GHP Guild of Healthcare Pharmacists

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18th March 2015

[redacted]
Self-Medication Unit,
MHRA,
Floor 4-O,
151 Buckingham Palace Road,
London SW1W 9SZ

CONSULTATION DOCUMENT: ARM 90 OTRIVINE EXTRA DUAL RELIEF NASAL SPRAY SOLUTION
REQUEST TO RECLASSIFY A MEDICINAL PRODUCT FROM PRESCRIPTION ONLY MEDICINE (POM) TO PHARMACY (P)

Response from the Guild of Healthcare Pharmacists

Thank you for the opportunity to respond to this consultation. The Guild of Healthcare Pharmacists represents UK wide around 4,000 pharmacists including the majority of hospital pharmacists, pharmacists employed by NHS Primary Care organisations and pharmacists employed by other public bodies such as Prisons and the Care Quality Commission. The Guild is part of the health sector of the union Unite.

The applicant's reasoning for the reclassification appears to be straightforward except for the following concerns regarding the supporting information:

1. The supporting information and the patient information leaflet provided by the applicant give inconsistent information regarding recommendations for use according to the age of the patient:

What You Need to Know Before You use Otrivine® Extra Dual Relief

Children and Adolecents:
"Otrivine Extra Dual Relief is not recommended for use in children and adolescents below 18 years of age due to lack of sufficient documentation.

Do not use Otrivine Extra Dual Relief
• In children below 18 years of age, as adequate information on safety and efficacy is not available

However, for elderly patients the statement reads:

Elderly:
There is only limited experience of use in patients above 70 years of age.

President: [redacted]
Professional Secretary: [redacted]
Email: [redacted] ***Website:*** www.ghp.org.uk

As there is only 'limited experience' in this age group then the leaflet should warn against using the product as for people under 18 years of age.

2. The 'Warnings and Precautions' section of patient information leaflet mentions the need to avoid spraying the inhaler in or around the eyes.

We feel that further information needs to be added. There have been isolated reports of ocular complications such as mydriasis, increased intraocular pressure, narrow-angle glaucoma, eye pain, with aerosolised ipratropium bromide. Patients who may be susceptible to glaucoma should in addition to being instructed in the correct administration of the inhaler, be warned against the accidental release of the contents into the eye and advised on the need for ocular protection. Protection of the eyes appears to prevent any increase in intra-ocular pressure.

Secondly, as the product is indicated for the symptomatic treatment of nasal congestion and rhinorrhoea in connection with common colds there is a strong possibility of close contacts e.g. family members, having these symptoms. Thus, the leaflet should also state:
'This medicine has been recommended for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours'

We hope these comments are of assistance. Our reply may be made freely available.

Yours faithfully

[redacted]
Professional Secretary
Guild of Healthcare Pharmacists

[redacted]
Chair of Practice
Guild of Healthcare Pharmacists