

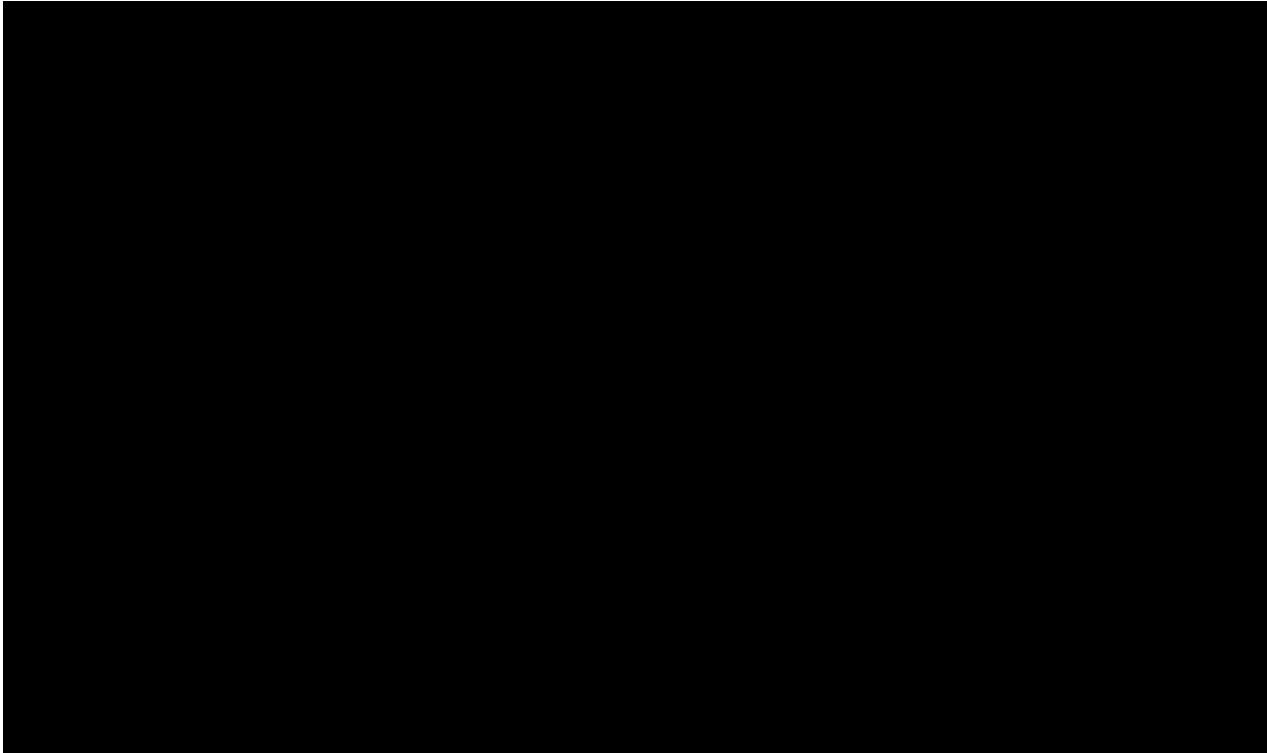
NOT FOR PUBLICATION

COMMITTEE ON SAFETY OF MEDICINES

MINUTES OF THE MEETING HELD ON THURSDAY 22 JUNE 1972

PRESENT:

ALSO PRESENT:



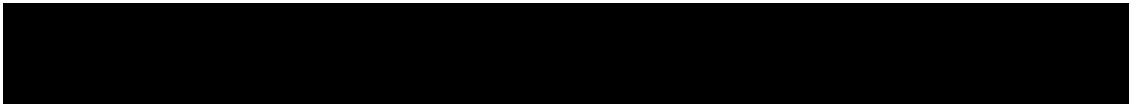
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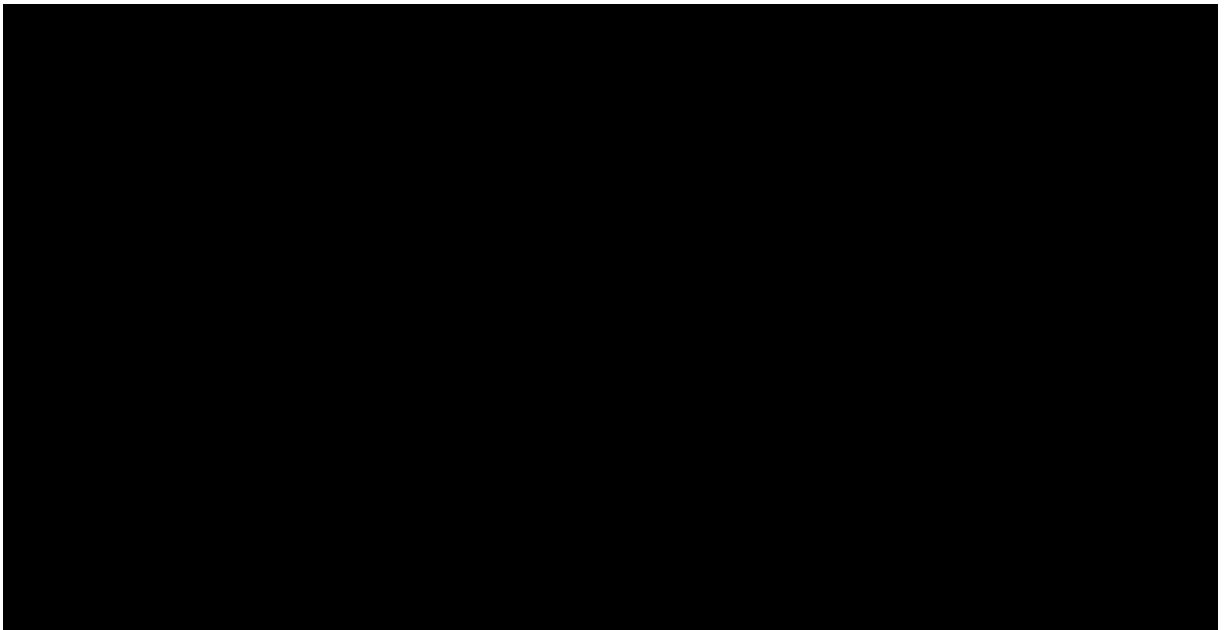
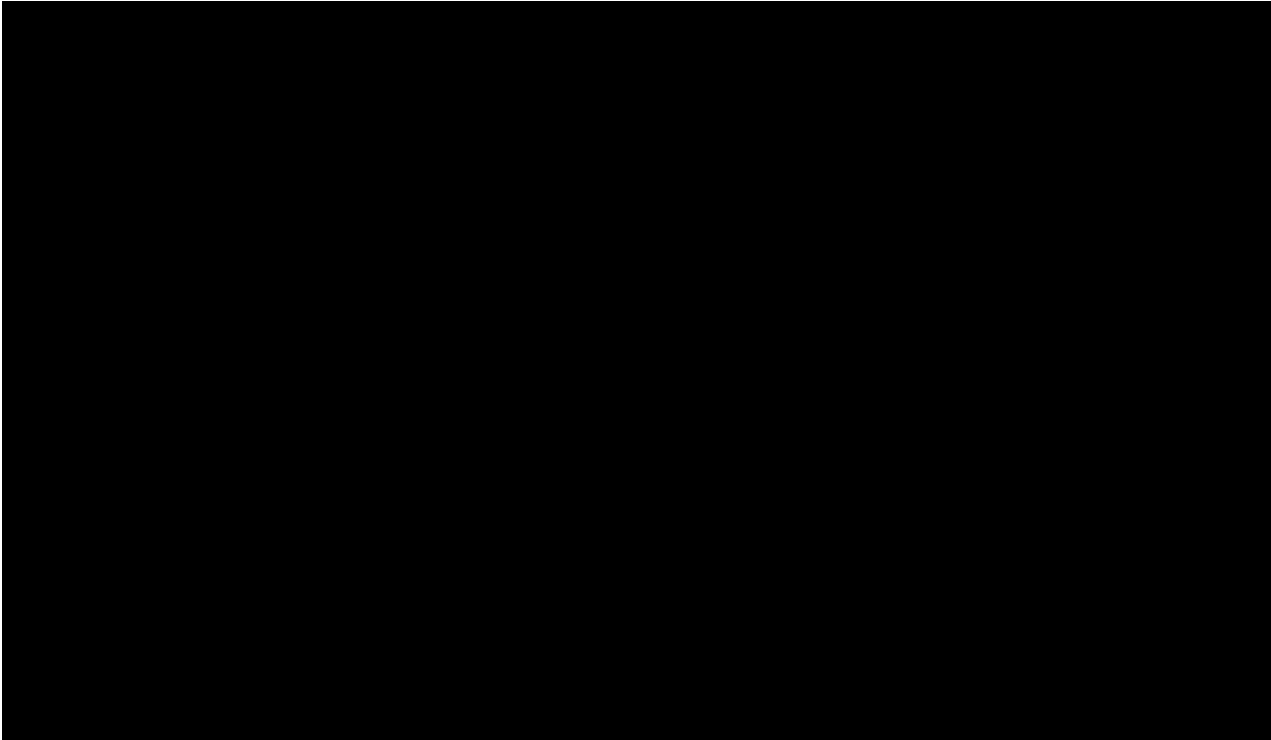
1. APOLOGIES FOR ABSENCE



