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France reaches important milestone towards permanent legalisation of medical cannabis

STENOCARE A/S (STENOCARE) provides an update on the regulatory development of the French medical cannabis programme. The long-awaited decree governing the evaluation, pricing and reimbursement of medical cannabis products has reportedly been submitted to the French Conseil d'État. The submission represents an important milestone towards establishing a permanent French medical cannabis framework.

On 11 February 2026, STENOCARE announced that its innovative ASTRUM 10-10 oil product is being targeted for the planned permanent medical cannabis framework in France. Since then, French policymakers and authorities have continued preparing the detailed regulatory framework required for implementation.

According to information reported by French media, the remaining decree governing the evaluation, pricing and reimbursement of medical cannabis products was submitted to the French Conseil d'État on 2 July 2026. This represents an important milestone towards establishing the permanent French framework for reviewing and approving products for the treatment of patients.

The Conseil d'État is France's highest administrative court and also advises the French Government by reviewing the legal form and compliance of certain proposed laws and regulatory decrees. Its review represents one of the final legal steps before the reimbursement decree can be formally adopted and published.

The reported submission is therefore an important milestone in France's transition from its limited medical cannabis pilot programme to a permanent, nationally regulated framework.

An important part of the regulatory framework

France has established the underlying legislative basis for a permanent medical cannabis programme. The future framework is expected to involve two key regulatory processes:

- Product authorisation by the French National Agency for Medicines and Health Products Safety (ANSM)
- Evaluation of therapeutic benefit and reimbursement by the French National Authority for Health (HAS)

The reimbursement decree is important because it is expected to provide the legal framework under which HAS can formally assess medical cannabis products and make recommendations regarding their eligibility for reimbursement through the French public healthcare system.

Without this part of the framework, medical cannabis products cannot progress through the complete pathway from regulatory assessment to reimbursed patient access.

The submission to the Conseil d'État does not in itself represent final approval of the decree, nor does it mean that medical cannabis products can immediately be prescribed under the permanent programme. The decree must first

complete its legal review and subsequently be formally adopted and published together with the remaining implementing regulations.

What this means for medical cannabis companies

Once the necessary decrees and implementing orders have entered into force, companies seeking access to the French market are expected to be able to submit product-specific applications.

The regulatory pathway is expected to require companies to document, among other matters:

- Pharmaceutical quality and manufacturing compliance;
- Product composition and specifications;
- Stability and analytical data;
- Safety and benefit-risk documentation;
- Pharmacovigilance and addict vigilance systems;
- Proposed indications, dosing and patient monitoring;
- Evidence supporting therapeutic benefit and reimbursement.

Medical cannabis products will not automatically be approved simply because they are already available in other European or international markets. Each product will be subject to a French regulatory assessment, and authorisation by ANSM will not necessarily guarantee reimbursement.

Following ANSM authorisation, HAS is expected to assess the therapeutic value of each individual product and determine whether it should be recommended for reimbursement through the French public healthcare system.

Companies with advanced regulatory dossiers, documented pharmaceutical quality and established French partners are expected to be better positioned to submit their products when the application procedures formally open. STENOCARE believes that ASTRUM 10-10 is well positioned and documented for this process.

Moving closer to a permanent French market

France has conducted a national medical cannabis pilot programme since 2021. The programme has generated clinical, safety and patient-experience data relating to several serious medical conditions, including refractory neuropathic pain, treatment-resistant epilepsy, painful spasticity associated with multiple sclerosis, cancer-related symptoms and palliative care.

The future permanent framework is expected to retain a highly controlled pharmaceutical approach, with medical cannabis primarily considered for patients who have not achieved sufficient benefit from existing treatments or who experience unacceptable adverse effects.

The remaining regulatory texts will determine the precise application requirements, reimbursement process and timing for broader patient access.

Thomas Skovlund Schnegelsberg, CEO of STENOCARE, comments:

"Submission of the reimbursement decree to the Conseil d'État is an important milestone because reimbursement is essential for creating a functional and sustainable medical cannabis market in France. It indicates that the authorities are progressing with one of the final regulatory components required to move from the experimental programme towards permanent patient access.

For companies, the French opportunity will be based on pharmaceutical standards and comprehensive product-specific documentation. It will not be sufficient simply to have a product available in another country. Companies

must be able to demonstrate quality, safety, regulatory compliance and therapeutic relevance to both ANSM and HAS.

Once the regulations have been formally published, companies with advanced dossiers and strong local partnerships should be in a position to move forward with their applications. This development therefore represents an important step towards enabling qualifying medical cannabis products to be reviewed, authorised and ultimately made available to French patients."

The next expected steps

The regulatory process is expected to include:

- Completion of the Conseil d'État's legal review;
- Any amendments requested as part of that review;
- Formal publication of the reimbursement decree and related implementing texts;
- Opening of the ANSM application pathway;
- Submission and assessment of individual medical cannabis products;
- HAS evaluation of therapeutic benefit and reimbursement;
- Pricing and reimbursement decisions;
- Practical preparation for distribution and patient access.

The timing of these steps remains subject to decisions by the French authorities. Until the relevant texts have been formally published, the permanent French medical cannabis market is not yet operational.

STENOCARE continues to follow the French regulatory process closely together with its French partner and will communicate further when concrete regulatory decisions or other material developments have been formally announced.

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About STENOCARE A/S
STENOCARE A/S, founded in 2017, supplies prescription-based medical cannabis to patients in Denmark and internationally. It was the first company to receive permission from the Danish Medicines Agency to import, distribute, cultivate, and produce medical cannabis. Today, STENOCARE sources its products from a selection of high-quality international suppliers that comply with the strict European Good Manufacturing Practices (EU-GMP). STENOCARE has developed a unique patented medical cannabis oil product, ASTRUM, which provides improved bioavailability of active ingredients for patients. The company has strategically invested in assets to operate within the highly regulated pharmaceutical industry, with products approved for sale in multiple countries.
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