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EU drugs regulator addresses challenges in psychedelic-assisted therapies

Scientific data “looks promising,” says the chief medical officer, but it needs to measure up to regulatory scrutiny.

The EMA is meeting regularly with the Psychedelic Access and Research European Alliance | Lex Van Lieshout/EFE via EPA

by **Helen Collis** · 5 HOURS AGO · 4 MINUTES READ

The European Medicines Agency is leaning into psychedelics.

“I’m excited by what we’ve seen so far in scientific literature. This looks promising,” the regulator’s Chief Medical Officer Steffen Thirstrup told POLITICO in interview.

Psychedelic-assisted therapies such as psilocybin, the chemical that gives magic mushrooms their hallucinogenic properties, and MDMA, also found in ecstasy tablets, are being tested in several hard-to-treat mental health disorders, including post-traumatic stress disorder (PSTD) and treatment-resistant depression.

And so far, the data, as Thirstrup says, look promising. From its Phase 2B study results, released last month, mental health care company COMPASS Pathways reported that 30 percent of patients with depression were in remission three weeks after treatment with a combination of synthetic psilocybin and psychotherapy, and 20 percent at week 12. These were patients among whom several previous treatments had failed.

For MDMA, which is not a psychedelic per se but a kind of neural stimulant, the Multidisciplinary Association for Psychedelic Studies (MAPS) reported in May last year that 67 percent of participants who received three MDMA-assisted therapy sessions no longer qualified for a PTSD diagnosis 18 weeks after treatment, compared with 32 percent who received a placebo.

In both cases, these types of therapies are delivering a ray of hope in a field in which it is notoriously hard to show a step change from existing therapies and standard of care.

“There is an unmet medical need,” said Thirstrup. “Depression is a big issue and treatment-resistant depression is causing first of all a lot of suffering, but it also costs a lot of money for society,” he said, pointing out that many patients are in midlife and of working age, but unable to work.

But while the scientific results are intriguing, there is a need to scrutinize the data through a regulatory lens, he said. And here, developers are likely to need the EMA’s help.

To this end, the EMA is meeting regularly with the Psychedelic Access and Research European Alliance, PAREA, to keep up to speed on these therapies’ developments and

to help to prepare developers for the regulatory task ahead. The regulator also meets with the European College of Neuropsychopharmacologists (ECNP) on the topic.

In addition, the EMA has been talking to “at least a good handful of developers since 2019,” said Thirstrup, “and some of them have gotten scientific advice from us into different areas.”

But the EMA wants to reach a wider scientific audience, especially since, to date, the work to clinically test psychedelic-assisted therapies has been carried out by academia and small companies, pointed out the CMO, who are less likely to be aware of the regulatory requirements.

So, the regulator is penning a paper to be published in a scientific journal later next spring. The paper will explore the regulatory challenges of developing psychedelic-assisted therapies, such as how to carry out placebo-controlled trials.

One suggestion is to use “an old antihistamine that makes people a little bit sleepy and dizzy, so they get an effect, which of course is not psychedelic, but it’s at least a CNS effect,” said Thirstrup.

Other challenges include how best to design the clinical trial, including how to identify a placebo response, “because we know for depression … the placebo response is enormous, it’s very large,” he said.

Regulators will also want to know that the effect they are seeing is “an effect of psychedelic” and not just from the psychotherapy that is required alongside the treatment.

These are the sorts of questions that payers will also ask, he said.

Another hurdle for payers, he said, is that these psychedelics have a very long half-life, so patients will require a hospital bed for the night, and “from a health care perspective, that could end up being expensive.”

While some companies are looking into shortening the duration of effect of their psychedelic chemicals, the other option is to consider early on “how can we generate data that demonstrates the benefits in terms of health care utilization, because we’re talking about maybe diseases that otherwise are very costly to treat from a societal perspective,” he added.