

To: Veronica Popo
Department of Health
MHRA
Room 14-138 Market Towers
1 Nine Elms Lane
LONDON SW8 5NQ

From: British Association of Dermatologists
4 Fitzroy Square _____
London W1T 5HQ _____

CONSULTATION LETTER ARM 59 BAZUKA TREATMENT GEL

Request to Reclassify a Product from P to GSL

* 1. ~~We have no comments to make on the proposals in ARM 60~~

* 2. Our comments on the proposals in ARM 60 are below/~~attached~~.

*Our reply may be made freely available

~~*Our reply is confidential~~

*Our reply is partially confidential (indicate clearly in the text any confidential elements)

Signed: _____

A handwritten signature in black ink, appearing to read 'V. Popo', is written over a light grey rectangular background.

*Delete as appropriate

Date: 20th October 2008 _____

Comments:

1. It would be most helpful if a reminder of the definitions of "P", "GSL", etc. could be included when sending consultations.
2. No.2 product details: to state that it may take up to 12 weeks for lesions to disappear may raise false expectations as they may not go at all. Also, pack size mentions 5g, 6g and 8g tubes whereas patient info leaflet (PIL) only mentions 6g.
3. We felt the fact that it should not be applied to facial warts and needed to be emphasised more in the PIL.
4. Overall we have no objections to the reclassification.