COMMITTEE ON SAFETY OF MEDICINES

APPENDIX A to Minutes of Meeting held on 25 January 1973

Summary of recommendations and advice on applications

CT/0012/0083

May & Baker Ltd

19,552 RP Injection
(Neuroleptic)

Sub-Committee on Toxicity and Clinical Trials

On the evidence before them the Sub-Committee recommend that, in view of the inadequacy of the reporting of the initial studies, the clinical trials of this preparation be extended to three centres only, with a maximum of 30 patients in each centre, treated for up to 24 weeks.

Remarks

(1) The attention of the Main Committee is drawn to the concern of the Sub-Committee regarding inclusion of women of child-bearing age in the trials despite the exclusion of such patients in the clinical trial certificate. (This has already been taken up with the firm by the Licensing Authority).

(2) It is noted that evidence of accumulation in man, although requested, has not been provided. This information would be required before a product licence application could be considered.

Main Committee

On the evidence before them the Committee advise that the clinical trials of this preparation be extended only to a total of three centres, with a maximum of 30 patients in each centre, treated for up to 24 weeks.

CT/0014/0143

The Boots Company Ltd

Cytembena Injection
(Antineoplastic Agent)

Sub-Committee on Toxicity and Clinical Trials

On the evidence before them the Sub-Committee recommend the issue of a clinical trial certificate for this preparation for the purposes indicated in the application.

Remarks

A statement regarding proposed monitoring should be provided. Data from the monitoring of this trial would be required before consideration could be given to an extension of the trials.

Total dosage levels to be employed in the trial should be clarified.

Main Committee

Subject to the Sub-Committee on Chemistry and Pharmacy being satisfied and on the evidence before them the Committee advise the issue of a clinical trial certificate for this preparation for the purposes indicated in the application.

CT/0029/0091

Imperial Chemical Industries Ltd

ICI 55,897 Tablets

(Treatment of Lipoproteinaemia)

Sub-Committee on Toxicity and Clinical Trials

On evidence before them the Sub-Committee recommend the issue of a clinical trial certificate for this preparation for the purposes indicated in the application.

Remarks

Further evidence of liver toxicity, carcinogenicity, and information concerning protein binding and interaction with anti-coagulants should be provided before consideration is given to an application for a product licence, together with results of higher dose intermediate term toxicity studies.

Main Committee

Subject to the Sub-Committee on Chemistry and Pharmacy being satisfied and on the evidence before them the Committee advise the issue of a clinical trial certificate for this preparation for the purposes indicated in the application.

Remarks

The Committee considered that information on lipid metabolism should also be provided in association with an application for a Product Licence.

CT/0057/0097

Pfizer Ltd

UK-10,111-01 Capsules

(Anorectic Agent)

Sub-Committee on Toxicity and Clinical Trials

On the evidence before them the Sub-Committee recommend the issue of a clinical trial certificate for this preparation for the purposes indicated in the application.

Remarks

Before consideration can be given to an application for a product licence, drug interaction studies with anti-hypertensive agents would be required.

Main Committee

Subject to the Sub-Committee on Chemistry and Pharmacy being satisfied and on the evidence before them the Committee advise the issue of a clinical trial certificate for this preparation for the purposes indicated in the application.

CT/1796/0002

Chemiewerk Homburg

D-Penicillamine Tablets

(Rheumatoid Arthritis Treatment)

Sub-Committee on Toxicity and Clinical Trials

On the evidence before them the Sub-Committee recommend the issue of a clinical trial certificate for this preparation for the purposes indicated in the application.

Main Committee

Subject to the Sub-Committee on Chemistry and Pharmacy being satisfied and on the evidence before them the Committee advise the issue of a clinical trial certificate for this preparation for the purposes indicated in the application.

[redacted]PL/0001/0051

Geigy Pharmaceuticals

Tandacote Tablets

(Non-steriodal Anti-inflammatory)

Sub-Committee on Toxicity and Clinical Trials

On the evidence before them the Sub-Committee recommend the grant of a product licence for this preparation for the purposes indicated in the application, provided that no claims are made for improved gastric tolerance.

Remarks

The Sub-Committee recommended however that all products of this nature should be noted for early consideration when product licences of right are reviewed.

Main Committee

On the evidence before the Committee advise the grant of a product licence for this preparation for the purposes indicated in the modified application.

