



Response to ARM22 ([Request to reclassify Germoloids HC Spray from P to GSL](#)) from the NPA.

Response of the National Pharmaceutical Association to ARM 22

Thank you for giving the National Pharmaceutical Association (NPA) the opportunity to comment on consultation letter ARM 22 on proposals to reclassify Germoloids HC Spray as a GSL product.

We wish to raise the following concerns regarding the proposed reclassification of this product.

Role of the pharmacist

When Germoloids HC is supplied through a pharmacy, pharmacists and their staff will provide information to the patient that is important for the appropriate treatment of haemorrhoids. Pharmacists or their staff will ensure that the patient has previously been diagnosed with haemorrhoids by a doctor before recommending a product for treatment. The symptoms of haemorrhoids can be confused with several other conditions some of which are potentially serious such as colorectal malignancy, inflammatory bowel disease or sexually transmitted diseases. Anal pruritis may also be due to worm infestations, which are becoming more prevalent due to increased travel abroad. In the pharmacy the patient will be asked about their symptoms and any patient who presents with alarm symptoms will be referred immediately. Any underlying disease or adverse effect can then be recognised and appropriate advice given. Such professional advice and prompt referral will not be available in a non-pharmacy outlet. The pharmacist can also advise if the haemorrhoids may be aggravated by other medication, for example drugs such as analgesics that can cause constipation as a side effect. As patients consider haemorrhoids to be an embarrassing condition patients may decide to self treat without seeking medical advice and more serious conditions may be masked without the involvement of the pharmacist. These safeguards will not be available if Germoloids HC is available as a GSL product.

In addition lifestyle advice is important in the treatment and prevention of haemorrhoids. The pharmacist is able to offer advice on increasing fibre and fluid intake in the diet and self care to help prevent and treat haemorrhoids. In many cases a soothing preparation is appropriate for the management of haemorrhoids. The pharmacist can advise if a more appropriate treatment for the patient's haemorrhoids may be suitable for instance short term use of a laxative. Prodigy guidance states that preparations containing anaesthetics can cause irritation and sensitisation. This advice will not be available to patients who purchase the product without the pharmacist's supervision.

Hazard to Health

The application states that extensive sales of topical hydrocortisone products in the UK have resulted in minimal numbers of adverse event reports. However this is misleading as these sales have all occurred under the supervision of the pharmacist. Topical hydrocortisone is associated with well known adverse effects especially if used for long periods. In the pharmacy, pharmacists and their staff ensure that topical hydrocortisone products are supplied only when appropriate for the patient and their medical condition and clear advice to ensure safe use (such as applying sparingly) is provided.

Although the product will be indicated for a maximum of 7 days this will be difficult to enforce without the supervision of the pharmacist. Neither topical hydrocortisone nor lidocaine hydrochloride are suitable for long term use without referral to a healthcare professional, and although this information is included in the leaflet the general public may not read or follow this advice. In a pharmacy patients would receive advice so that patients did not purchase repeat supplies without referral to their practitioner. As the product is available in a spray form this means that it may be easier to use inappropriately on other parts of the anatomy, the pharmacist can advise on the dangers of inappropriate use. It is proposed that the age limit for the product be increased to 16 years however this will be difficult to enforce without the supervision of the pharmacist. These safeguards will not be available if Germoloids HC is available as a GSL product.

Convenience to the purchaser

We are not aware of any evidence which suggests that this product is difficult to access by the public and do not believe that patient care will be improved by the increased availability of the GSL product. The long term implications and complications associated with inappropriate use of the product may increase the burden on healthcare rather than reducing it, due to continued long term use of the product rather than seeking professional advice.

Advertising and product information

If despite our concerns the product is approved for GSL status we recommend further information should be included on the pack and patient information leaflet. All the advice that is available from the pharmacist, as listed above, should be included. There should be a clear recommendation to consult a pharmacist or general practitioner if symptoms persist or worsen. Product information and advertisements must state that further advice is available from the pharmacist. Also, because of the issues outlined above, advertisements should contain a clear recommendation to read the product literature before use.

We hope you take our comments on board.