

25<sup>th</sup> April 2018

[REDACTED]  
European Medicines Agency  
30 Churchill Place  
Canary Wharf  
London  
E14 5EU  
United Kingdom

**Subject:** Withdrawal of RESTAYSIS (ciclosporin) 0.5 mg/mL eye drops emulsion in single-dose container;  
EMA product reference: **EMEA/H/C/004229**

Dear [REDACTED]

I would like to inform you that, at this point of time, Allergan Pharmaceuticals International Limited has taken the decision to withdraw the application for Marketing Authorisation of RESTAYSIS (ciclosporin) 0.5 mg/mL eye drops emulsion in single-dose container, which was intended to be used for:

- Treatment of moderate dry eye disease in adult patients which is inadequately controlled despite treatment with tear substitutes or ocular lubricants.

This withdrawal is based on the following reason:

- Allergan Pharmaceuticals International Limited has taken this decision based on the CHMP's view that the data provided do not allow the committee to conclude on a positive benefit risk balance for the proposed indication.

Allergan Pharmaceuticals International Limited maintains that there is an unmet medical need in patients with moderate dry eye disease, that can be safely and effectively treated with RESTAYSIS, but acknowledges the CHMP's need to be provided with additional efficacy data for marketing authorisation approval in this population.

It is not expected that this withdrawal will have any consequences on ongoing clinical trials and compassionate use programmes.

Allergan Pharmaceuticals International Limited would like to sincerely thank the (Co) Rapporteurs, EMA, PRAC and the CHMP for their time dedicated to reviewing this application and the valuable support and helpful guidance providing during the review process.

**Allergan Limited**  
Marlow International  
Parkway  
Marlow,  
Buckinghamshire  
SL7 1YL  
UK

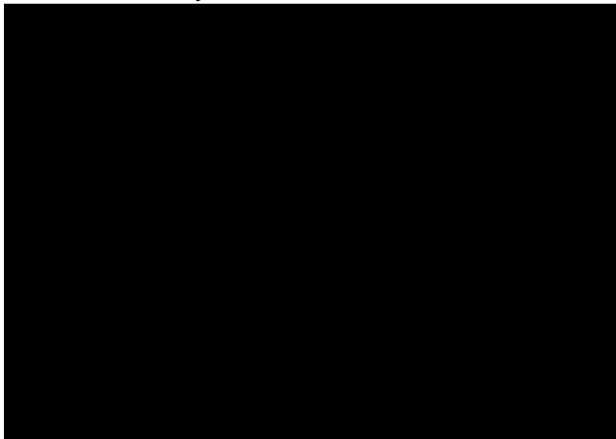
[REDACTED]  
[www.allergan.com](http://www.allergan.com)



Allergan Pharmaceuticals International Limited reserves the right to make further submissions at a future date in this or other therapeutic indication(s).

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

Yours sincerely



**On behalf of Allergan Pharmaceuticals International Limited**

**Allergan Limited**  
Marlow International  
Parkway  
Marlow,  
Buckinghamshire  
SL7 1YL  
UK

  
[www.allergan.com](http://www.allergan.com)

Registered No. 1049760 England. VAT No. GB 997 3461 63 Registered Office: As above