

TTS Pharma prepares hemp distributors for changing South African and EU cannabis regulations

15 Dec 2020 --- TTS Pharma is preparing CBD companies to adhere to new novel food regulations amid a burgeoning international hemp market.

Via a two-year supply agreement with TTS Pharma, Agribiomed Africa has introduced two CBD products into the South African market.

Meanwhile, TTS Pharma will also supply its CBD to UK-based cannabis company CiiTech, to be used in the latter's portfolio of CBD consumer brands for the UK and European markets.

From March 31, 2021 onward, all CBD finished products must align with a [novel food application](#), submitted to both the European Food Safety Authority (EFSA) and the UK's Food Standards Agency (FSA) to remain on the EU and UK market.

"Our primary European focus offers a 'switch' B2B service for those seeking a novel food compliant supply chain to ensure brand continuity or for a successful new launch as a private label," Tucker tells **NutritionInsight**.



TTS Pharma's CBD Endopure brand is supported by the UK's first novel food application.

These partnerships come hot on the heels of the European Commission (EC) allowing CBD to be qualified as food. Earlier this month, the UN also recognized the medical value of cannabis and accepted a World Health Organization recommendation to reschedule the category.

Regulatory differences in South Africa and the UK

The South African and EU markets are highly regulated, TTS Pharma highlights. There is increased pressure on hemp manufacturers to ensure that their products yield a consistent quality at every stage of development.

TTS Pharma will supply Agribiomed with its THC-free finished cannabis products from its Endopure brand under a new licensing arrangement.

In the Northern Hemisphere, CiiTech's partnership with TTS Pharma guarantees it will meet the March 2021 novel food deadline. In December 2019, TTS Pharma submitted its Novel Food dossier to the EC and established an EU-compliant supply chain.

In terms of regulatory differences in South Africa and the UK, Tucker explains that the finished product is "essentially the same." The difference lies in the legal Recommended Daily Allowance (RDA) limits: 70 mg per day in the UK and 20 mg per day in South Africa.

"This means that the labeling/package and promotional materials in South Africa all have to be adjusted to meet local South African Health Products Regulatory Agency (SAHPRA) regulations and educational materials for both the healthcare professional at the point of sale," Tucker affirms.

"Europe has clearly chosen the regulated route to market, whether that is through novel food regulations or licensed medicines. The UK and South Africa are currently

aligned with that approach, albeit with different internal criteria."

Downsides of North American regulation

CBD regulations in Europe are "significantly clearer" than the "confused and incompatible" North American market, according to Tucker.

He shares that regulation is key to a healthy, competitive hemp market. "Many countries are rejecting the [total liberalization approach](#) advocated by Canada and have recognized that the industry's attempt at self-regulation hasn't worked," says Tucker.

The entrepreneurial instinct that has created the current market now has to "give way" to the improved quality and provenance demanded by consumers in a "maturing marketplace," he continues.

"Even the US Food and Drug Administration (FDA) has delayed deregulation while it understands the underlying evidence better and adopts new analytical standards."

However, that delay comes at the price of an [established regulatory pathway](#) to legally market dietary supplements containing hemp-derived CBD in the US.

"The downside is that the delays in many individual states adopting [relaxed regulations](#) mean that [supply still vastly exceeds](#) demand in North America – much of which ends up in Europe illegally," Tucker adds.



"The OTC consumer market for food supplements will grow but consumers will want transparency in the supply chain."

"The over-the-counter (OTC) consumer market for topicals and food supplements will grow, but [consumers will want transparency](#) and quality in the supply chain just like the regulator has demanded," Tucker foretells.

"Enforcement will follow as the grace period comes to an end and those who are unprepared will fall by the wayside. This is the natural Darwinian process of any market as it grows up."

By *Anni Schleicher*

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The UK and South African hemp markets align with Europe's regulation route, varying only with different internal criteria.

Survival of the fittest

In stronger doses, the single cannabis plant holds "enormous untapped potential" for addressing myriad clinical conditions both in humans and animals.

"There is a massive lack of scientific evidence and that gap has to be filled before the benefits can be fully realized via normal, regulated pathways."

Tucker further expects highly focused groups to emerge within the hemp sector, considering "no one company could possibly hope to fulfill the many potential applications [of cannabis.]"

While the future of the hemp industry is promising, regulatory oversight will remain at its core.

