



ANNEX 1

Response document for MHRA public consultation on the proposal to make Acnecide Face Gel and Acnecide Face Wash available from general sales outlets without prescription

Ref: ARM 98

Your details

Name: [REDACTED]

Position (if applicable): Professional Support Pharmacist

Organisation (if applicable): Royal Pharmaceutical Society

Email:

1. Do you consider that Acnecide Face Gel and Acnecide Face Wash should be available as General Sale List (GSL) medicines?

Yes ☐ No ☒ Not sure ☐

Please provide any comments or evidence to support your response:

The RPS does not support the move of Acnecide to GSL. Due to the following reasons:
The directions for usage are complicated and people would benefit from the advice of a trained member of pharmacy staff supervised by a pharmacist on instructions for use, managing the condition and potential side effects.

There is a reliance on the individual to self-diagnose mild acne and differentiate this from moderate and severe forms. We do not believe that the information on the packaging provides enough support this. People would need to refer to the patient information leaflet to support them further with differentiating, which would usually require one to open the packaging to refer to the leaflet. The images in the leaflet are rather small. If the product is used for moderate or severe acne there is the risk of a delay in receiving the appropriate treatment as described in the consultation document.

Skin reactions commonly occur, reportedly in 1 in 10 or more people, we suggest that people should be advised of this – advice that they would not receive from a general sales outlet but would receive from a pharmacy. There are also side effects that require closer monitoring (page 8), if the product is sold from a pharmacy, people will have the opportunity to discuss any side-effect with the pharmacist.

There are many references to people speaking to their pharmacist or doctor, we suggest that managing even minor side effects should be discussed with a pharmacist, even stepping down usage to alternate days – this is because it may be appropriate for the person to stop Acnecide and not re-start it.

Acnecide appears to have a good safety profile, when used correctly – but currently this is under the advice of a healthcare professional.

2. Do you have any specific comments on the leaflets or the labels provided in the public reclassification report for Acnecide Face Gel and Acnecide Face Wash?

Both products state in the event of severe skin irritation that the advice of a doctor should be sought – we propose that this could also be a pharmacist, for example they could advise on self-care if over a weekend or refer to out of hours or A&E (depending upon the severity of the reaction).

We have some reservations on the lack of details as to how to deal with side effects (particularly mild to moderate side effects) and where to go to for further advice when products have been purchased from general sales outlets; a person would have access to more information from a pharmacy.

3. Do you have any other comments on the reclassification?

With there being P and GSL products available with differing indications, this may cause confusion for members of the public.

The RPS welcomes the advice that a person should speak to a pharmacist or doctor should more information or advice be required.

4. The MHRA may publish consultation responses. Do you want your response to remain confidential?

Yes ☐

Partially* ☐

No ☒

*If partially, please indicate which parts you wish to remain confidential. In line with the Freedom of Information Act 2000, if we receive a request for disclosure of the information, we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. Responses to consultation will not normally be released under FOI until the regulatory process is complete.

Responses can be continued onto a separate page if required. This form should be returned by email (reclassification@mhra.gov.uk) to arrive by **30 May 2019**. Contributions received after that date cannot be included in the exercise.