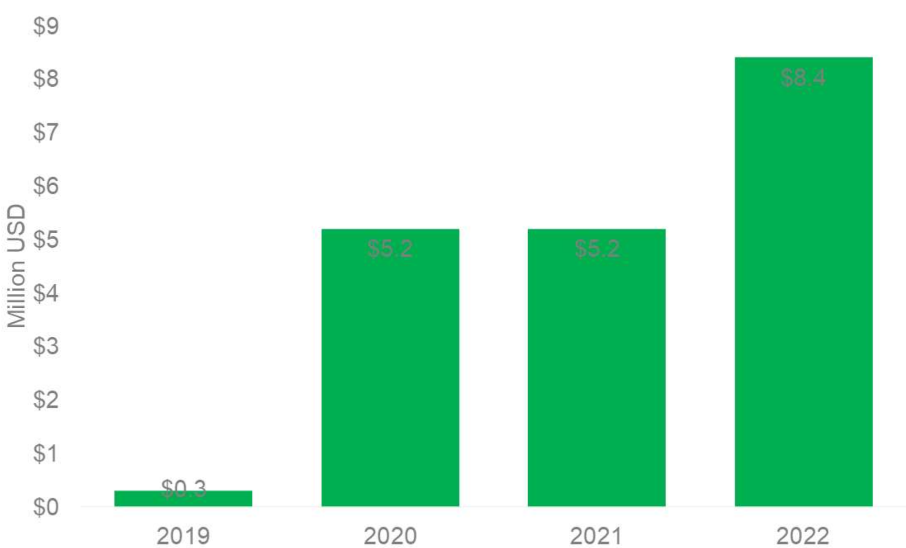


Source: ANVISA (Brazilian Health Regulatory Agency), KayaMed.

Colombia

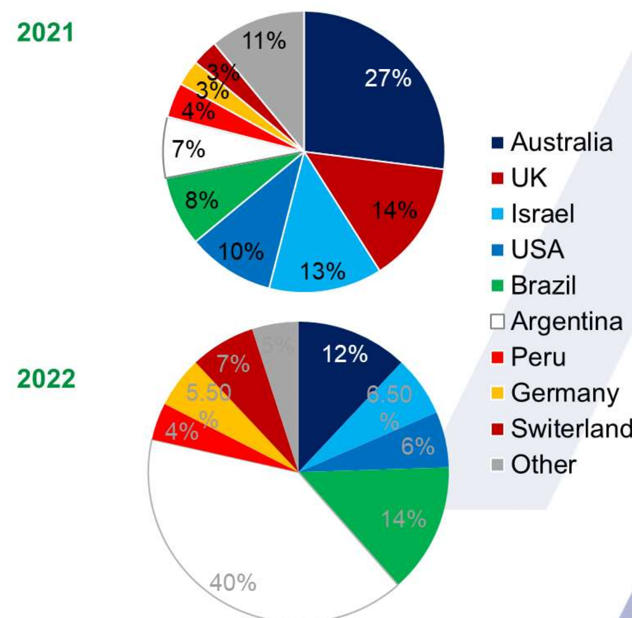
- Colombia emerged as a potential legal **cultivation powerhouse** following legalisation in 2017, which saw the development of hundreds of cultivation projects all around the country to produce both non-psychoactive and psychoactive cannabis products.
  - Many of the top Colombian cannabis producers have Canadian financial backing, including the likes of Clever Leaves and Khiron.
- Most of the exports until 2022 consisted of CBD extracts to Australia, the UK or small, developing markets in Latin America such as Argentina or Peru. The levy on the ban on exportation of flower in mid 2022 allowed Colombian exports to pick up pace, with multiple Colombian companies reporting exports of tonnes of medicinal flowers to Europe and Israel.
- In 2022 and 23 we see a shift in Colombian production to **focus on regional markets** of the likes of Brazil and Argentina instead of European or international markets.

Value of Colombian cannabis exports – U$M



Source: Dane-dian (National Directorate of Taxes and Customs), ProColombia.

