

Royal Pharmaceutical Society of Great Britain

Helping pharmacists achieve excellence

Ms Veronica Popo
Department of Health
Medicines and Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London
SW8 5NQ

PRACTICE AND QUALITY
IMPROVEMENT DIRECTORATE
Practice Division
Telephone: 020 77572 2537
Facsimile: 020 7572 2501
e-mail: sadia.khan@rpsgb.org

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Dear Ms Popo,

Re: ARM 38 - Request to reclassify Orajel Mouth Gel 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:

- Benzocaine is in the POM order and has been subject to various reclassifications.
- There are three different Orajel products with similar names:

Orajel Dental Gel (GSL) / Orajel Mouth Gel (P) [subject of this reclassification] / Orajel Extra Strength Dental Gel (P)

In terms of patient safety it may be confusing to customers to have several different formulations with similar names.

- The Royal Pharmaceutical Society previously responded to ARM 28 (Request to reclassify Orajel Dental Gel from P to GSL- see <http://www.rpsgb.org.uk/pdfs/consdoc907.pdf>).

The points made by the Society concerning the Patient Information Leaflet (PIL) also apply equally to this particular switch i.e.

The PIL states: 'Before taking your medicine: Make sure it is safe for you to apply Orajel Dental Gel. If you answer yes to any of the following questions, or you are unsure, talk to your pharmacist, doctor or dentist'.

The customer will read the PIL after they have purchased the product and may consider that as they already have the product at hand they will proceed to use it. If a pharmacist was involved in the sale the customer may not purchase the product in the first instance.

The PIL also states: 'If you apply or swallow too much gel: contact your hospital casualty department, doctor or dentist immediately'. If that is the case there are safety issues concerning what is deemed as applying or swallowing 'too much' that the customer requires immediate medical attention.

- Concern that the main side effects are allergic dermatitis and methaemoglobinaemia.
- Although the product is indicated for temporary relief from the pain and tenderness associated with mouth ulcers or from wearing dentures it is possible that some customers use it for any type of mouth irritation.
- Symptoms of more serious conditions (eg infected ulcers, oral cancer) may be masked. In addition, over-use of the product could result in mouth irritation.
- Some customers may visit a pharmacy to get a diagnosis and advice and then go to alternative retail premises to make the purchase.

The proposal to reclassify Orajel Dental Gel 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.

We hope these comments are helpful.

Thank you for consulting the Society.

Yours sincerely,

Sadia Khan
Lead Pharmacist for Self-care