



26 February 2025

To : EMA Executive Director
CHMP Chair
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam, The Netherlands

Ref: CINAINU cutaneous solution
Centralized Marketing Authorization Application - Withdrawal
Submission sequence number: [REDACTED]
Reference number: EMEA/H/C/0004155/0000

Dear EMA Executive Director, Dear CHMP Chair,

Legacy Healthcare (France) SAS, the Applicant, hereby notifies the EMA of the withdrawal of the Marketing Authorization Application (MAA) of CINAINU cutaneous solution. CINAINU is composed of extracts from four plants (onion, lemon, guarana, cocoa) and was proposed for the treatment of moderate to severe alopecia areata in children and adolescents.

On November 14, 2024, the CHMP issued a negative opinion on Cinainu MAA. The CHMP clinical and non-clinical grounds for refusal are in direct contradiction with the EMA-approved Paediatric Investigation Plan (PIP) for Cinainu and the positive opinion from the EMA Paediatric Committee (PDCO) confirming compliance with the agreed PIP. Furthermore, despite the CHMP raising quality-related concerns, the Committee on Herbal Medicinal Products (HMPC), EMA's designated expert body for herbal medicinal products, was never consulted during the CHMP assessment procedure.

Additionally, new analysis and associated data submitted during re-examination were not evaluated on the basis of an unadopted procedural advice, and the ad-hoc expert group convened for CINAINU was not provided with essential regulatory documents, including the PIP, PDCO opinion, and key quality dossier elements (eCTD Modules 2.3 & 3). Thus, the Applicant has made the decision to withdraw the application and requests at this point of time from EMA the retraction of CHMP opinion and forthcoming EPAR.

We consent for this letter to be published on EMA website.

Yours sincerely,

[REDACTED], CEO
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Legacy Healthcare (France) SAS
27 avenue de l'Opéra
75001 Paris | France



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SCIENCE MEDICINES HEALTH

EMA's statement with regards to the applicant's withdrawal letter dated 26 February 2025

EMA does not accept the purported procedural issues and inconsistencies that the applicant alleged to have occurred during the regulatory assessment procedure for Cinainu and has responded accordingly to the applicant addressing said allegations.