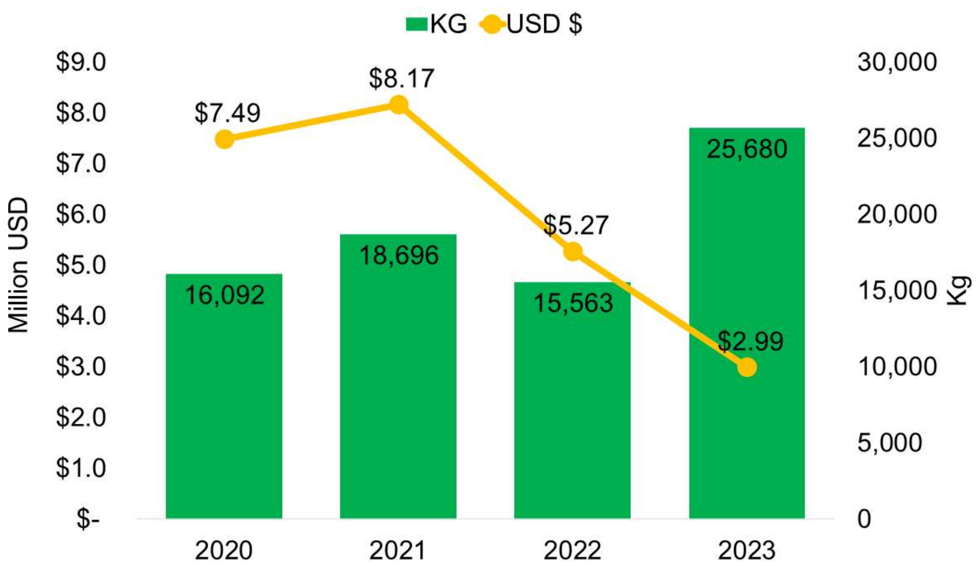
Colombian cannabis exports by destination country



Uruguay

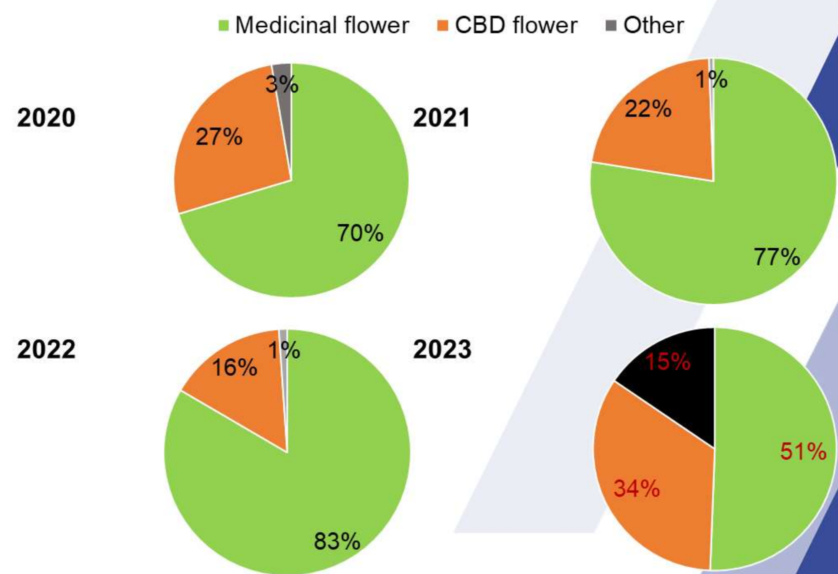
- Uruguay was the first country to **legalise recreational cannabis** in the world in 2013, with the aim of harm reduction and limiting the economic capacity of drug-trafficking mafias.
  - Users can purchase cannabis at the pharmacy grown by several licensed producers. However, many more users are registered in users' associations in the country.
  - The introduction of higher-THC varieties of about 15% during 2023 has led to a spike in pharmacy sales of recreational products that had stagnated before.
- The country has emerged as a **hub for cultivation of both hemp/CBD and medicinal cannabis** the destination of which is entirely for exportation. CBD flower is mostly exported to Switzerland as a smokable herb by companies such as C-Plant, while Fotmer Life Science is the primary exporter of medicinal cannabis in the form of flower.
- Uruguay is a minor importer of CBD raw materials from Switzerland to be used as API to produce nutraceuticals for distribution in the country.

