

ADVISORY COMMITTEE ON BORDERLINE SUBSTANCES

APPENDIX 5

THE MECHANISM FOR ENSURING THAT PATIENTS ARE PROTECTED WHEN DERMATOLOGICAL PRODUCTS ARE CLASSIFIED AS “BORDERLINE SUBSTANCES”

An active working relationship exists between the following organisations

- Medicines and Healthcare products Regulatory Agency (MHRA)
- Advisory Committee on Borderline Substances (ACBS)

The purpose of both groups is to ensure that products are appropriately classified and that patient safety is ensured (as far as is practicable) in terms of product safety and subsequent administration. The table below describes the principal components of the process.

Stage	Agency	Purpose
1. Determination that the product is not a medicine	MHRA	<p>To confirm that the product is not a medicinal product and therefore does not require to be licensed under the terms of:</p> <ul style="list-style-type: none">- The Consolidated Pharmaceutical Directive (EU/2001/83) relating to medicinal products for human use- The Medicines for Human Use (Marketing Authorisations etc) Regulations 1994 as amended <p>Note: The MHRA will only state whether or not the product is a medicinal product. Any further definition has to be determined by other authorities</p>

<p>2. Confirmation that, although the product is not a medicine, it has specific attributes justifying its prescription in the community at NHS expense as part of the clinical management of a specific condition</p>	<p>ACBS</p>	<p>To confirm that the product is effective and efficacious in the management of specific clinical conditions and to ensure that the prescription is as safe as possible.</p> <p>Note: The ACBS is, by definition, advisory rather than regulatory. However, decisions made by the ACBS on justifiable requirements in the interests of patient safety are likely to be upheld by the DH</p> <p>“In considering whether a particular substance, preparation or item should be approved, the ACBS will have regard to the need to ensure that substances, preparations or items which have a therapeutic use in the management of disease in the community can be provided as economically as possible under the NHS”.</p>
--	-------------	--