The Committee also advise that this product should be regarded as new for the purpose of a special directive for the reporting of adverse reactions.

Remarks

The Committee noted and endorsed the Sub-Committee's recommendation that the group of products into which this preparation falls should be given early consideration in the product licence of right review.

PL/0003/0036

Wellcome Foundation Ltd

Imuran Tablets 50mg

(Immunosuppresive)

Sub-Committee on Toxicity and Clinical Trials

The Sub-Committee recommend that a decision on this product should be deferred pending receipt of the opinions from three dermatologists.

Main Committee

The Committee agree that a decision on this product should be deferred pending receipt of the opinions from three dermatologists.

PL/0004/0219
PL/0004/0220

Glaxo Laboratories Ltd

Dermovate Cream
" Ointment

(Topical Corticosteroid)

Sub-Committee on Toxicity and Clinical Trials

On the evidence before them the Sub-Committee recommend the grant of product licences for these preparations for the purposes indicated in the application.

Main Committee

Subject to the Sub-Committee on Chemistry and Pharmacy being satisfied and on the evidence before them the Committee advise the grant of product licences for these preparations for the purposes indicated in the application.

The Committee also advise that these products should be regarded as new for the purpose of a special directive for the reporting of adverse reactions.

PL/0011/0025

John Wyeth & Brother Ltd

Nordiol Tablets
(Oral Contraceptive)

Sub-Committee on Toxicity and Clinical Trials

On the evidence before them the Sub-Committee recommend the grant of a product licence for this preparation for the purposes indicated in the application, provided that treatment of primary and secondary amenorrhoea and oligomenorrhoea are removed from the recommended clinical uses.

Main Committee

On the evidence before them the Committee advise the grant of a product licence for this preparation for the purposes indicated in the application, provided that treatment of primary and secondary amenorrhoea and oligomenorrhoea are removed from the recommended clinical uses.

Remarks

During discussion on this application the Committee agreed that in conjunction with the Product Licence of Right review consideration should be given to whether action was needed to remove the indications amenorrhoea and oligomenorrhoea from those included in the recommendations for use of similar products already on the market.

[redacted]/0011/0040
John Wyeth & Brother Ltd
d-Norgestrel Tablets
(Oral Contraceptive)

Sub-Committee on Toxicity and Clinical Trials

On the evidence before them the Sub-Committee recommend the grant of a product licence for this preparation for the purposes indicated in the application.

Main Committee

On the evidence before them the Committee advise the grant of a product licence for this preparation for the purposes indicated in the application.

The Committee also advise that this product should be regarded as new for the purpose of a special directive for the reporting of adverse reactions.

PL/0038/0074

[redacted]ham Group Limited

Pollen (B_2 Grass) Tyrosine Adsorbate (Pollen Bradaphesin)

(Protection against Hay Fever or Pollen Asthma)

Sub-Committee on Biologicals

On the evidence before them the Sub-Committee on Biologicals recommend the grant of a product licence for this preparation for the purposes indicated in the application.

Main Committee

On the evidence before them the Committee advise the grant of a product licence for this preparation for the purposes indicated in the application.

The Committee also advise that this product should be regarded as new for the purpose of a special directive for the reporting of adverse reactions.

PL/0053/0065

[redacted]ing Chemicals Ltd

Neogynon & Neogynon ED Tablets

(Oral Contraceptive)

Sub-Committee on Toxicity and Clinical Trials

On the evidence before them the Sub-Committee recommend the grant of a product licence for this preparation for the purposes indicated in the application.

Main Committee

On the evidence before them the Committee advise the grant of a product licence for this preparation for the purposes indicated in the application.

The Committee also advise that this product shall be regarded as new for the purpose of a special directive for the reporting of adverse reactions.

PL/0053/0068

Schering Chemicals Ltd

Microlut Tablets
(Oral Contraceptive)

Sub-Committee on Toxicity and Clinical Trials

On the evidence before them the Sub-Committee recommend the grant of a product licence for this preparation for the purposes indicated in the application.

Main Committee

On the evidence before them the Committee advise the grant of a product licence for this preparation for the purposes indicated in the application.

The Committee also advise that this product should be regarded as new for the purpose of a special directive for the reporting of adverse reactions.

