Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Response document for MHRA public consultation on the proposal to make Nasonex Allergy Control available in Pharmacies
Ref: ARM92

Your details

Name: [redacted]

Position (if applicable): Professional Support Pharmacist

Organisation (if applicable): Royal Pharmaceutical Society

Email: [redacted]

1. Do you consider that Nasonex Allergy Control should be available as a Pharmacy medicine?

Yes ☑ No ☐ Not sure ☐

Please provide any comments or evidence to support your response:

The Royal Pharmaceutical Society supports the reclassification of Nasonex Allergy Control from POM to P. Pharmacists are experts in medicines, and have the necessary skills and training to ensure the safe and efficient supply of pharmacy medicines.

2. Do you have any specific comments on the leaflet or the label provided in the public reclassification report for Nasonex Allergy Control?

The patient information leaflet includes the following statements in section 2 – What you need to know before you use Nasonex Allergy Control:

- 'While you are you using Nasonex Allergy Control, talk to your doctor -if your immune system…..'
- 'Talk to your doctor before using Naxonex Allergy Control if you are pregnant, trying to become pregnant or are breastfeeding.'

We would suggest that both of the above sections should include an option of speaking to their pharmacist. The pharmacist could re-assess or assess the patient in these situations, perhaps suggest an alternative therapy or if appropriate refer them to the doctor. This may help reduce unnecessary doctor referrals.

3. Do you have any other comments on the reclassification?

We agree that this product should be classified as a Pharmacy medicine to ensure that it is sold under the supervision of a pharmacist to support patients to assess the suitability of this product for them and that patients receive advice on the correct use and nasal spray technique; as well as providing patients with an opportunity to speak to a healthcare professional about their symptoms.

Section 3 (proposal to make Nasonex Allergy Control available as a pharmacy medicine) of the public consultation document lists that the maximum pack size is 9000mcg (which we understand to be 180 sprays), this does not correlate to the packaging you have included in Annex 1, which lists 60 sprays.

4. The MHRA may publish consultation responses. Do you want your response to remain confidential?

Yes ☐ Partially* ☐ No ☑

*If partially, please indicate which parts you wish to remain confidential. In line with the Freedom of Information Act 2000, if we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. Responses to consultation will not normally be released under FOI until the regulatory process is complete.

Responses can be continued onto a separate page if required. This form should be returned by email (reclassification@mhra.gsi.gov.uk) to arrive by **12 December 2016.** Contributions received after that date cannot be included in the exercise.