

Is Aphria Inc. Still Harbouring U.S. Expansion Ambitions?

# Description

Low-cost marijuana producer **Aphria Inc.** (TSX:APH) has chosen to use a unique set of Good Manufacturing Practices (GMP) standards in a move that could signal a different strategic focus from other Canadian licensed producers, namely **Aurora Cannabis Inc.** (TSX:ACB), **Canopy Growth Corp.** (TSX:WEED), **CanniMed Therapeutics Inc.** (TSX:CMED), and **Cronos Group Inc.** (TSXV:CRON)( <u>NASDAQ:CRON</u>), which chose to get the European Union version (E.U. GMP) of the critical quality certifications for their cannabis-production facilities.

Aphria announced on March 16 that its Ontario growing and processing facilities have received current GMP certification under United States Food and Drug Administration (USFDA) current GMP standards of CFR 21 parts 210/211 for Active Pharmaceutical Ingredients and Finished Pharmaceuticals.

Aphria became the first Canadian marijuana firm to ever get GMP certification for its operations under United States-established current GMP standards, while most other GMP-certified cannabis growers have chosen to get certified under E.U. GMPs.

### Is this a significant issue?

While GMP standards are quite similar in nature and serve the same batch-to-batch quality-assurance purpose, there isn't a universal set of the standards. The E.U. has its own sets of GMPs, North America has its own, and Australia and New Zealand have their own variations, while most developing countries apply the World Health Organisation-designed GMP equivalents.

A company has to carefully choose which quality standards to go with so as to smoothly serve its target market without any hassle from manufacturing and distribution standards inspection and approval bodies when products hit the target patient market.

In this regard, Aurora, Canopy, and other Canadian medical marijuana producers <u>have chosen E.U.</u> <u>GMP certifications</u> because they intend to export products into Europe. Any future expansion into the E.U. territory will require strict adherence to E.U. GMP standards.

On the contrary, Aphria has chosen to obtain an USFDA current GMP certification from SGS, while

concluding a takeover deal of Nuuvera Corp., a smaller marijuana industry innovator with an E.U. expansion strategy that may require product imports from Canada as raw material in its production labs.

#### **Never tried in Europe?**

While USFDA current GMPs are in no way inferior to E.U. GMPs, there are some marked differences between the standards, including the inclusion of some process specifications and guidelines that are not as specified in current GMPs.

Hence, it is not a given that Aphria's current GMP-certified product will be as acceptable as Aurora's or Canopy's E.U. GMP-certified products in Europe.

This is not to say that Aphria may not export to the E.U., but its products may have to undergo another thorough inspection by a designated *gualified person* under E.U. GMP standards before they can be accepted into an E.U. member state.

That's an additional and costly task that Aphria could easily have avoided just by receiving its certification under E.U. GMP guidelines. To my understanding, no company has tried exporting marijuana to the E.U. under the USFDA current GMP standards yet; if Aphria could manage to do that, atermark then that would be another first.

#### Investor takeaway

Aphria's choice of USFDA current GMP standards may imply that the company is not looking at Europe as a possible growth market and may still be keen on advancing a North American expansion strategy, even after recently divesting its U.S. assets after a potential delisting threat from the TSX last year for doing marijuana-related business in a jurisdiction where marijuana is not yet federally legal.

One would think that Aphria's recent acquisition of Nuuvera, which has strategic business arrangements in Europe as well as a GMP-certified manufacturing plant in Malta, would enable the company to focus on an E.U. expansion strategy, but Aphria's choice of GMP compliance standards puts a small dent on that belief, until the current GMP experiment for cannabis has proven to work in the E.U.

That said, the current GMP certification may boost Aphria's growth prospects in South America and in other jurisdictions where USFDA current GMP standards are highly regarded, as well as be a step towards Aphria applying for a federal marijuana pharmaceutical licence in the United States.

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