



4 April 2022

[REDACTED]  
European Medicines Agency  
Domenico Scarlattilaan 6  
1083 HS Amsterdam  
The Netherlands  
31 March 2022

**Subject: Withdrawal of Neffy 1 mg adrenaline nasal spray EMEA/H/C/005584**

[REDACTED]  
I would like to inform you that, at this point of time, ARS Pharmaceuticals IRL, Limited has taken the decision to withdraw the application for Marketing Authorisation of Neffy 1 mg adrenaline nasal spray, which is intended to be used for the emergency treatment of allergic reactions, including anaphylaxis

This withdrawal is based on the CHMP requests for additional information and the need to generate additional data in response to Day 120 questions. We consider that the points raised by CHMP can be adequately addressed, and we will include the additional data in a new Marketing Authorization Application.

The withdrawal of this application is without prejudice to future applications and we will be submitting a new application for Marketing Authorisation as soon as is possible.

The withdrawal of this application has no impact on ongoing clinical trials.

ARS Pharmaceuticals IRL would like to sincerely thank the (Co-)Rapporteurs, EMEA, PRAC and the CHMP members for the time and support given in reviewing the application.

I agree for this letter to be published on the EMEA website.



Please feel free to contact the undersigned [REDACTED]  
[REDACTED] if you have any questions or comments concerning  
this submission.

Sincerely,

[REDACTED]