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): Freelance Regulatory Consultant

Organisation (if applicable): [Semi-Retired]

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 SmPC states that only limited data and inconclusive results were obtained from the few pediatric studies. Presumably this is why the proposed label limits use to patients over 18 years of age, but the Wikipedia entry for Mometasone Furoate states that Nasonex is approved for allergic rhinitis in children over 2 years old. https://en.wikipedia.org/wiki/Mometasone_furoate Reference 10

The same Wikipedia entry also states that mometasone is more potent (as a corticosteroid) than hydrocortisone.

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

The proposed label states 'do not use under 18 years of age'.
Would the dispensing pharmacy have responsibility for ensuring that Nasonex Allergy Control is not made available to children and adolescents under 18 years of age?
Would this pharmacy control function need to be documented and monitored?

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

Additional pediatric studies are probably needed to clear up the ambiguities for pediatric indications and to identify any target sub-adult population(s) before granting POM to P approval for Nasonex Allergy Control.

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.