PL/0086/0021
[redacted]/0086/0022

Hoechst Pharmaceuticals

BL 191 Tablets
BL 191 Injection

(Vasodilator)

Sub-Committee on Toxicity and Clinical Trials

The Sub-Committee recommend that a decision on these products should be deferred for consideration of additional data which has been submitted and clarification of indications.

Main Committee

The Committee agree that a decision on these products should be deferred pending:-

(i) consideration of additional data which has been submitted

(ii) clarification of the indications

(iii) receipt of the views of the Sub-Committee on Chemistry and Pharmacy.

[redacted]/0116/0011

Travenol Laboratories Ltd

Hemofil

(Blood product)

Sub-Committee on Toxicity and Clinical Trials
(December 1972)

Subject to the Sub-Committee on Biologicals being satisfied and on the evidence before them the Sub-Committee recommend the grant of a product licence for this preparation for the purposes indicated in the application.

Sub-Committee on Biologicals (January 1973)

On the evidence before them the Sub-Committee on Biologicals recommend the grant of a product licence for this preparation for the purposes indicated in the application, provided that:-

(i) the potency of the product is expressed in international units

(ii) the supply of the product is restricted to hospitals and haemophilia centres

(iii) the TSA batch release procedure shall apply.

Main Committee
(January 1973)

On the evidence before them the Committee advise the grant of a product licence for this preparation for the purposes indicated in the application, provided that:-

(i) the potency of the product is expressed in international units

(ii) the supply of the product is restricted to hospitals and haemophilia centres

(iii) the TSA batch release procedure shall apply.

The Committee also advise that this product should be regarded as new for the purpose of a special directive for the reporting of adverse reactions.

PL/0161/0012

Rona Laboratories Ltd

Madecassol Tablets
(Wound Healing Agent)

Sub-Committee on Toxicity and Clinical Trials

On the evidence before them the Sub-Committee recommend the grant of a product licence for this preparation provided that the indications are limited to defective scars and keloids.

Remarks

Before consideration could be given to an extension to include the other proposed indications, adequately controlled clinical studies would be required.

Main Committee

On the evidence before them the Committee decided to refer this application back to the Sub-Committee on Toxicity and Clinical Trials to review their recommendation in the light of the views of the Sub-Committee on Chemistry and Pharmacy, in particular on the question of definition of the active constituents.

PL/0286/0010

Syntex Pharmaceuticals Ltd

Normenon Tablets
(Oral Contraceptive)

Sub-Committee on Toxicity and Clinical Trials

(September 1972)

On the evidence before them the Sub-Committee recommend the grant of a product licence for this preparation for the purposes indicated in the application.

Remarks

Release for marketing to be granted after the report on carcinogenicity studies has been published.

Main Committee

(September 1972)

On the evidence before them the Committee advise the grant of a product licence for this preparation for the purposes indicated in the application on the understanding that the product is not released for marketing until the report on carcinogenicity studies has been published.

The Committee also advise that this product should be regarded as new for the purpose of a special directive for the reporting of adverse reactions.

Note:

At the Chairman's request communication of this decision to the Licensing Authority was subsequently deferred pending consideration of further developements.

Main Committee

(January 1973)

Following recommendation of this application and on the evidence before them the Committee concluded provisionally that on the grounds of safety they would be unable to advise the grant of a product licence for this preparation for the purposes indicated in the application in view of inadequate evidence of safety with particular reference to carcinogenicity potential.

Accordingly it was agreed that action under Section 21(1) of the Medicines Act would be required.

PL/0607/0001

A[redacted] Laboratories Ltd

Dermoplast

(Topical Analgesic Aerosol)

Sub-Committee on Toxicity and Clinical Trials
(December 1972)

On the evidence before them the Sub-Committee are unable to recommend that the clinical indications of this preparation be extended for the purposes proposed in the application for the following reasons:-

(i) lack of evidence of efficacy

(ii) possibility of allergy.

Main Committee (December 1972)

The Committee decided to refer this application back to the Sub-Committee on Toxicity to review the terms of their recommendation with particular reference to the question of efficacy.

Remarks

The Committee drew attention to the fact that there might be a conflict of name with an adhesive dressing.