Cannabis exports from Uruguay



Source: Uruguay XXI.

Cannabis exports from Uruguay by product format (% of USD)



APAC

MEDICAL MARKETS

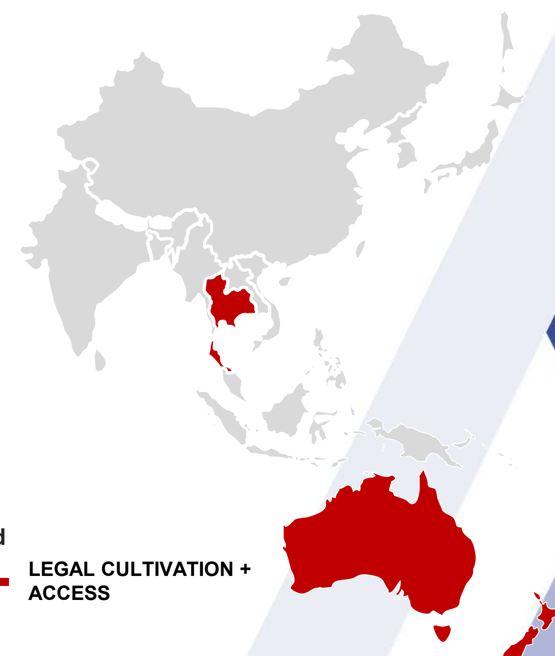
Asia-Pacific: Oceania
& East Asia

Thailand, Australia and New Zealand pave the way of reform, but most of the Asia-Pacific countries still promote stringent prohibitionist policies.

- Most Asia-Pacific countries have a **policy of zero tolerance** against cannabis, with hefty fines and prison sentences for those caught trafficking.
    - Some countries that allow the importation of CBD supplements, like **Japan**, have a legal requirement of complete absence of THC.
    - However, the traditional use of cannabis as a medicine or for religious purposes, such as aryuvedic medicine or bhang in India, is very strong and tolerated in some regions.

- Australia, New Zealand and Thailand are the only countries to have developed advanced cannabis policies by legalising medicinal cannabis:
    - **Thailand** legalised the medical and industrial uses of cannabis in 2018 and since June 2022 cannabis is not considered a narcotic, leading to an explosion of the recreational market.
    - **Australia** has allowed the access to imported cannabis products in special circumstances.
    - **New Zealand** has a small medicinal market and a referendum to legalize recreational cannabis failed to pass in 2020.
    - **South Korea** allows the marketing of pharmaceutical cannabis products like those of GW Pharma, while **Japan** announced a reform to its narcotic bill in November 2023 to allow the marketing of Epidiolex in the country, currently under a clinical trial in the East Asian nation for rare forms of epilepsy.
    - Traditional forms of medicine that use cannabis as an ingredient are still alive in South Asian regions such as Sri Lanka and certain Indian states, where it is also tolerated for religious contexts in certain festivities.