2. MINUTES OF THE MEETING HELD ON 25 MAY 1972

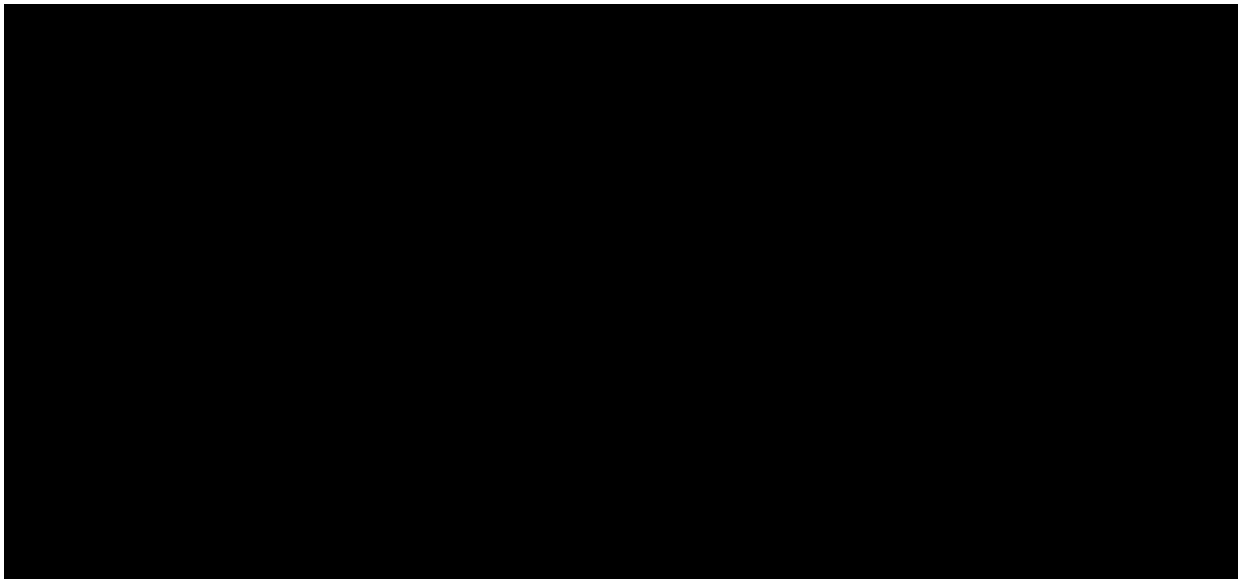


3. MATTERS ARISING FROM THE MINUTES

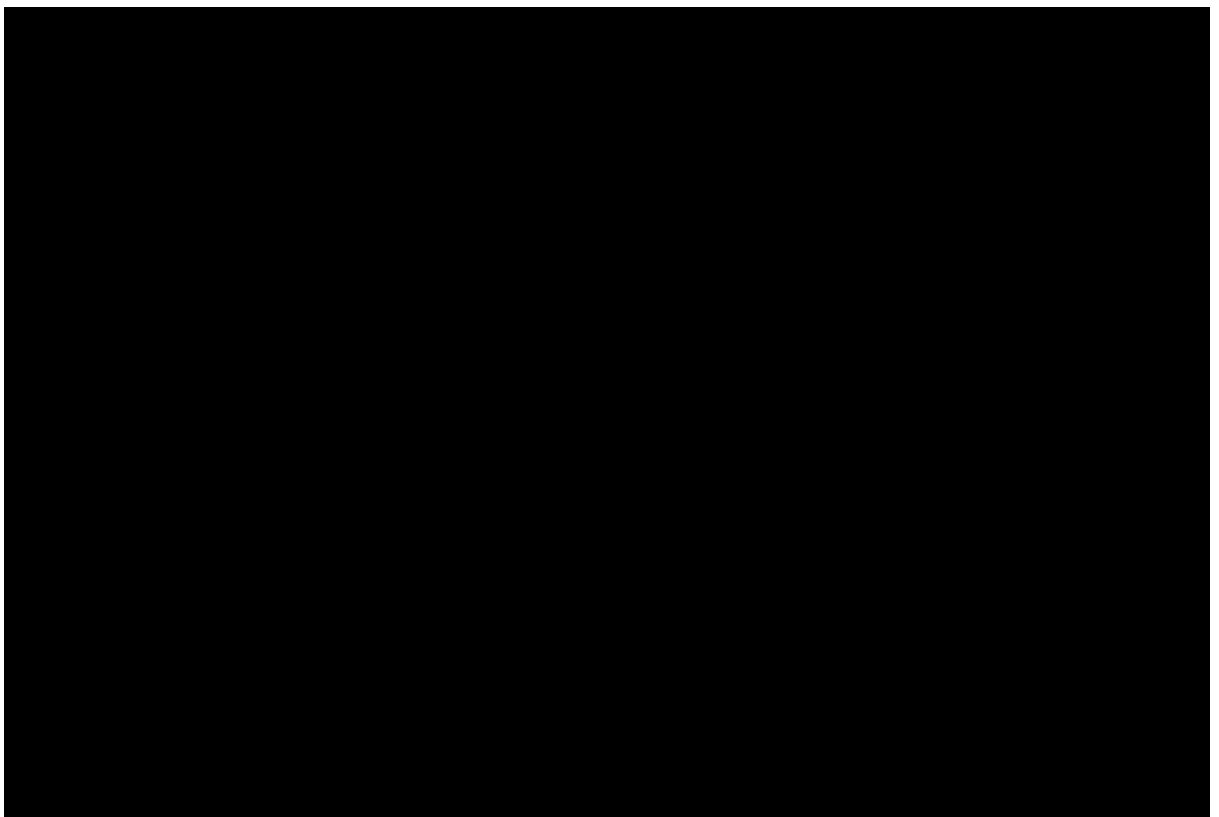


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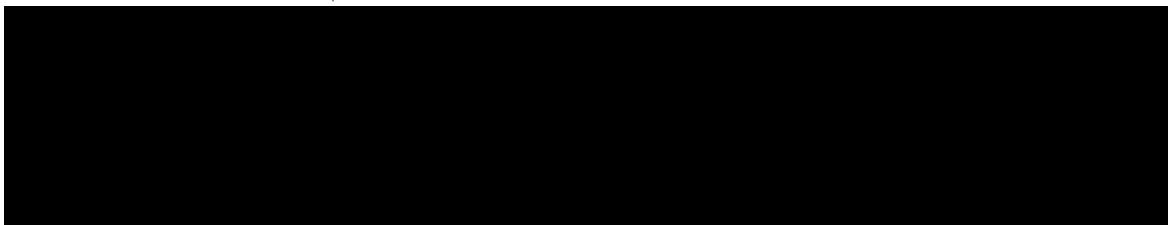
CONSIDERATION OF APPLICATIONS FOR CERTIFICATES AND LICENCES



