ROYAL PHARMACEUTICAL SOCIETY

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Dear [redacted]

Re: ARM 90 Otrivine Extra Dual Relief Nasal Spray Solution

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 supports the reclassification of Otrivine Extra Dual Relief Nasal Spray from POM to P. Pharmacists are experts in medicine, and have the necessary skills and training to ensure the safe and efficient supply of pharmacy medicines. However we do believe the following points require clarity to ensure that the product is safe and appropriate for its intended use as a P medicine.

Section 2. Product Details

Dosage including age-limits

The dosage details indicate that "Otrivine Extra Dual Relief is not recommended for use in children and adolescents below 18 years of age due to lack of sufficient documentation". However the RPS feels that this is inconsistent with the British National Formulary 69 which states that both individual products are suitable for adults aged 12 and above.

Regarding the elderly population it states" there is only limited experience of use in patients above 70 years of age". The RPS feels that this information is not reflected in the Patient Information Leaflet and we would like clarification on whether or not there is an upper age limit.

Section 3. Introduction and Rationale for the Reclassification

Role of the active ingredients and their role in combination

Regarding the dosage of the ipratropium bromide we would like further clarification on the 84µg dose, as the British National Formulary 69 suggests that 42µg is suitable for treatment. Is there any clinical data to support this and any additional associated risks with the higher dosage?

The British National Formulary 69 also recommends a dosage of xylometazoline hydrochloride 0.1%, 1 spray into each nostril 1-3 times daily when required. The dosage of xylometazoline in

the Otrivine Extra Dual Relief spray is only half of this, 0.05% 1 spray into each nostril up to 3 times daily. We would like clarity on why this lower dosage has been chosen and if there is any clinical data to support it effectiveness for treatment at this lower dose.

Section 3. Criterion 1: Evaluation of danger to health when used correctly (pages7-8)
The information on when the product should not be used is detailed to patients in the product packaging and in pack leaflet such as:
• Patients with known hypersensitivity to the active ingredients or other constituents or
• Patients with glaucoma.
• Patients are also advised to discuss with their doctor or pharmacist if they have narrow-angle glaucoma or heart disease, thus addressing the identified risk of increased intraocular pressure, atrial fibrillation and laryngospasm & pharyngeal oedema.

The RPS feels that the third bullet point placement under the category of 'when the product should not be used' is not consistent with the Patient Information Leaflet which places this information under the title of 'Warnings and precautions'.

One of our key roles as the professional body for pharmacists is to produce practical professional guidance for members, and we would be keen to see the full Risk Management Plan as mentioned on page 8: "The applicant has proposed additional risk minimisation measures as for this product
due to the wider exposure through pharmacy supply. These are discussed in more detail in the Risk Management Plan and a summary is provided below".
This would be useful in helping us develop any relevant member resources.

Section 3. The applicant will provide educational materials for pharmacists and pharmacy counter assistants (page 8).
Reference is made to providing educational materials for pharmacists and pharmacy counter assistants to support OTC use of the product. We would be keen to see these to ensure they are appropriate and practical for the pharmacy team to use, and to ensure that any guidance we produce aligns to this.

We are also aware that in practice patients may request a second product if the first has not been successful, which could result in consecutive sale of 2 products containing xylometazoline which could lead to an excess of 7 days treatment. Perhaps the training material could highlight a cumulative maximum of 7 days treatment for products containing xylometazoline.

Section 6. Safety Profile
"The negligible systemic absorption associated with topical administration minimises the potential for systemic adverse events and drug-drug interactions. The estimated degree of systemic exposure with the proposed topical regimen is minimal. Systemic symptoms following accidental ingestion or overdose are therefore unlikely."

The RPS feels this statement could cause confusion. It refers to systemic absorption with regards to topical administration. It does not mention systemic absorption following accidental ingestion.

Package Leaflet

Introduction states "ask your pharmacist if you need more information or advice". See comments above. The RPS seeks feedback on the contents of the pharmacy training package and the information that pharmacy staff will be expected to provide.

“You must talk to a doctor if you do not feel better or if you feel worse”. The society feels that this should include to talk to a pharmacist if you do not feel better or feel worse. The pharmacist could re-assess the patient, perhaps suggest an alternative therapy or if appropriate refer them to the doctor. This may help reduce unnecessary doctor referrals. It should also include a timescale as to when the patient should talk to their doctor or pharmacist if they do not feel better or feel worse.

We hope these comments are helpful.

Thank you for consulting the Royal Pharmaceutical Society.

Kind regards,

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