Legalization status of medical cannabis in Asia-Pacific



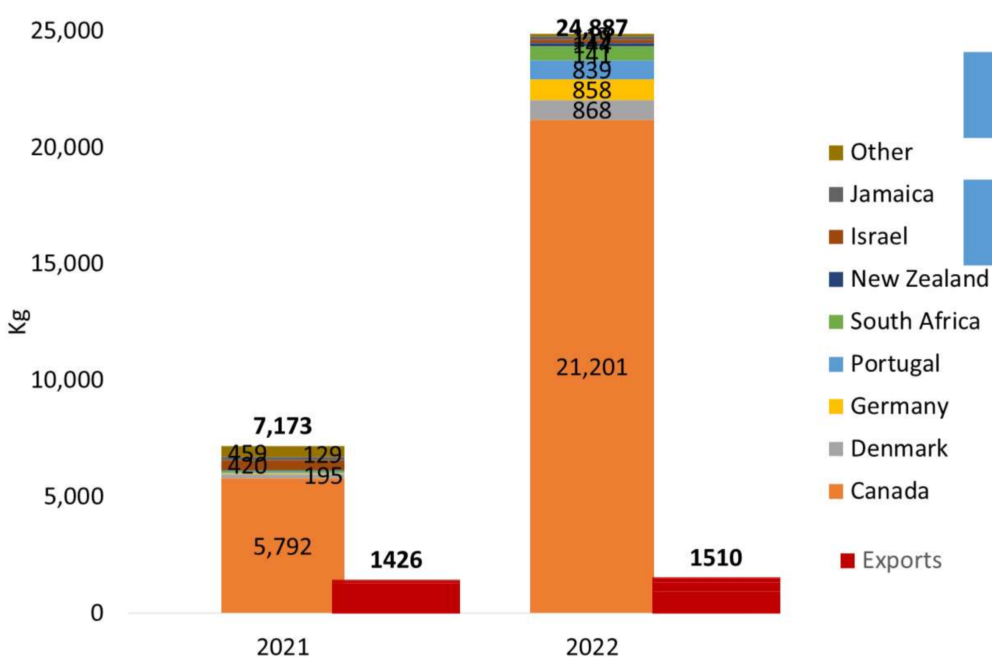
Legend

LEGAL CULTIVATION + ACCESS

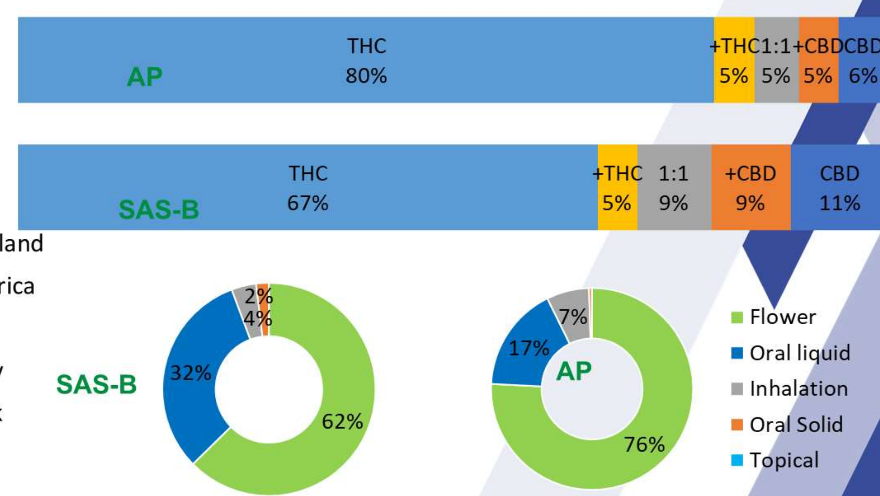
Australia (I)

- Despite the presence of dozens of licensed producers, the Australian market is a **net importer of medical cannabis**: initially through primarily extract-based products, but in the last quarters a ‘flower boom’ has been happening with importation of inflorescences (particularly from Canada) skyrocketing.
- While Australian LPs have targeted export opportunities, the balance of trade remains very **skewed towards importation**. However, Australian-produced extracts are being distributed to patients in Germany and the UK among other international medical cannabis jurisdictions.