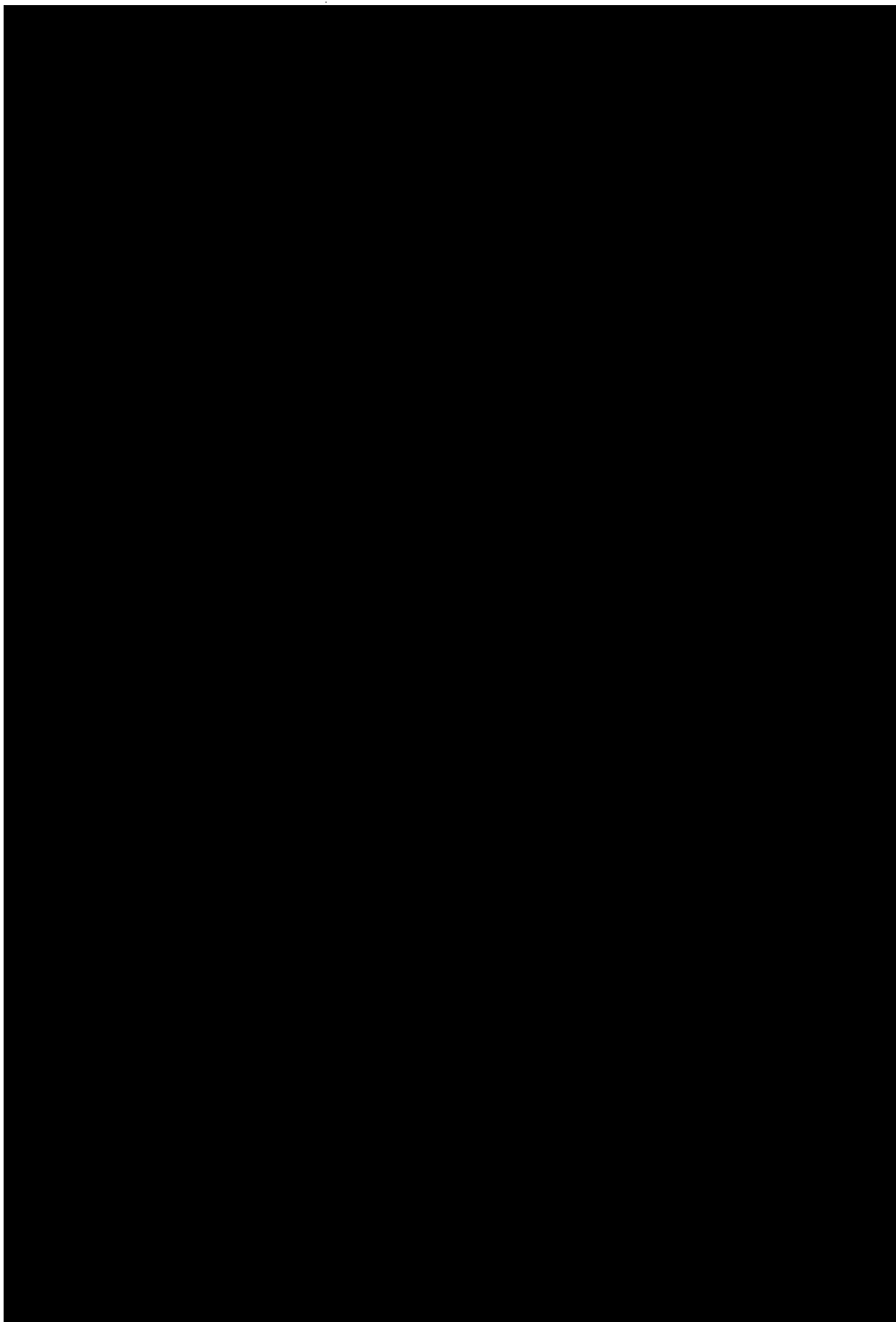
5. APPLICATIONS PREVIOUSLY DEFERRED (CSM/72/26)



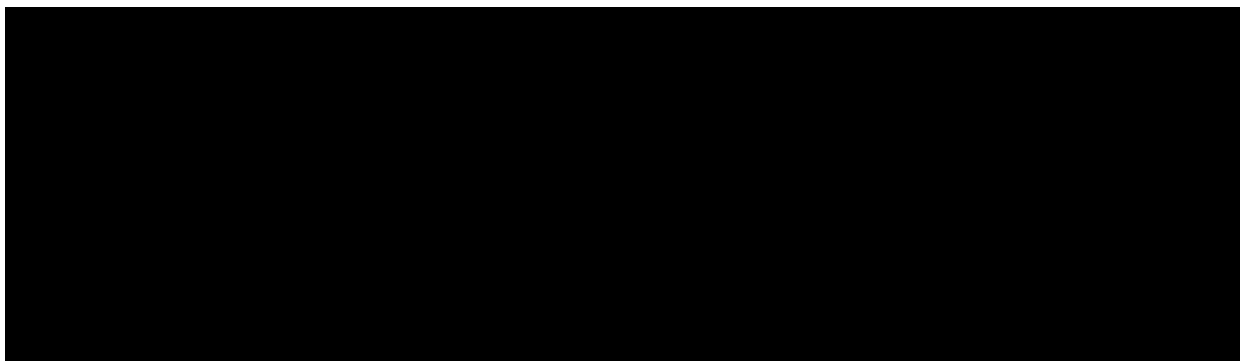
6. APPLICATIONS SUBJECT TO OUTSTANDING SECTION 21(1) PROCEDURE  
(CSM/72/60)



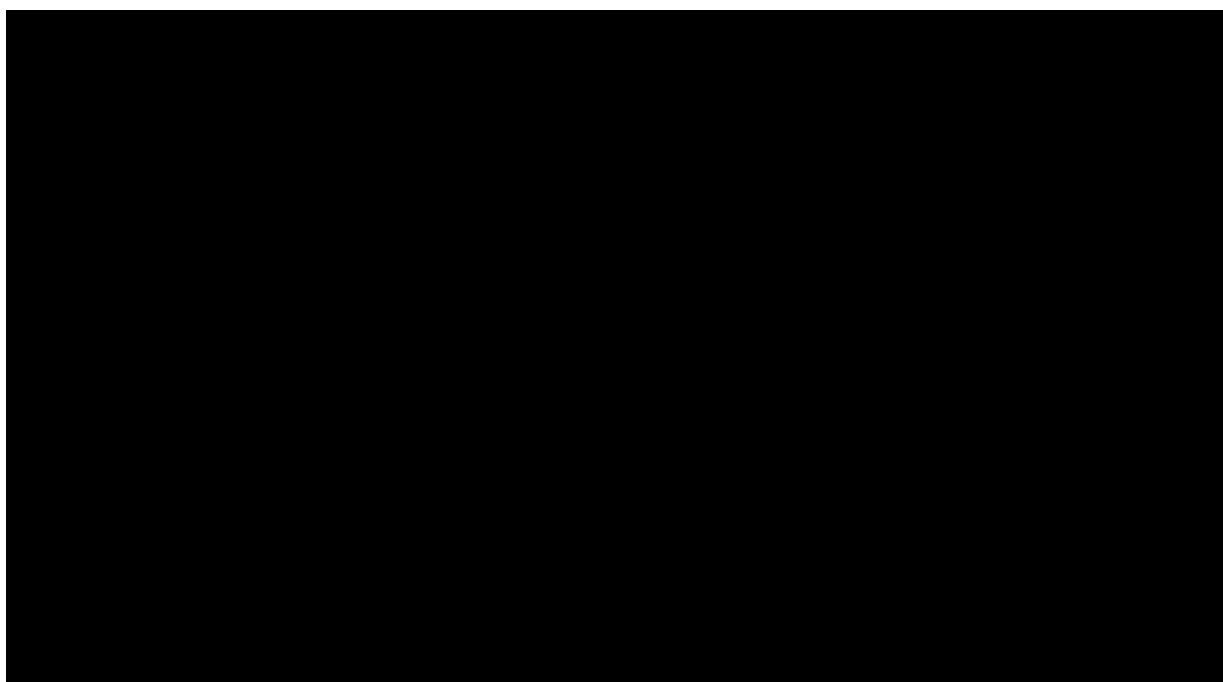
The Committee noted that regarding:



