Brexit Britain becomes unlikely psychedelic haven as Albert Labs IPOs

The country is becoming an ideal place to develop psychedelic medicines

BY **TIM SMITH IN BARCELONA** 10 MARCH 2022

The UK is still working out what kind of country it wants to be since it left the EU, but there are early signs that taking the title of Europe's capital for innovation in psychedelic therapy is one option.

Canadian psychedelic medicine startup Albert Labs, which is today listing on the Canadian Securities Exchange, plans to conduct its clinical trials in Manchester and the surrounding area.

The company is developing a psilocybin (the psychoactive compound in so-called magic mushrooms) treatment for cancer patients with depression and anxiety — a group who can't take traditional antidepressants due to being on other cancer medications. The IPO money will also be used to develop a psilocybin production facility in Cheshire.

Albert Labs and other startups working on psychedelic-assisted therapies are trying to prove that these mind-altering substances are safe and effective drugs that should be available on prescription, in combination with psychotherapy.

"World leading"

The clinical trials process is a long and expensive one, but the UK is increasingly looking like an ideal place to conduct such research, says Albert Labs' chief medical officer Dr Malcolm Barratt-Johnson.

"It's world-leading in the innovative drug development sector. There are no other regulators doing this," he says.

Barratt-Johnson is referring to a new drug licensing process in the UK, the Innovative Licensing and Access Pathway (ILAP), which is part of a wider plan from the government to make the country "one of the best places in the world to conduct fast, efficient and cutting-edge clinical research".

What ILAP does, according to Barratt-Johnson, is give drug developers a constant feedback loop from the UK's Medicines and Healthcare products Regulatory Agency (MHRA), the government body responsible for ensuring drugs are safe.

It also gives developers a direct communication channel with the UK's National Institute for Health and Care Excellence (NICE), the body that controls which drugs are suitable and affordable for use in the NHS.

While this might not sound particularly groundbreaking, Barratt-Johnson says it marks a big

"Without the MHRA and without Brexit, I think we would have been several months behind on our side," he says.

And it's not the only psychedelic therapy startup looking to benefit from the new fast-tracked drug application process. London-based Small Pharma, a company developing a psychedelic-assisted therapy for major depressive disorder, was granted an ILAP just five months after the system was launched.

The company's chief medical officer Dr Carol Routledge said that the designation marked "an important step forward towards an accelerated drug approval pathway" for bringing the company's therapy to market.

Taking back control

The new, streamlined ILAP system is a direct result of Brexit. The UK used to benefit from the fact that the European Medicines Agency (EMA), the centralised body for approving drug licences in Europe, was based in London.

This meant that much of Europe's pharmaceutical science went through Britain. When the country left the EU, it lost its status as the natural home of clinical research on the continent.

"When it was announced that Brexit was coming in, it was a shock not just to the government. It was a shock to the MHRA," says Barratt-Johnson. "The UK was — I hate to say it — forced into doing something a little bit radical."

This isn't the only sign of the UK's desire to speed up clinical research. Barratt-Johnson believes that the development of psychedelic drugs for clinical use will benefit from the general approach the country took in fast-tracking the approval of the AstraZeneca-Oxford Covid-19 vaccine.

The vaccine development programme made use of what is called "real world evidence" to speed up the development and licensing process. What this essentially means is giving a drug to either patients or individuals in a general population prior to its approval.

In the case of the Covid-19 vaccine, the vaccine was provided to groups of individuals in the general population.

"You saw the criticism they got from the Germans. They said, 'How can the MHRA make decisions so quickly, using real-world evidence?'," says Barratt-Johnson. "This willingness by the MHRA to make decisions rapidly and pragmatically, based on the use of real-world evidence, is a huge bonus for both the MHRA and UK-based clinical development "

Albert Labs says it is now benefitting from the MHRA's new guidance as it is able to use "extended data sources" for review and assessment by regulatory authorities.

This is partly due to the fact that psilocybin has been used widely in society (even if, at times, illegally) for centuries, and that it's been studied in an academic context by institutions like Imperial College.

"Psilocybin has been used for a very long time," says Barratt-Johnson. "The safety profile is good."

Albert Labs says that the use of real-world data streamlines the clinical trial route to drug approval, allowing a faster route to testing new treatments in patient groups that would benefit from them.

Brexit boons

approved in the UK rather than going through the EMA and getting access to 27 EU member states.

In October 2020 the MHRA joined the Access Consortium, a coalition of regulators which includes Australia, Canada, Singapore and Switzerland.

This means that getting a drug licensed in the UK will lead to easy approval in those countries too. And while four countries is less than 27, Barratt-Johnson says that wider geographic reach helps drug developers access global markets.

"It means we've got both hemispheres covered and makes it much easier to transfer from Australia into southeast Asia. It makes it much easier to get from Canada into the United States," he says.

This access to the global market was one of the central promises of the Brexit campaign: that Britain would become a swash-buckling beacon of international trade and science, unshackled from European red tape and regulation.

UK prime minister Boris Johnson has also said he'll consider calls to move psilocybin from a schedule 1 drug to schedule 2, which campaigners say would speed up clinical trials even more.

The move seems somewhat out of step with the government's plans to crack down on "lifestyle" drug use, bucking the trend of decriminalisation elsewhere in Europe.

But for all the mixed messages, psychedelic entrepreneurs aren't complaining about Britain's new, streamlined drug approval process. If Albert Labs' psilocybin-assisted treatment is shown to be safe and effective, neither will patients.

Tim Smith is Sifted's Iberia correspondent. He tweets from @timmpsmith

Join the conversation

Start the discussion...

Subscribe

Please follow us