Imports and exports of medical cannabis in Australia



Format count of patient authorizations in Australia (H1 2023)

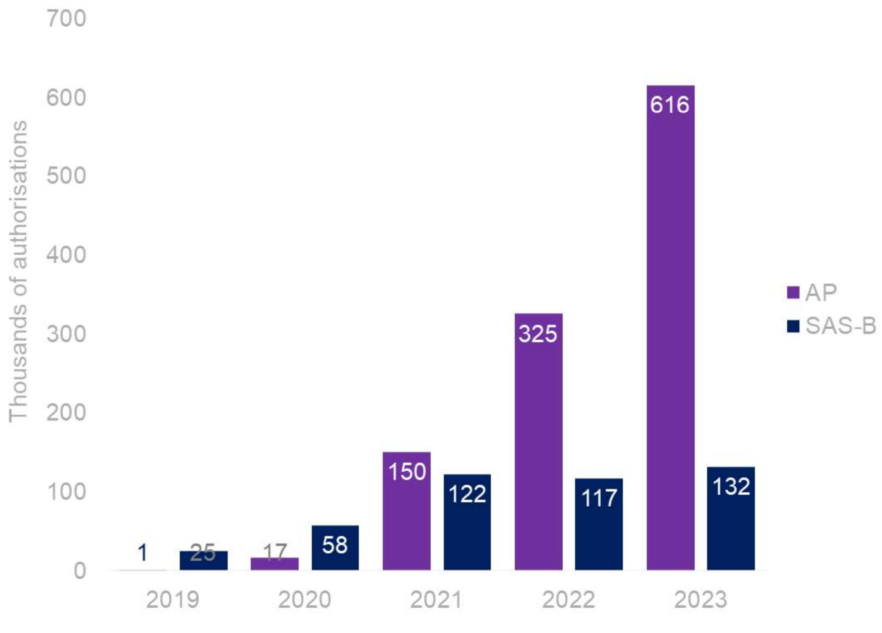


Source: Office of Drug Control, TGA (Therapeutic Goods Administration), MCIA (Medicinal Cannabis Industry Australia)

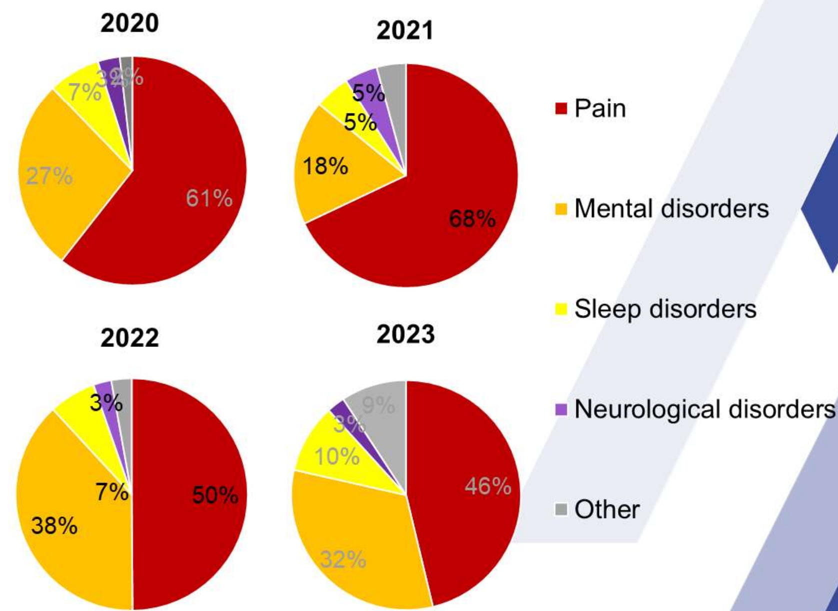
Australia (II)

- Australian patients can access unlicensed medical cannabis products under prescription through multiple regulatory pathways:
  - **SAS-B** scheme is the most popular pathway to access medical cannabis products requiring an application to be submitted.
  - Doctors in the **Authorised Prescriber (AP)** scheme can directly write prescriptions without further authorisation.
  - For seriously ill patients, **SAS-A** scheme can be used which requires only the notification of products to be accessed, but not an authorisation.
- Pain has been reducing its share as a dominant indication in the market as prescriptions particularly for anxiety have skyrocketed. Mental and sleep disorders, including PTSD, insomnia, depression or ADHD have been gaining ground.