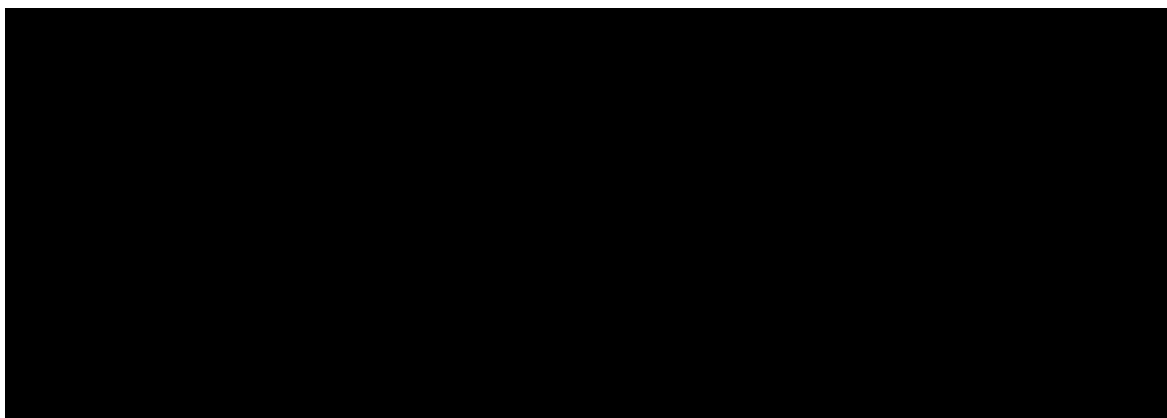
7. MEDICAL ASSESSOR'S REPORT



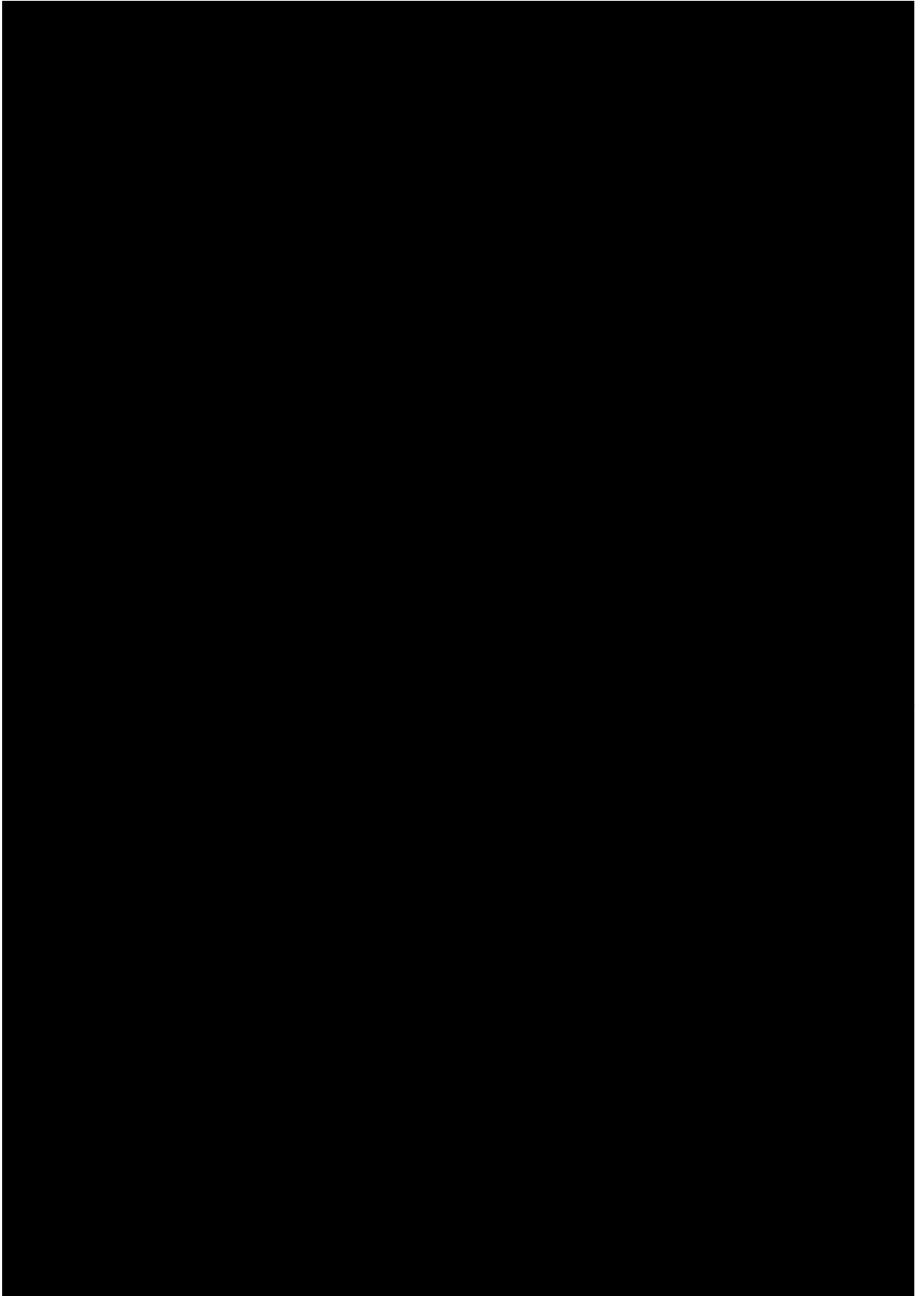
8. CONFIDENTIALITY OF INFORMATION SUPPLIED UNDER THE PROVISIONS OF THE MEDICINES ACT (CSM/72/59).



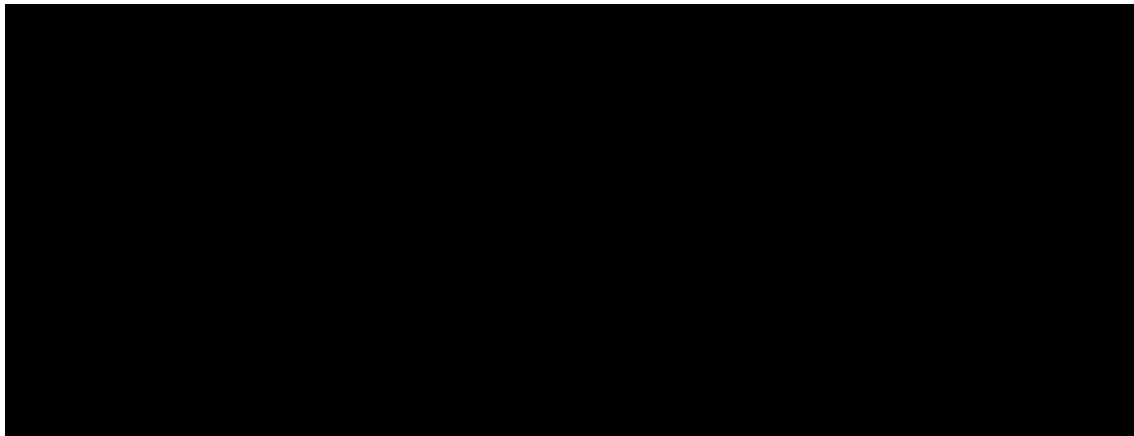
9. MINUTES OF THE SUB-COMMITTEES



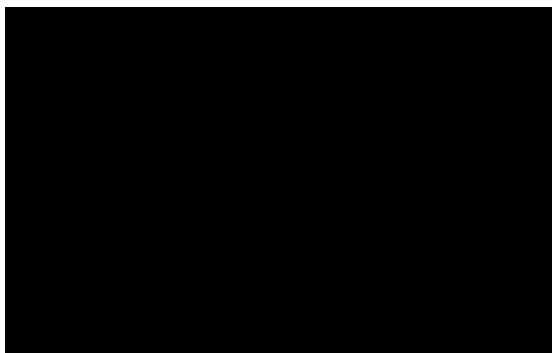
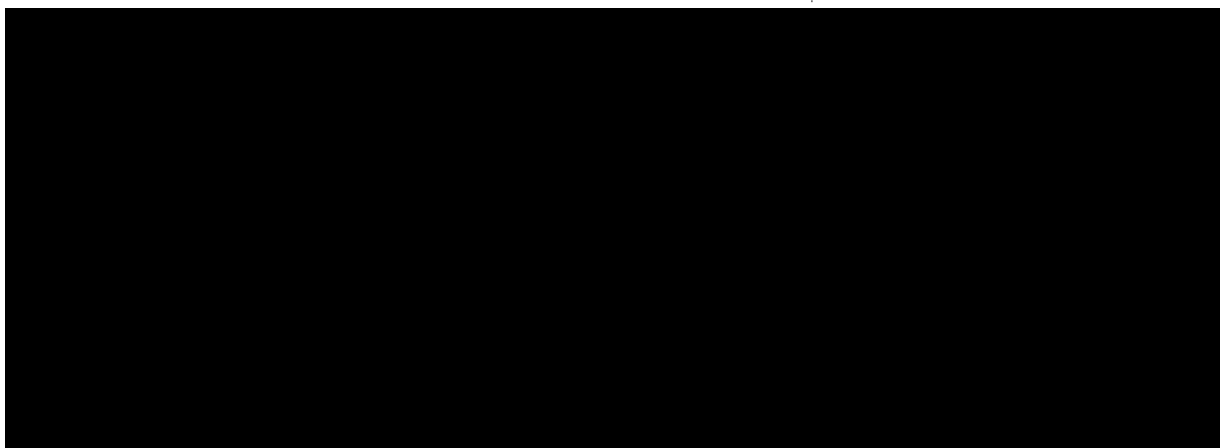
10. OTHER BUSINESS



