Royal Pharmaceutical Society
of Great Britain

Helping pharmacists achieve excellence

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Dear Ms Popo,

Re: ARM 42 - Request to reclassify Imodium Capsules and Imodium Instants (loperamide 2mg) from P to GSL

I write on behalf of the Royal Pharmaceutical Society of Great Britain to respond to the above consultation.

The Royal Pharmaceutical Society of Great Britain is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, which is expected to become statutory under anticipated legislation.

The primary objectives of the Society are to lead, regulate, develop and represent the profession of pharmacy.

The Society leads and supports the development of the profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

The Society has responsibility for a wide range of functions that combine to assure competence and fitness to practise. These include controlled entry into the profession, education, registration, setting and enforcing professional standards, promoting good practice, providing support for improvement, dealing with poor performance, dealing with misconduct and removal from the register.

The Society requests that the following points be taken into consideration:

Reclassification Summary

Section 2 – Product Details

- Refers to recommended dose in the following format '2 dosage forms initially'. Suggest that the actual strength of the product is cited in both the Reclassification Summary and the Patient Information Leaflet.

- Section on symptomatic treatment of acute episodes of diarrhoea associated with irritable bowel syndrome in adults states 'up to a maximum of 6 dosage forms daily'. The British National Formulary 43 (March 2007) however states maximum 16mg daily not 12mg.

- 'The maximum pack size will be 6 dosage forms, equivalent to one day's treatment if the maximum dose is taken'. Suggest consider changing to 24 hours treatment.

Section 3.2 Risk of Misuse

- 1st Paragraph – states 'This product is only to be indicated for the symptomatic treatment of acute episodes of diarrhoea associated with Irritable Bowel Syndrome in adults previously diagnosed by a doctor'. If the product is available as a GSL it may be difficult to verify whether or not IBS has been previously diagnosed by a doctor.

- 3rd Paragraph – The Society has concerns regarding patient safety and possible misdiagnosis of the condition. If a customer experiences digestive symptoms of unknown cause, pharmacy staff could control the sale and refer to a doctor if necessary. If the product was available as a GSL medicine it would be left to the customer to decide whether to seek further advice.

- 4th Paragraph – states 'Individuals will not continue to self-medicate unnecessarily'. The Society believes that there is a possibility that some individuals may possibly continue to self-medicate unnecessarily / inappropriately. We request evidence behind the statement provided.

Section 3.3 Role of the Pharmacist

- There will not be a specific role for the pharmacist if the product is available as a GSL for the indications proposed.

Patient Information Leaflet

When Not To Use This Medicine

- 3rd Bullet – states 'you think that you may have allergic reaction to any form of Imodium or any of the inactive ingredients'. The Society has concerns regarding how a customer will know whether they have previously had an allergic reaction.

- Suggest add a further bullet relating to travellers' diarrhoea - 'If you have recently travelled abroad'

- Section 'If you have Irritable Bowel Syndrome' – states 'if any of the following now apply, do not use this product without consulting your doctor'. This advice could be too late if the customer has already purchased the product.

What Special Precautions Should Be Taken When Using This Medicine?

- 2nd Paragraph – refers to use of oral rehydration therapy and states 'Ask a pharmacist for advice'. The British National Formulary refers to use of antimotility drugs in uncomplicated acute diarrhoea and states that 'fluid and electrolyte replacement may be necessary in case of dehydration'. If the products were available in a pharmacy setting, pharmacy staff could give appropriate advice when the customer initially presents.

The proposal to widen the indication of both products 'for the symptomatic treatment of acute episodes of diarrhoea associated with IBS in adults aged 18 years and over following initial diagnosis by a doctors' cannot be supported by the Society. Sale through pharmacies has shown to be safe because there is a pharmacist available to counsel the purchaser and / or deal with questions that arise.

In non-pharmacies where General Sales List medicines are supplied, there is no professional advice available to customers.

Diarrhoea is not always treated by loperamide. If the licensed indication is widened, a self-misdiagnosis by the patient in a non-pharmacy setting could lead to complications, dehydration and so on.

We hope these comments are helpful.

Thank you for consulting the Society.

Yours sincerely,

Sadia Khan
Lead Pharmacist for Self-care