ADVISORY COMMITTEE ON BORDERLINE SUBSTANCES

NOTES OF GUIDANCE TO MANUFACTURERS ABOUT INFORMATION TO BE INCLUDED IN SUBMISSIONS FOR DERMATOLOGICAL PRODUCTS TO BE CONSIDERED BY THE ACBS

1. PRESENTATION

- description of the appearance and form of the product e.g. solid, powder, liquid, cream, ointment, lotion, foam, shampoo, gel, paste
- how it will be supplied e.g. in a bag, bottle, aerosol, canister, tube etc
- weight / volume of each unit
- outer package size and weight / number of contents

2. FORMULATION

The details required will depend on the type of product

2.1 Skin preparations and other products

2.1.1 Composition

The composition or formula should be given in terms of actual amounts of ingredients in the finished product in SI units or % weight for weight.

2.1.2 Pharmaceutical information

2.1.2.1 Quantitative and qualitative listing of all the ingredients which should include:
- a listing of all the active ingredients
- bioavailability of the active ingredients
- a listing of all the excipients used in the product
- nature of the vehicle / base
- nature of the preservatives e.g. germicides and bacteriostatics
- nature of any penetration-enhancing agents e.g. DMSO, Azone etc
- nature of any photo sensitising agents e.g. Bergamot, perfumes

2.1.2.2 Stability and shelf life, expiry date.

2.1.2.3 Date when first manufactured if already available in the UK.
2.2 Sunscreens

Please refer to the Appendix.

3. SAMPLES

Samples of the product, preferably in the draft packaging, should be provided for the Committee’s inspection.

Note: One sample of each product being submitted will suffice.

4. MEDICINES ACT

A statement of exemption from the licensing and other provisions of the Medicines for Human Use (Marketing Authorisations etc.) Regulations 1994 or the Medicines Act 1968 and associated legislation must be obtained prior to any submission to the Advisory Committee on Borderline Substances by writing to the Medicines and Healthcare products Regulatory Agency (MHRA), Borderline Substances Policy Unit, Room 16,143-8, Market Towers, 1 Nine Elms Lane, London SW8 5NQ, enclosing details of the product to be considered.

NOTE: If a product is not classified as a medicine by the MHRA, this does not mean that it will automatically be considered for approval by the ACBS for reimbursement at NHS expense.

Applicants must confirm that the product is not registered / nor in the process of being registered in line with the Medical Devices Directive.

Any information sent to the MHRA (i.e. information on the ingredients, copies of the packaging, information leaflets and promotional material) must be exactly the same as the information submitted to the ACBS, otherwise the MHRA certificate will not be valid. If any discrepancy between the two submissions is found, the ACBS will advise the MHRA who may then require a complete re-submission to confirm the original certification.

5. INFORMATION SHEET

An information sheet should be provided and should include information about the pharmacological / pharmokinetic properties of the product.
6. SUPPORTING DOCUMENTARY EVIDENCE

The following information will be required for all submissions:

6.1.1 Reports of completed clinical trials of the product which demonstrate its therapeutic usefulness in the management of disease in the community for the indications sought.

Note: Details of the rationale for and the level of a sunscreen factor should be given for sunscreen products. Please also refer to the Appendix.

6.1.2 Details of any clinical trials still in progress e.g. in-house data, published references, personal communications.

6.1.3 Any available comparative studies for the product and similar existing products where relevant and/or when clinical trials are difficult to complete or control.

6.1.4 Objective clinical efficacy in patients with skin disorders for which approval is sought and evidence for lack of any irritancy or sensitisation potential.

6.1.5 A brief description of the arrangements for quality control and confirmation that relevant standards have been followed in the manufacturing process.

General Note:
Articles from books and journals may be referenced in the submission but should only be enclosed if they are directly relevant to the product or if the indications for which the approval is sought are uncommon. Where a document is in a foreign language, a translation must be provided.

7. ADMINISTRATION TO THE PATIENT

Where appropriate, dosage or frequency of administration/application for both adults and children should be given. Methods and routes of administration or application should be described. If the product is for topical application, the potential need for applicators should also be described.

8 CONTRAINDICATIONS AND OTHER PRECAUTIONS

Information about the following must be provided:
- details of warnings / precautions – especially for patients who have been prescribed drugs which cause photosensitivity
- potential interactions / incompatibilities / allergies and sensitivities
- contraindications
- side effects / adverse reactions
- use in pregnancy and during lactation
- any potential for overdose

9. PACKAGING AND SAMPLES

Details of packaging or proposed packaging for all sizes should be provided, including labelling for outer packaging. Any changes to existing foreign packaging required for the UK market should be provided. Copies of the final packaging should be sent as soon as they are available.

10. PROMOTIONAL AND DESCRIPTIVE LITERATURE

A statement of the present and proposed promotional policy e.g whether the product will be advertised solely to the medical profession and / or to approved prescribers should be provided.

11. AVAILABILITY

A statement that the product will be available in single units for dispensing by Community Pharmacists should be provided.

If the product is not yet available in the UK, a statement of the date from which it is expected to be introduced to the UK should also be provided.

12. PRICE TO THE NHS

A statement of the proposed price of the product to the NHS should be provided. The Committee is required by its terms of reference to “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”. To this end, it has divided the products it recommends into a number of therapeutic categories, based on their agreed indications, in order that meaningful price comparisons may be made.
APPENDIX : SUNSCREENS

1. Sunscreens will only be recommended for the photoprotection of skin in patients who have abnormal photosensitivity. Labelling and promotional material should not refer to “safe tanning”.

2. Sunscreens which are recommended will be indicated for “protection from UV radiation in abnormal cutaneous photosensitivity resulting from genetic disorders or photodermatoses, including those resulting from radiotherapy and chronic or recurrent herpes simplex labialis.

3. Only products with an appropriately evidenced UVB/SPF of 30 or more will be considered for approval for reimbursement at NHS expense.

4. The ACBS will wish to see evidence of UVB SPF testing using the FDA\(^1\), DIN\(^1\), or COLIPA\(^1\) methods by a source independent of the manufacturer or supplier.

5. The ACBS wishes to encourage the use of sunscreens that provide significant protection against UVA. In the absence of an agreed method of testing UVA protection, companies which make UVA protection claims for their products should give details of the methodology used in each case. The ACBS will keep this under review and adopt a UVA protection criterion when an internationally accepted testing method has been established.


7. If water resistance is claimed, evidence must be produced using the FDA or Australian Standard\(^2\) methods and the SPF before and after water submersion should be stated in the application. The SPF remaining after water submersion should be more than 50% of that before.

8. Protection factors should be shown on the product container with instructions recommending frequent application during exposure to the sun. Guidance on the frequency of reapplication after water immersion should be given on the label.

9. Evidence should be provided to demonstrate the lack of significant irritancy and allergenicity by testing the actual formulation rather than the individual constituents.

10. Approval of a product by the ACBS does not convey recognition of any rating system other than given in the criteria above,

Deutsches Institut für Normung: *Normenausschuss Lichthechnik*, Berlin 1984

European Cosmetic, Toiletry and Perfumery Association: *Colipa Sun Protection factor Test Method*, (1994) 289