10.4 APPLICATIONS IN RESPECT OF ORAL CONTRACEPTIVE APPLICATIONS



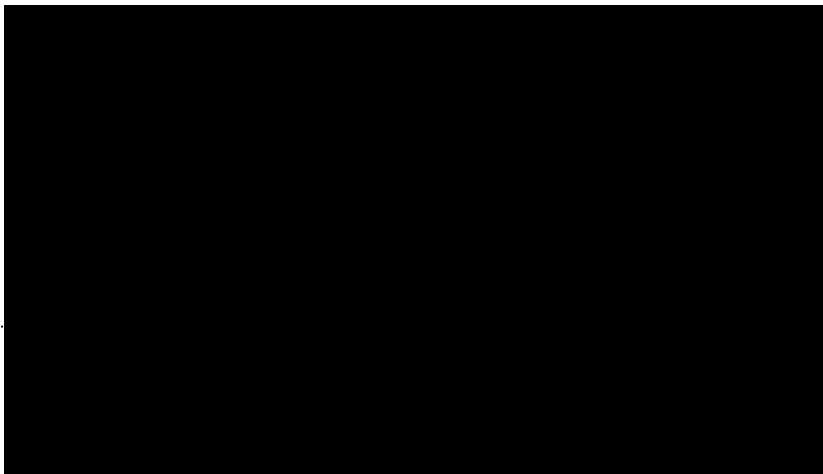
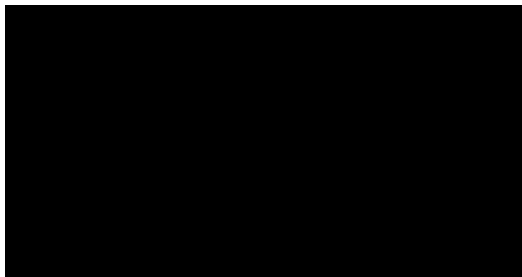
11. DATE AND TIME OF NEXT MEETING

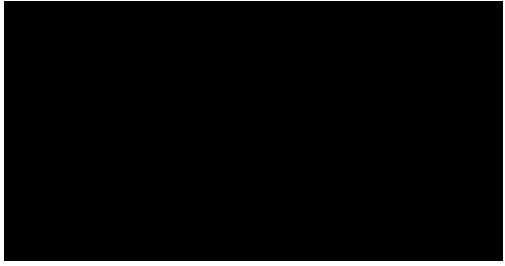


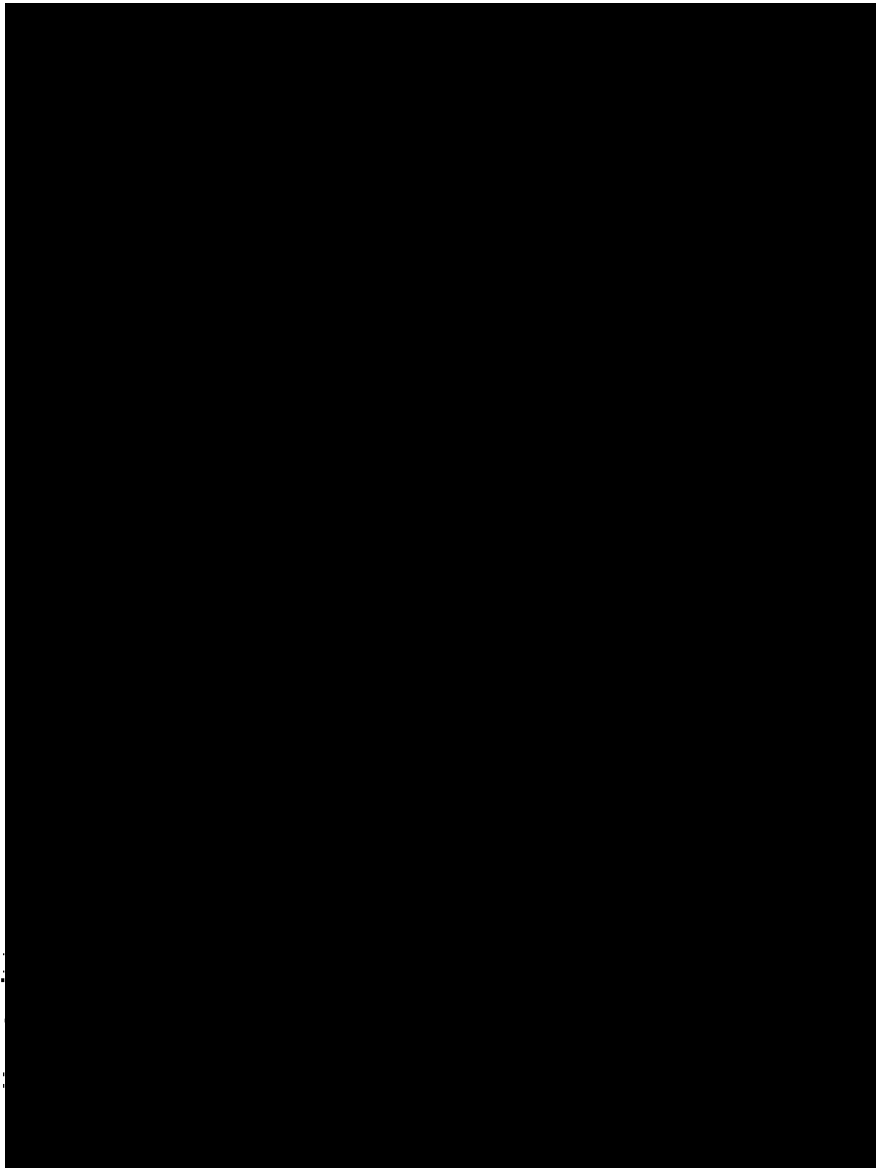
COMMITTEE ON SAFETY OF MEDICINES

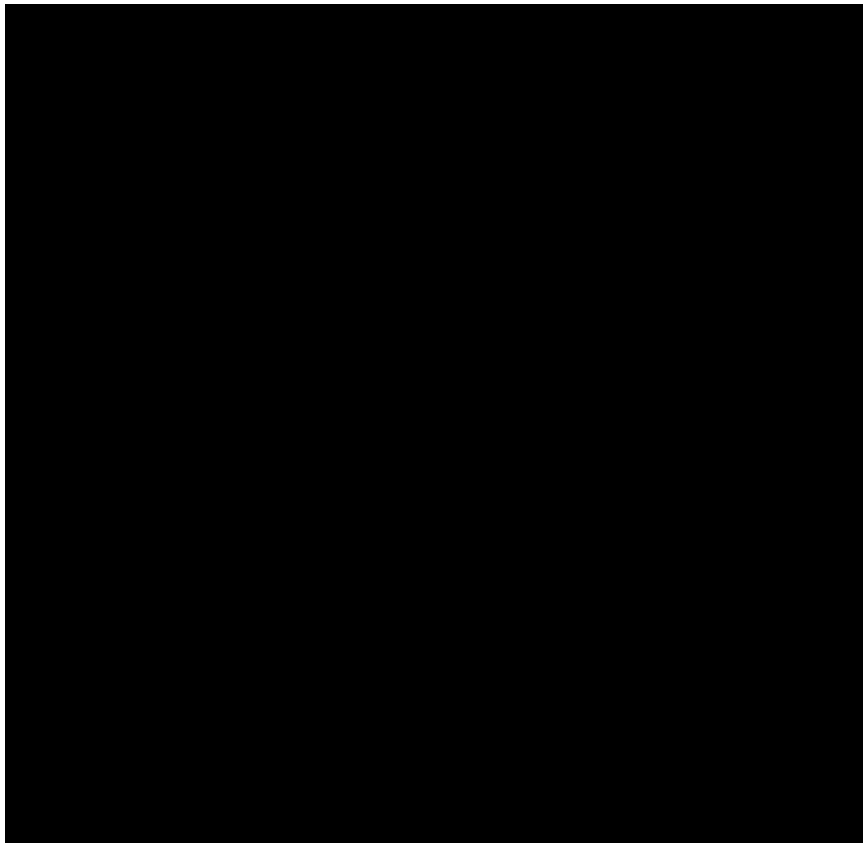
Appendix A to minutes of meeting held on 22 June 1972

