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Withdrawal of application for the marketing authorisation of Cinainu (extracts from *Allium cepa* (onion) fresh bulb and *Citrus limon* (lemon) fresh fruit, *Paullinia cupana* (guarana) seed, and *Theobroma cacao* (cocoa) seed)

Legacy Healthcare (France) S.A.S. withdrew its application for a marketing authorisation of Cinainu for the treatment of alopecia areata (hair loss) in children.

The company withdrew the application on 26 February 2025 during a re-examination.

What is Cinainu and what was it intended to be used for?

Cinainu was developed as a herbal medicine for treating moderate-to-severe alopecia areata in children from 2 to 17 years of age.

Alopecia areata is a condition in which the body's immune system attacks hair follicles in skin, causing hair loss on the scalp or other parts of the body.

Cinainu contains as its active substance extracts from onion, lemon, guarana and cocoa and was to be available as a solution to be applied on the skin.

How does Cinainu work?

The way Cinainu works is not clear. It was suggested that the medicine could reduce cell death and inflammation in the scalp and influence different phases of the hair growth cycle.

What did the company present to support its application?

The company presented results of a main study in 107 children from 2 to 17 years of age who had moderate-to-severe alopecia areata affecting between 25% and 95% of the scalp. The participants had twice daily sprays of Cinainu or a placebo (dummy treatment) for 24 weeks.

The study looked for improvements in the SALT score, a standard rating score for alopecia that ranges from 0, meaning no hair loss, to 100, meaning complete hair loss.

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How far into the evaluation was the application when it was withdrawn?

The initial evaluation finished in November 2024 and the European Medicines Agency recommended refusing marketing authorisation. The company then requested a re-examination of the Agency's recommendation, but it withdrew the application before this re-examination had finished.

What did the Agency recommend at that time?

Based on the review of the data and the company's response to the Agency's questions, the Agency had recommended refusing marketing authorisation for Cinainu for the treatment of alopecia areata (hair loss) in children.

The Agency's human medicines committee (CHMP) noted that the company had not shown conclusively that the medicine used in the main study was comparable to the medicine it intended to place on the market.

In addition, the results of the main study did not show that the medicine was effective in treating moderate-to-severe alopecia areata. There were also others concerns about the study, including the fact that a relatively small proportion of participants were included in the final analysis presented to the Agency.

As the medicine was for long-term use, the Committee was also concerned that the company had not provided sufficient safety data from laboratory studies, such as toxicity studies. Finally, there were problems related to quality control and stability of the medicine and the risk of impurities.

Therefore, the Agency's opinion was that the benefits of Cinainu did not outweigh its risks and it recommended refusing marketing authorisation.

Following a request from the company for Cinainu, the CHMP re-examined the available data and also sought the advice of a group of experts who were asked to address several questions about the quality of the product, its effectiveness and safety. At the time of the withdrawal, the Committee's concerns had not been resolved by the applicant.

What were the reasons given by the company for withdrawing the application?

The reasons given by the company are available in the withdrawal letter on EMA's website.

Does this withdrawal affect patients in clinical trials or compassionate use programmes?

The company informed the Agency that there are no consequences for patients in clinical trials or in compassionate use programmes using Cinainu.

If you are in a clinical trial or compassionate use programme and need more information about your treatment, speak with your clinical trial doctor.