

ASX Announcement | 14 March 2024
Althea Group Holdings (ASX: AGH)

France to Legalise Medicinal Cannabis Extracts

Highlights:

- France outlines their proposal for the regulation of the medical use of cannabis-based medicines
- Althea intends to work closely with the ANSM to gain the necessary product authorisation(s) for its innovative range of softgel capsules
- In an advantage to Althea over cultivators, French authorities have confirmed their decision not to include dried flower cannabis products within the framework

14 March 2024: **Althea Group Holdings Limited (ASX:AGH) ('AGH', or 'the Company')**, a global leader in the manufacturing, sales and distribution of cannabis-based medicines and recreational cannabis products, is delighted to share pivotal developments in France's generalisation of the use of medicinal cannabis.

Recap of pilot program and Althea's participation

In 2021, Althea played a pivotal role in France's national pilot program, selected as a second source supplier of medicinal cannabis products for assessment by the French National Agency for Medicines and Health Products Safety (ANSM). This program aimed to evaluate the feasibility of legalising medicinal cannabis in France.

Althea's participation in the trial, which included approximately 3,000 patients across five treatment areas, positioned the company for a competitive advantage in the anticipated legalised French medicinal cannabis market.

Generalisation of the medical use of cannabis-based products

France's latest cannabis regulation developments conclude the medicinal cannabis experiment on March 26, 2024, and the Social Security Financing Act for 2024 provides for the generalisation of the medical use of cannabis by defining a status for cannabis-based drugs and the issuance of authorizations by the ANSM, for a period of 5 years.

This means that medicinal cannabis will be accessible to patients on medical prescription in indications defined and evaluated during the pilot scheme, according to the current prescription conditions defined in the LFSS 2024.

Reimbursement for medicinal cannabis will be available under the new regulatory framework.

Althea softgel capsules - Product Authorisation

Althea intends to work closely with the ANSM to obtain the necessary 5 year product authorisation(s) for its innovative range of full-spectrum softgel capsules, which offers a fixed-dose formulation and provides consistent dosing in a familiar and convenient format, supporting overall compliance for patients.

Each capsule of **Althea CBD3:THC2** contains 3 mg of CBD and 2.5 mg of THC. Each capsule of **Althea THC10** contains 10 mg of THC and <0.5 mg CBD. Each capsule of **Althea CBD25** contains 25 mg of CBD.

Althea's softgel capsules may be preferred by doctors for the management of chronic conditions such as pain, sleep difficulties and drug-resistant forms of epilepsy, where medicinal cannabis is most commonly prescribed.

Althea plans to obtain authorisation(s) issued by the ANSM no later than December 31, 2024.



ANSM focuses on oral formulations

The ANSM have taken the decision to only include oral formulations in their framework. In an advantage to Althea over licenced producers of cannabis (cultivators), dried flower cannabis and granules are excluded. In addition, certain products based on purified and isolated cannabinoids, whatever their origin, are also excluded.

AGH CEO and Managing Director, Joshua Fegan said: “The ANSM announcement regarding the legalisation and commercialisation of medicinal cannabis in France is excellent news for Althea and its European aspirations. It's important to note that the legislation specifies that only cannabis extracts will be permitted, excluding the supply of dried flower cannabis. France is unlikely to be the only country to exclude dried flower cannabis products under a medicinal cannabis framework. This strategic decision aligns perfectly with Althea's focus on high-quality extracts and sets the stage for our softgel capsules. With high barriers to entry for competitors in this segment, Althea is well-positioned to capitalise on this exciting opportunity.”

-ENDS-

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Althea Group Holdings Limited (ASX:AGH)

Althea Group Holdings Ltd ('AGH') is a global leader in the manufacturing, sales and distribution of cannabis-based medicines and recreational cannabis products. AGH services these sectors via two distinct business units. Althea, the company's pharmaceutical business, offers a comprehensive range of cannabis-based medicines which are made available to patients via prescription. Peak Processing Solutions, AGH's recreational cannabis business, produces legal cannabis products purchased by adult consumers in retail stores.

AGH operates in highly regulated and legal cannabis markets across the world with burgeoning operations in Europe, North America, Australia and Africa.

To learn more about Althea Group Holdings, please visit: www.altheagroupholdings.com

For more information on Peak, please visit: www.peakprocessing.com

For more information on Althea, please visit: www.althea.life