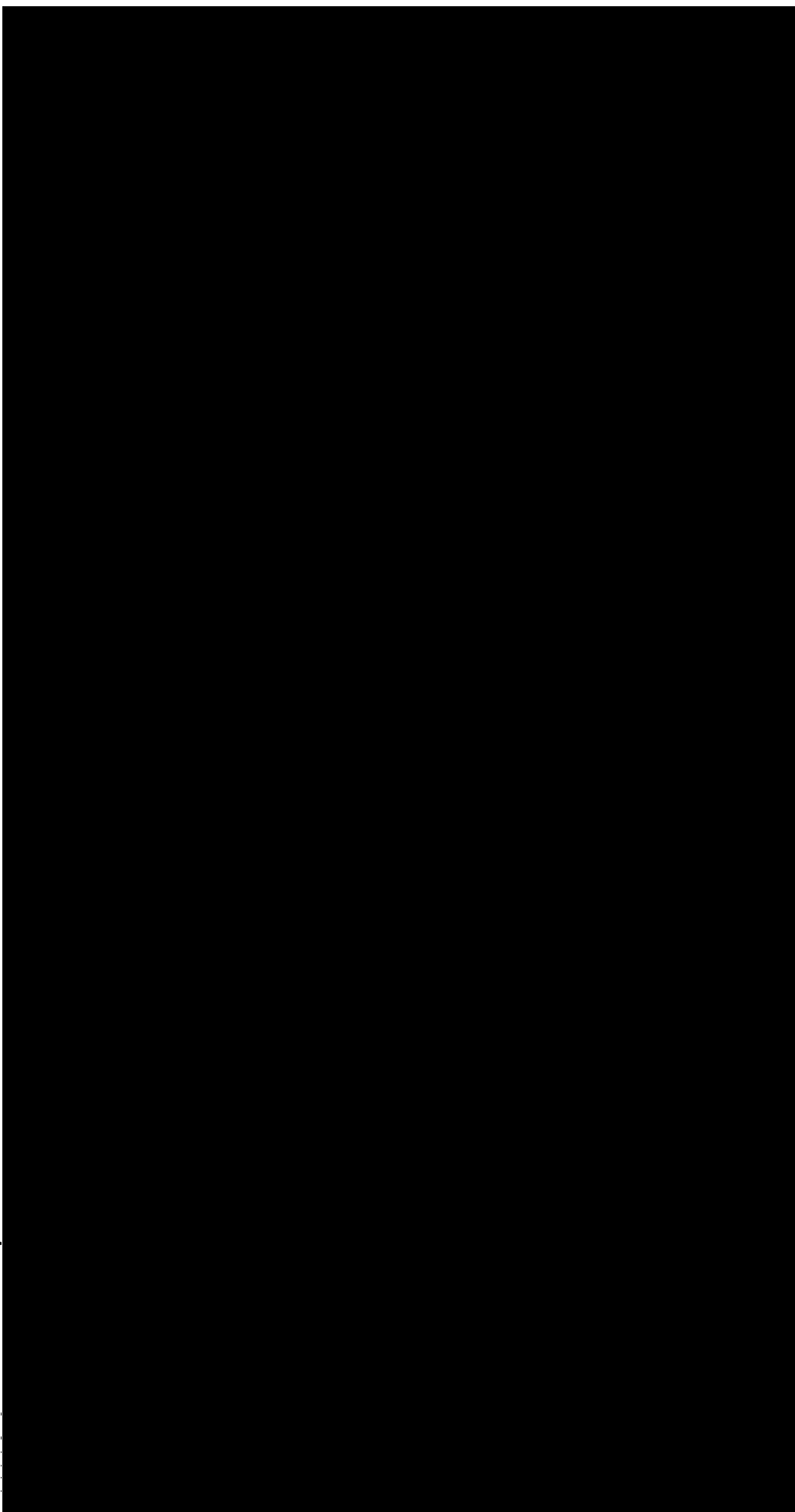
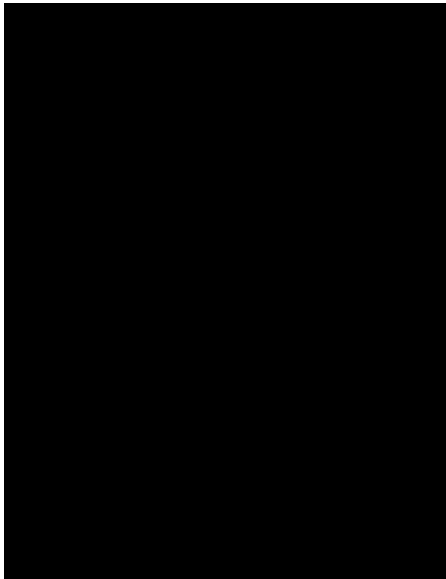
Summary of recommendations and advice on applications



