

ECS Botanics Holdings Ltd (ASX:ECS)



ASX Announcement

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New German GMP Guidance Reinforces ECS's Integrated Manufacturing Strategy

ECS Botanics Holdings Ltd (ASX: ECS) ("ECS" or the "Company"), a leading medicinal cannabis company, notes the publication of new Good Manufacturing Practice (GMP) guidance by Germany's Hesse State Office for Health and Care (HLfGP), which ECS believes reinforces the importance of integrated GMP-compliant medicinal cannabis manufacturing for products supplied into Germany.

ECS believes its existing integrated cultivation and GMP manufacturing platform is well aligned with the regulatory expectations outlined in the new guidance.

Highlights:

- **German regulator issues new GMP guidance clarifying expectations for medicinal cannabis supplied into Germany**
- **Guidance states the regulator is unaware of any validated process demonstrating that GACP-grown flower can be transported long distances before later GMP processing without quality loss**
- **ECS believes the guidance may increase regulatory scrutiny of fragmented supply chains relying on post-import GMP processing**
- **ECS operates an integrated cultivation and GMP manufacturing platform and recently launched OzSun in Germany through Nimbus Health, headquartered in Hesse**
- **ECS believes increasing regulatory expectations may reduce the availability of compliant supply into Germany and place upward pressure on prices for products manufactured through validated GMP post-harvest processes**

Hesse is one of Germany's largest states and home to Frankfurt, one of Europe's principal pharmaceutical distribution hubs. ECS believes guidance issued by the state's pharmaceutical regulator is likely to be closely followed by participants across the German medicinal cannabis industry.

The guidance clarifies that drying under controlled conditions is a critical manufacturing step directly affecting product quality and therefore subject to GMP requirements. It further states that these obligations apply irrespective of manufacturing standards permitted in the country of cultivation or partial manufacture.

Importantly, the guidance states: HLfGP is not aware of any validated process demonstrating that cannabis flowers cultivated under GACP conditions can be transported, stored, imported and subsequently processed over long distances without quality loss.



ECS believes the guidance reinforces increasing regulatory expectations for fully validated GMP supply chains and may increase barriers to entry for cultivators unable to demonstrate GMP compliance across critical manufacturing stages.

ECS also believes the requirement for GMP-compliant post-harvest processing may reduce the pool of supply capable of meeting German regulatory expectations. If non-integrated or fragmented supply chains are unable to demonstrate GMP compliance across drying, trimming and other critical post-harvest steps, ECS expects this may constrain compliant product availability and support stronger pricing for the higher cost GMP-manufactured medicinal cannabis flower.

This is strategically important for ECS because the Company already operates cultivation, drying, post-harvest processing, quality control and product release within an integrated pharmaceutical quality framework. ECS believes this provides greater regulatory certainty for German partners and may strengthen the Company's commercial position if compliant supply becomes more limited.

The guidance is particularly relevant to ECS as the Company recently launched its OzSun branded medicinal cannabis products in Germany through Nimbus Health and has an established commercial relationship with Ilios Santé. Both partners are headquartered in Frankfurt, Hesse, where the guidance has been issued. ECS believes its integrated cultivation and GMP manufacturing platform is well aligned with the regulatory expectations outlined by the HfGP.

Germany remains Europe's largest medicinal cannabis market, previously estimated by ECS at approximately €500 million in 2025.

ECS Botanics Managing Director, Nan-Maree Schoerie, commented:

"This guidance is significant because it goes beyond clarifying technical GMP requirements. It reinforces the expectation that medicinal cannabis supplied into regulated pharmaceutical markets should be manufactured through a validated GMP-compliant supply chain."

"ECS has invested heavily in an integrated cultivation and GMP manufacturing platform because we believe pharmaceutical quality should be established throughout the manufacturing process from harvest through to final product release. Our strategy has always been to build a platform capable of meeting the expectations of the world's most highly regulated medicinal cannabis markets."

"As we expand OzSun in Germany, we believe increasing regulatory scrutiny and higher compliance expectations will favour established GMP manufacturers with validated quality systems. If the market can no longer rely on later-stage GMP processing to address earlier non-GMP post-harvest steps, compliant supply may become more limited and pricing may better reflect the cost and value of genuine pharmaceutical-grade manufacturing."

"We believe this strengthens the strategic rationale behind the investments ECS has made in pharmaceutical manufacturing capability and supports our long-term growth ambitions in Europe."

Authorised for release by Nan-Maree Schoerie, Managing Director

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About ECS Botanics Holdings Ltd

ECS Botanics Holdings Ltd (ASX: ECS) is an Australian medicinal cannabis cultivator and manufacturer located in Northwest Victoria. ECS utilises progressive and innovative cultivation methodologies to produce quality medicine in a sustainable way, adopting regenerative and organic horticultural practices and renewable energy sources. Licenced by the Australian Therapeutic Goods Administration to manufacture GMP (equivalent to PIC/S, EU agencies are all PIC/S members) certified products, ECS has become a leading provider of high quality, affordable medicinal cannabis.