Sub-Committee on Toxicity and Clinical Trials
(January 1973)

On the evidence before them the Sub-Committee recommend that the clinical indications of this preparation be extended for the purposes indicated in the modified application, provided that a warning against use for extensive burns is included in the labelling, and that it is made clear that the product should not be used to treat children under one year of age.

Main Committee
(January 1973)

On the evidence before them the Committee advise that the clinical indications of this preparation be extended for the purposes indicated in the modified application, provided that a warning against use for extensive burns is included in the labelling, and that it is made clear that the product should not be used to treat children under one year of age.

Remarks

The Secretariat was asked to check that a warning regarding avoidance of use near eyes and mouth would be included.

PL/1424/0003

Westone Products Ltd

Fluogel

(Dental Caries Prophylactic)

Sub-Committee on Toxicity and Clinical Trials

On the evidence before them the Sub-Committee recommend the grant of a product licence for this preparation for the purposes indicated in the application.

Main Committee

In view of the lack of evidence of fluoride absorption and the possible hazard of Hydrofluoric Acid the Committee agreed that this application should be deferred pending receipt of the views of dental experts, and subsequently further consideration by the Sub-Committee on Toxicity and Clinical Trials.

PL/2645/0001

W [redacted] Mudge

Mudge Anti-Smoking Tablets

(Anti-Smoking Agent)

Sub-Committee on Toxicity and Clinical Trials

On the evidence before them the Sub-Committee are unable, on the ground of safety, to recommend the grant of a product licence for this preparation for the purposes indicated in the application due to the hazard of potassium bromide.

Main Committee

On the evidence before them the Committee concluded provisionally that on the ground of safety they may be unable to advise the grant of a product licence for this preparation for the purposes indicated in the application due to the hazard of potassium bromide.

Accordingly it was agreed that action under Section 21(1) of the Medicines Act would be required.

PL(R)/0001/5011

Geigy Pharmaceuticals

Hygroton Tablets
(Diuretic)

Sub-Committee on Toxicity and Clinical Trials

On the evidence before them the Sub-Committee are unable, on the grounds of safety and efficacy, to recommend that the product licence of right be extended for the purposes indicated in the application in view of inadequate evidence of safety and efficacy in relation to the proposed indications.

Main Committee

On the evidence before them the Committee concluded that on the grounds of safety and efficacy they are unable to advise that the product licence of right be extended for the purposes indicated in the application in view of the inadequate evidence of safety and efficacy in relation to the proposed indications and agreed that the Licensing Authority should be informed accordingly.

PL(R)/0076/5033

Janssen Pharmaceuticals

Oral: Tablets

(Tranquilliser)

Sub-Committee on Toxicity and Clinical Trials

On the evidence before them the Sub-Committee recommend that the product licence of right be extended for the purposes indicated in the application.

Remarks

The applicant should be informed that the product should not be promoted as a hypnotic agent.

Main Committee

On the evidence before them the Committee advise that the product licence of right be extended for the purposes indicated in the application.

PL(R)/0286/5008

[redacted] Pharmaceuticals Ltd

Anapolon 5 Tablets

(Anabolic/Androgenic Steroid)

Sub-Committee on Toxicity and Clinical Trials
(December 1972)

On the evidence before them the Sub-Committee are unable to recommend that the product licence of right for this preparation be extended for the purposes indicated in the application for the following reasons:-

(i) the demonstrated toxicity of the drug in the proposed indications

(ii) inadequate evidence of efficacy.

Remarks

The attention of the Sub-Committee on Adverse Reactions should be drawn to the current indications for this product.

Main Committee (December 1972)

The Committee decided to refer this application back to the Sub-Committee on Toxicity to review their recommendation in the light of additional information on toxicity.

Sub-Committee on Toxicity and Clinical Trials
(January 1973)

Having reviewed this application the Sub-Committee saw no reason to depart from their recommendation that the product licence of right for this preparation should not be extended as requested because of the demonstrated toxicity of the product in the proposed indications.

Remarks

The Sub-Committee noted that the problem of hepatocellular carcinoma associated with the use of this steroid will be discussed at the next meeting of the Sub-Committee on Adverse Reactions.

Main Committee
(January 1973)

On the evidence before them the Committee concluded that on the ground of safety they are unable to advise that the product licence of right for this preparation be extended as requested because of the demonstrated toxicity of the product in the proposed indications, and agreed that the Licensing Authority should be informed accordingly.