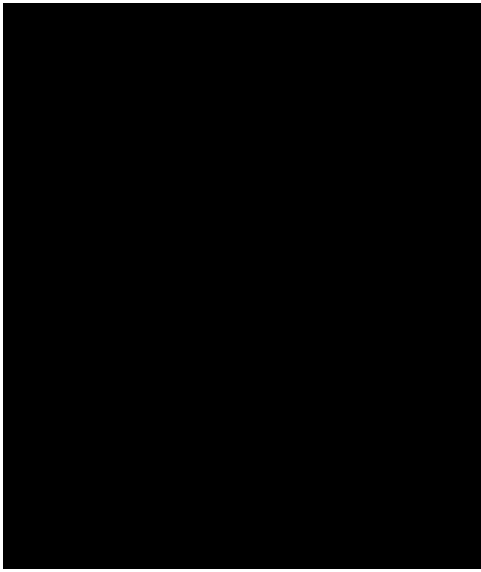


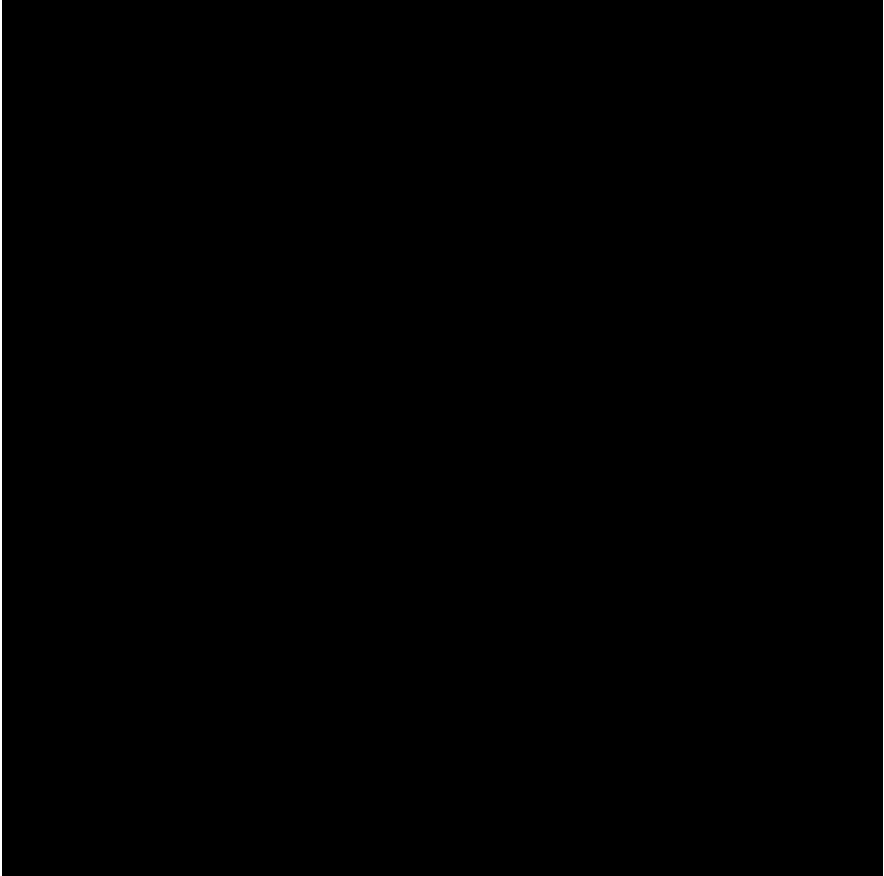


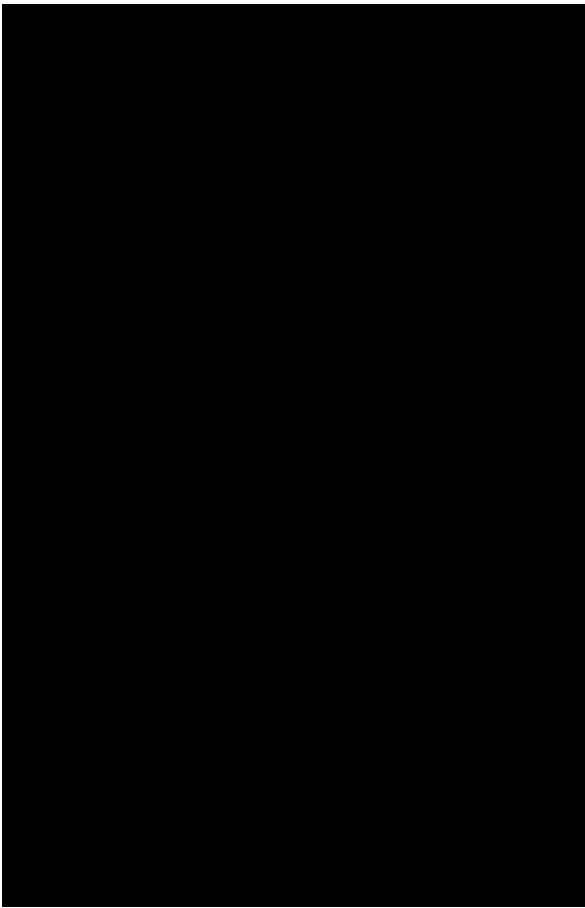


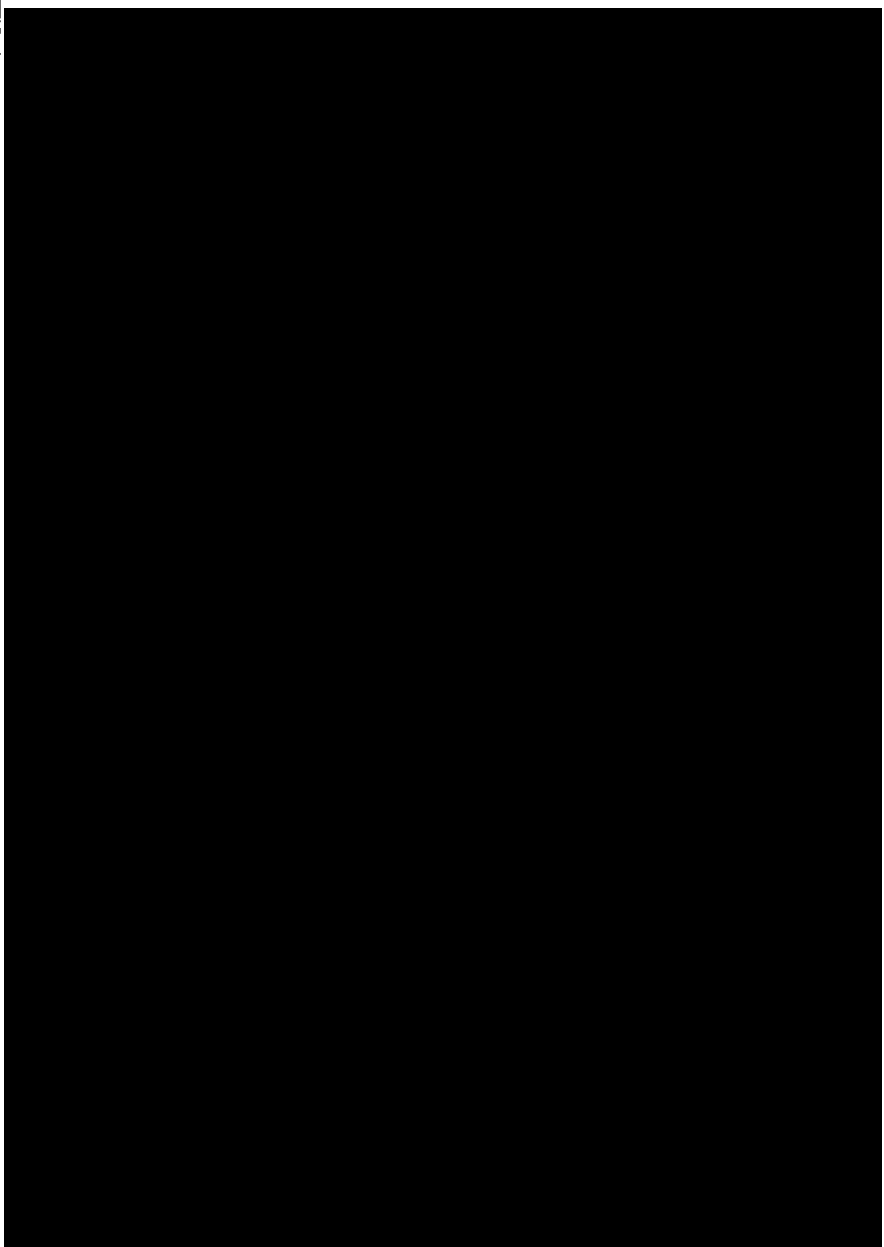


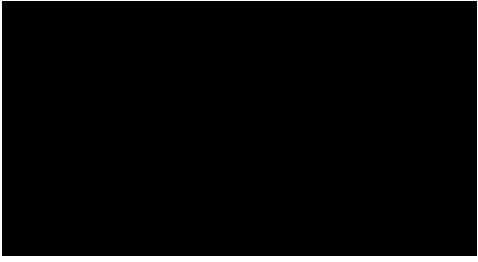
(continued on page 5a)



