Royal Pharmaceutical Society
of Great Britain

Helping pharmacists achieve excellence

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Medicines and Healthcare products Regulatory Agency
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Dear Ms Popo,

Re: ARM 48 - Request to reclassify Galpharm Four in One Flu Relief 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:

Section 2. Product details. The product contains phenylephrine – a substance that tends to raise blood pressure and may be unsuitable for patients with existing high blood pressure or a history of haemorrhagic stroke etc. Although the product may be a suitable and effective remedy for many patients, reclassifying to GSL status would increase the chances of the product being sold to individuals for whom it may be unsuitable.

The Society has concerns regarding the full dosage of paracetamol (1000mg per dose). Paracetamol tablets are a single dosage form and the risk of taking more than two tablets by accident is low. Customers may possibly drink the liquid formulation directly from the bottle and as the liquid contains the full dosage there is a more of a risk of accidental overdose. The danger may be compounded if the medicine is GSL as customers may perceive it to be 'safer' than other P medicines.

Under indications it refers to dry tickly sore throat and chesty cough - this is confusing as customers may think it can be used for both dry cough and chesty cough. We suggest that 'dry tickly sore throat' is replaced with 'sore throat'.

Section 3. Rationale. Safety issues arise as the product exceeds the maximum strength of 2.5% currently permitted for GSL supply of liquid paracetamol preparations for adults.

The Society seeks further information on whether the use of liquid paracetamol products by adults is common. Under 'Risk of Misuse' it states there is "little evidence if any evidence of intended misuse of the liquid preparation". The Society believes that if this product was reclassified there may be more risk of a mistake and possible accidental administration to a child.

Section 5. Specific GSL requirements - highlights that the labelling states "This product contains a decongestant. Do not take with other products for the relief of colds, flu or congestion". There may be a risk of potential interactions in patients with other medical conditions and also taking other medications.

The Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, as amended contain labelling requirements for GSL paracetamol products. Compliance with these Regulations would be necessary.

Section 6. Safety profile - states "no published evidence that deliberate paracetamol-related overdosing occurs with liquid cold and flu preparations for adults." The Society believes that consideration needs to be given to the risk of accidental overdosage in children.

Patient information leaflet: refers again to dry tickly sore throat and chesty cough – as previously mentioned this is potentially confusing.

'Warning' states 'This product contains 19%v/v ethanol'. The Society is concerned that the level of ethanol appears to be high and seeks clarification on why the formulation contains this quantity. The patient information leaflet also states that "the amount of alcohol in this medicinal product may alter the effects of other medicines and may impair ability to drive or use machines".

The proposal to reclassify Galpharm Four in One Flu Relief 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