



Abiodun Aderogba,
MHRA
Reclassification Unit
Room 3-M
151 Buckingham Palace Road,
London,
SW1W 9SZ

17th August 2012

Dear Ms Aderogba,

RE: ARM 82 Clarityn Allergy 1mg/ml Syrup (Loratidine) 70ml Pack Size

We write on behalf of the Royal Pharmaceutical Society (RPS) to respond to the above consultation document.

The Royal Pharmaceutical Society (RPS) is the professional body for pharmacists in Great Britain. We represent all sectors of pharmacy in Great Britain and we lead and support the development of the pharmacy profession including the advancement of science, practice, education and knowledge in pharmacy. In addition, we promote the profession's policies and views to a range of external stakeholders in a number of different forums.

The Royal Pharmaceutical Society does not support the reclassification of Clarityn Allergy 1mg/ml (Loratidine) 70ml Pack Size from P to GSL.

The patient information leaflet consistently advises patients to seek advice from a doctor or pharmacist. In non-pharmacy outlets where GSL medicines are sold, professional advice is not available. Pharmacy sale of GSL medicines have shown to be safe, as pharmacists and trained healthcare advisors are on hand to counsel the patient on the medicine they are being supplied.

In addition, we request that the following points be taken into consideration:

Patient Information Leaflet

Section 1

This section provides information on the medicine's mechanism of action and symptoms it can help to reduce.

Pharmacists are well placed to offer additional, key lifestyle advice around the management of the allergic condition where the patient presents with any of the symptoms listed – a provision that would not be on offer at non pharmacy outlets.

Furthermore, given the variety possible symptoms that could be experienced and their similarity to a range of other ailments, pharmacists could provide a valued diagnosis of the patient's particular symptoms whereas non-pharmacy staff could not. Incorrect assessment or identification of symptoms could result in a patient self-treating inappropriately and/ or masking

a different condition, a risk that could be reduced, had the pharmacist been involved in the supply of the medicine.

Section 2

This section advises patients who are taking any other medication to discuss with their doctor or pharmacist before using Clarityn Allergy Syrup. Non-pharmacy outlets would not be able to provide this support or discuss the possibility of drug interactions with the patient.

This section also includes a statement that Clarityn Allergy Syrup should not be used in patients under two years of age and that it is not recommended for patients who are pregnant, think they might be pregnant or breast-feeding. For these patient groups, it is advised that they speak to their doctor, pharmacist or nurse before taking this medicine. Pharmacists and their trained pharmacy staff can ensure that these recommendations are followed and that patients are referred to their doctor, where appropriate- a safeguard that would not be in place in non-pharmacies.

Sections 3 and 4

These sections repeatedly emphasise the importance of informing a pharmacist in the event that the dosing guidance hasn't been followed and has caused adverse effects or, where the patient presents with side effects. Again, with lack of emphasis on patient care, sale of this medicine from non-pharmacies could result in a delay in the patient contacting or being referred to an appropriate health professional regarding a noted side effect.

We hope these comments are useful.

Thank you for contacting the Royal Pharmaceutical Society.

Yours sincerely,

Julie Douglas