Authorizations to access medical cannabis under SAS-B & AP schemes



Main indication of patients SAS-B approvals

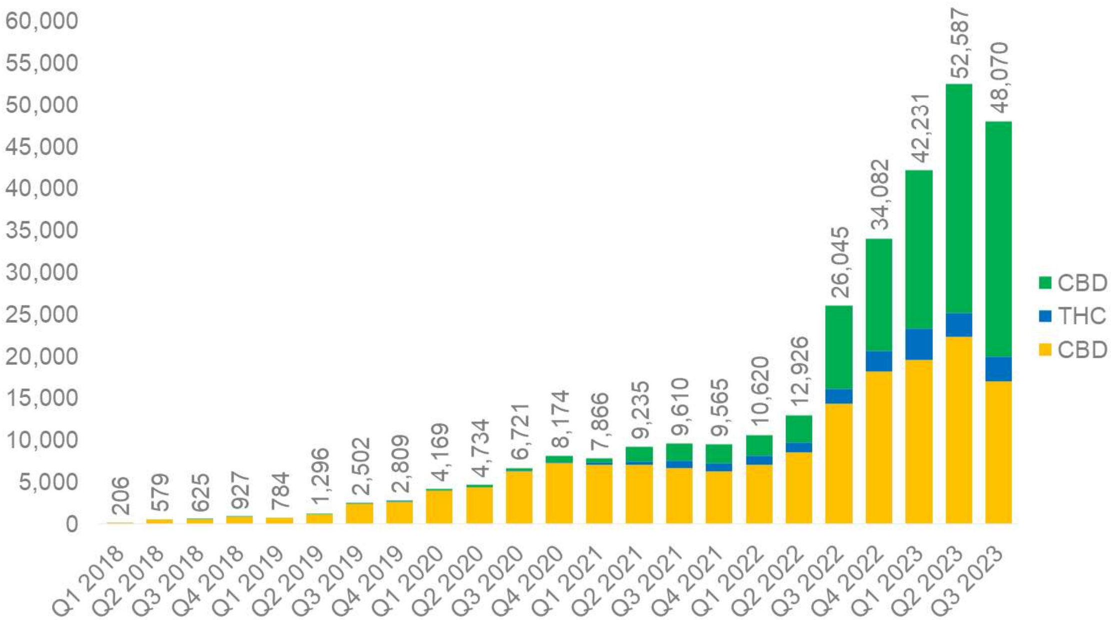


Source: TGA (Therapeutic Goods Administration).

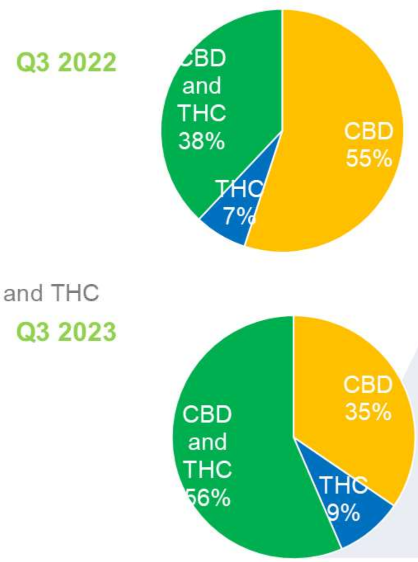
New Zealand

- New Zealand is home to a selected number of licensed producers of medical cannabis, but it also allows imports from abroad, particularly from Australia. Since the 1st of January of 2022 to 1st of November of 2023 **1.3 tonnes of cannabis flower** of adequate quality were imported into the country.
- Initially the New Zealand scheme was heavily focused on CBD products, but as of late there is a trend of higher supply of **balanced products with both THC and CBD**, which have exploded during 2023 to represent most of the market.
- A referendum on the legalisation of recreational cannabis took place in New Zealand in September 2020, marginally opposing the reform: 48.4% in favour, 50.7% against.

