



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

2nd February 2012

Dear Abiodun,

Re: ARM 80 Clarityn Allergy 10mg Tablets (Loratidine) 30 Tablet Pack Size
Request to reclassify a product from P to GSL

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

The RPS is the professional body for pharmacists in Great Britain. We are the only body that represents all sectors of pharmacy in Great Britain.

The RPS leads and supports 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 RPS does not support the reclassification of Clarityn Allergy 10mg Tablets (Loratidine) 30 Tablet Pack Size from P to GSL. The patient information leaflet repeatedly advises patients to seek advice from a doctor or pharmacist. In non-pharmacies where general sale list medicines are supplied professional advice is not available to customers. Sales through pharmacies have been shown to be safe because trained staff are available to counsel customers appropriately about medicines and/or deal with any questions that may arise.

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

Patient Information Leaflet

Section 2 : Before you take *Clarityn Allergy Tablets*

This section advises patients who have liver disease, take any other medicines or who are lactose sensitive to discuss this with their pharmacist or doctor before using *Clarityn Allergy 10mg Tablets*. Non health professionals are unlikely to be able to advise against the use of this product to certain individuals or highlight potential allergy risks whereas pharmacists and

trained staff could ensure that patients are directed, where necessary, to an appropriate health professional.

Section 3 : How to take Clarityn Allergy Tablets

In this section, it is suggested that *Clarityn Allergy syrup* may be preferable for children and it highlights the importance of knowing the child's weight before dosing, to ensure that the correct amount of medicine is given. Pharmacies will have trained staff ready to advise and counsel all patients types who are interested in using this product while enabling the patient to make the most clinically appropriate choice . This safeguard will not be in place if the product is available from non-pharmacy outlets.

This section also includes the statement that, "if you take more tablets than recommended contact your pharmacist or doctor". Again, with lack of emphasis on patient care, non-pharmacy staff are unlikely to pass on this advice when selling this product.

Section 4 : Possible Side Effects

Although it has been regarded that significant side effects are rarely experienced, if serious side effects develop or adverse reactions not included in the list are felt, it is advised that a doctor or pharmacist be notified.

If a larger pack is made available as a GSL medicine, patients may continue to use the product and delay seeking advice from an appropriate health professional. The availability of smaller pack sizes may prompt patients to ask for further guidance before purchasing another pack.

We hope these comments are useful.

Thank you for contacting the Royal Pharmaceutical Society.

Yours Sincerely,

Julie Douglas.