Nº of items supplied to patients in New Zealand



Share of dispensed medical cannabis items in New Zealand

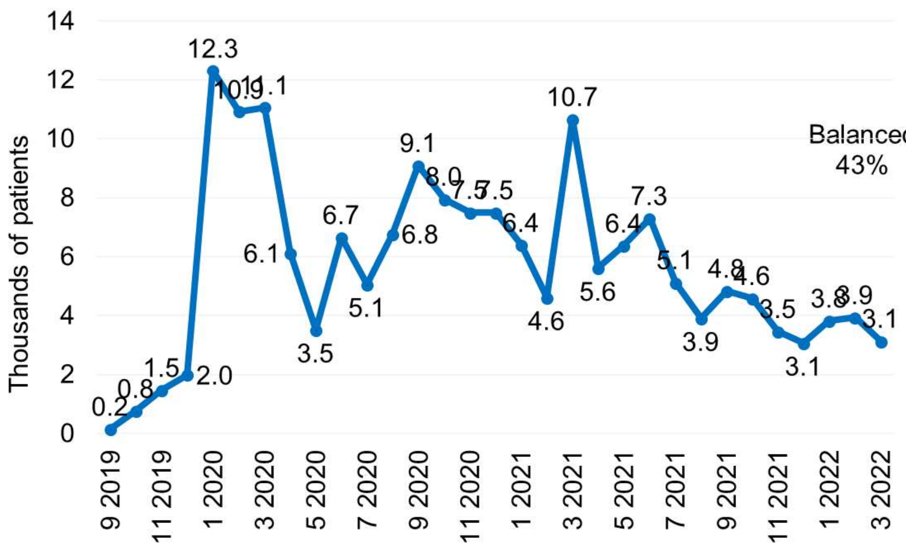


Source: MedSafe (New Zealand Medicines and Medical Devices Safety Authority)

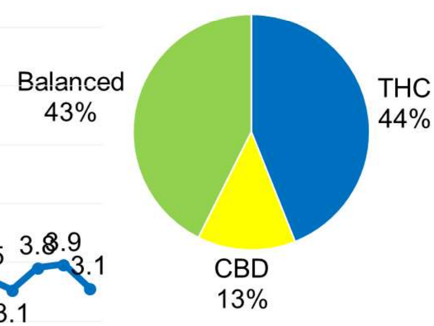
Thailand

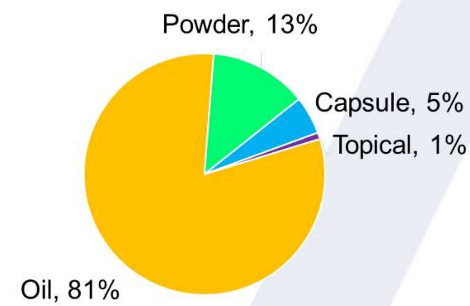
- Thailand legalised the medical and industrial uses of cannabis in 2018 and since 2019 up to 120,000 patients have been able to access cannabis products. The use of cannabis in traditional medicine is recognised by the government and a variety of traditional products (e.g. powders) are traded.
- Since June 2022 **cannabis is not considered a narcotic**, leading to an explosion of the recreational market in the country, despite the lack of regulations specifying the standards and conditions under which commercial trade can happen. It is estimated that **6,000 dispensaries** opened in the country.
- In 2023 the government announced a **rectification of its previous liberal policy**, claiming that cannabis should only be available for medicinal use. In February 2024, the Minister claimed that a bill rolling back some of the loopholes created in 2022 will be ready at the end of the year.
- However, it is uncertain to what degree the cat can be put back into the bag after the explosion in foreign investment, facilities and dispensaries of the last quarters.

Nº of patients accessing medical cannabis products in Thailand



Share of dispensed medical cannabis products in Thailand (2022)





Source: FDA Thailand (Food and Drug Administration).

Questions?