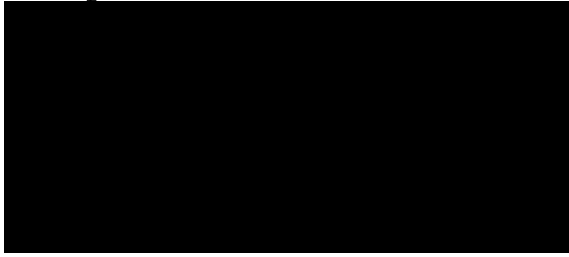


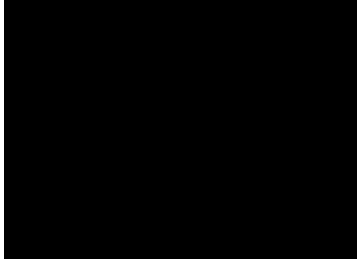


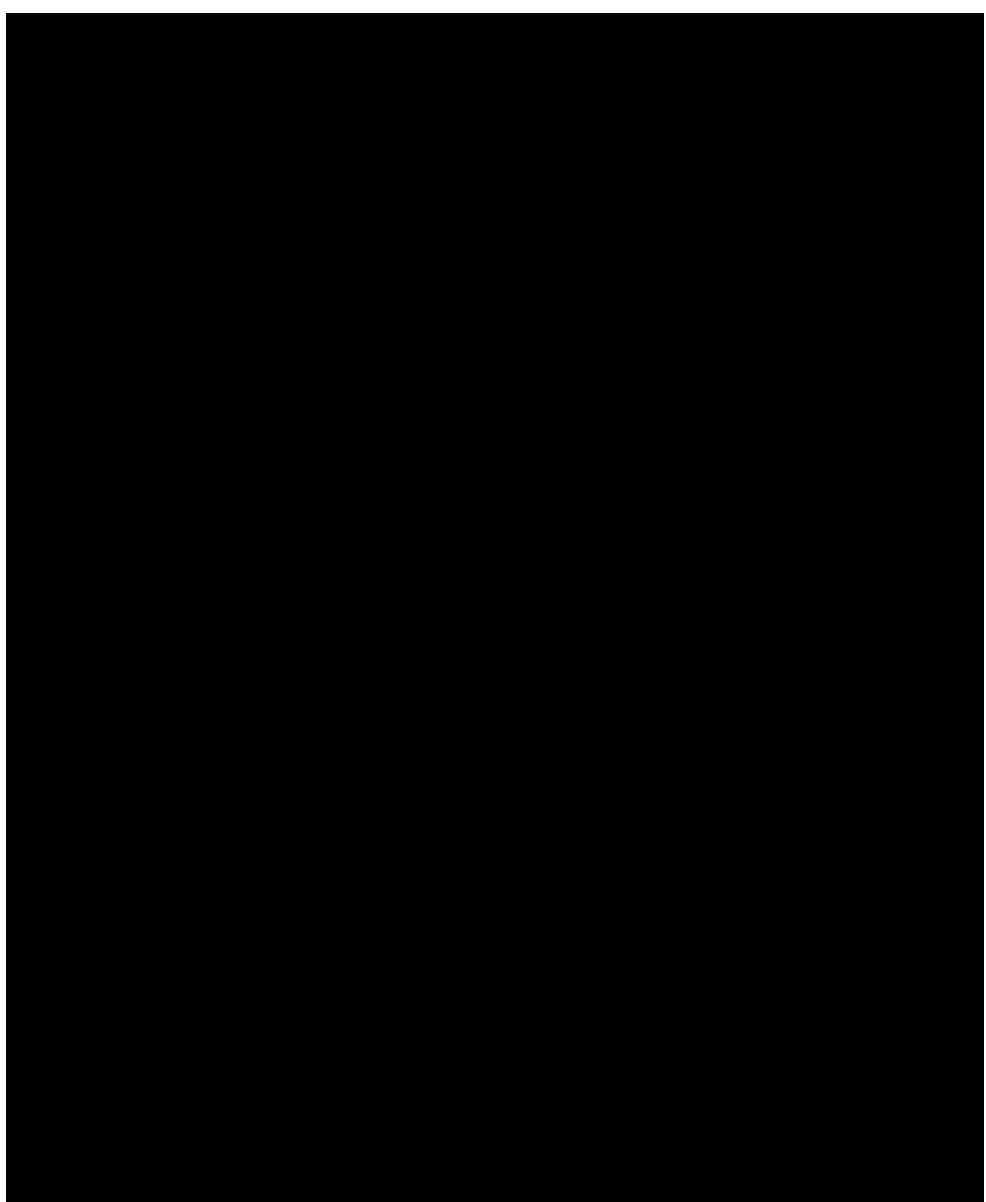
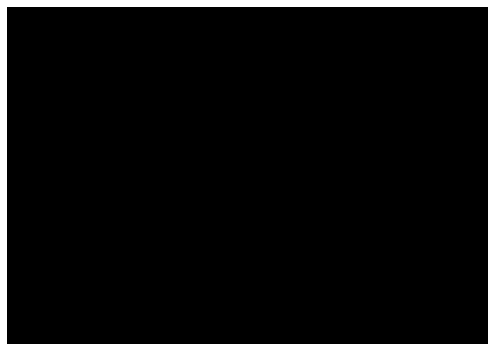






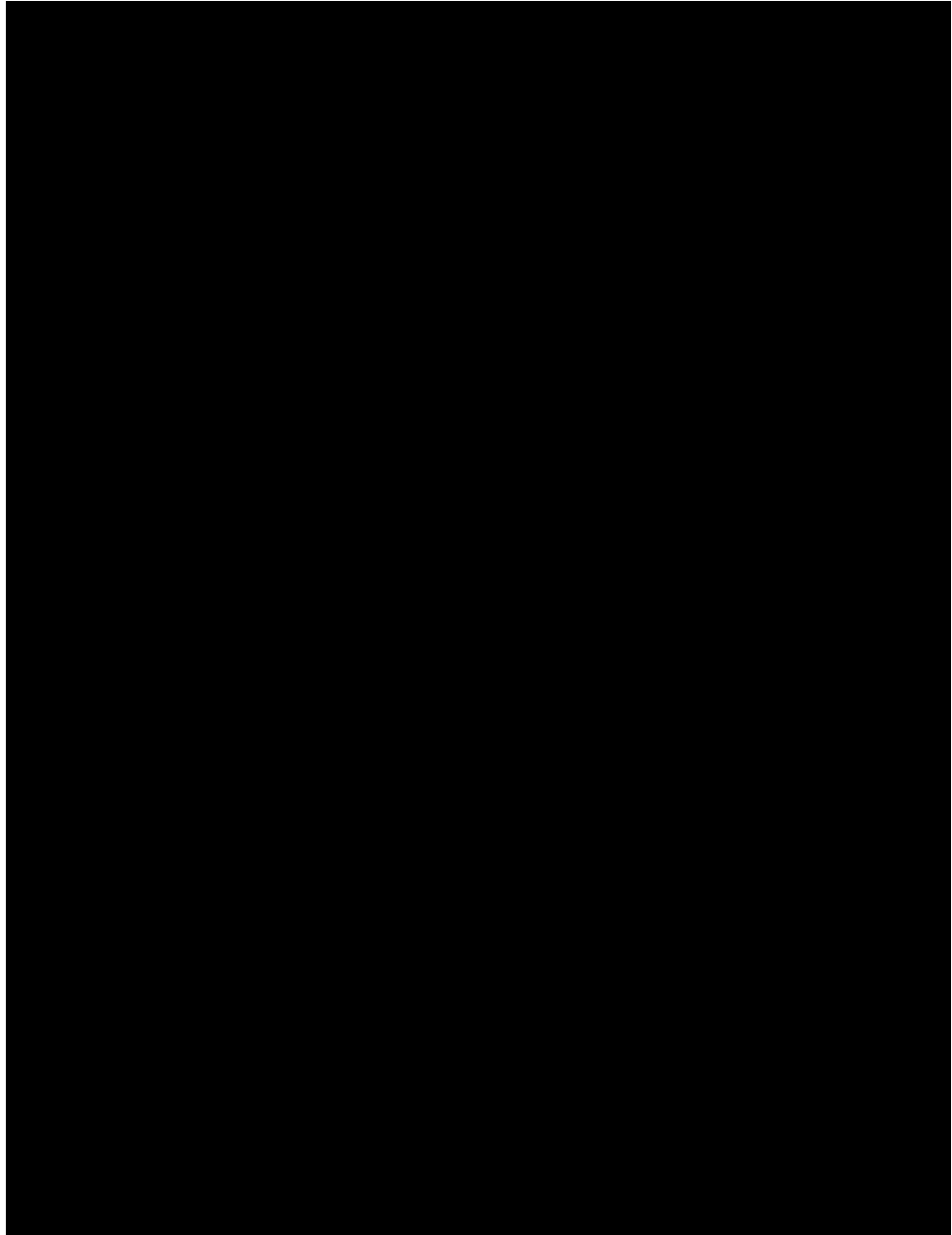
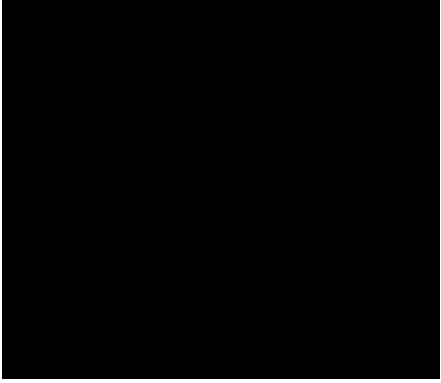


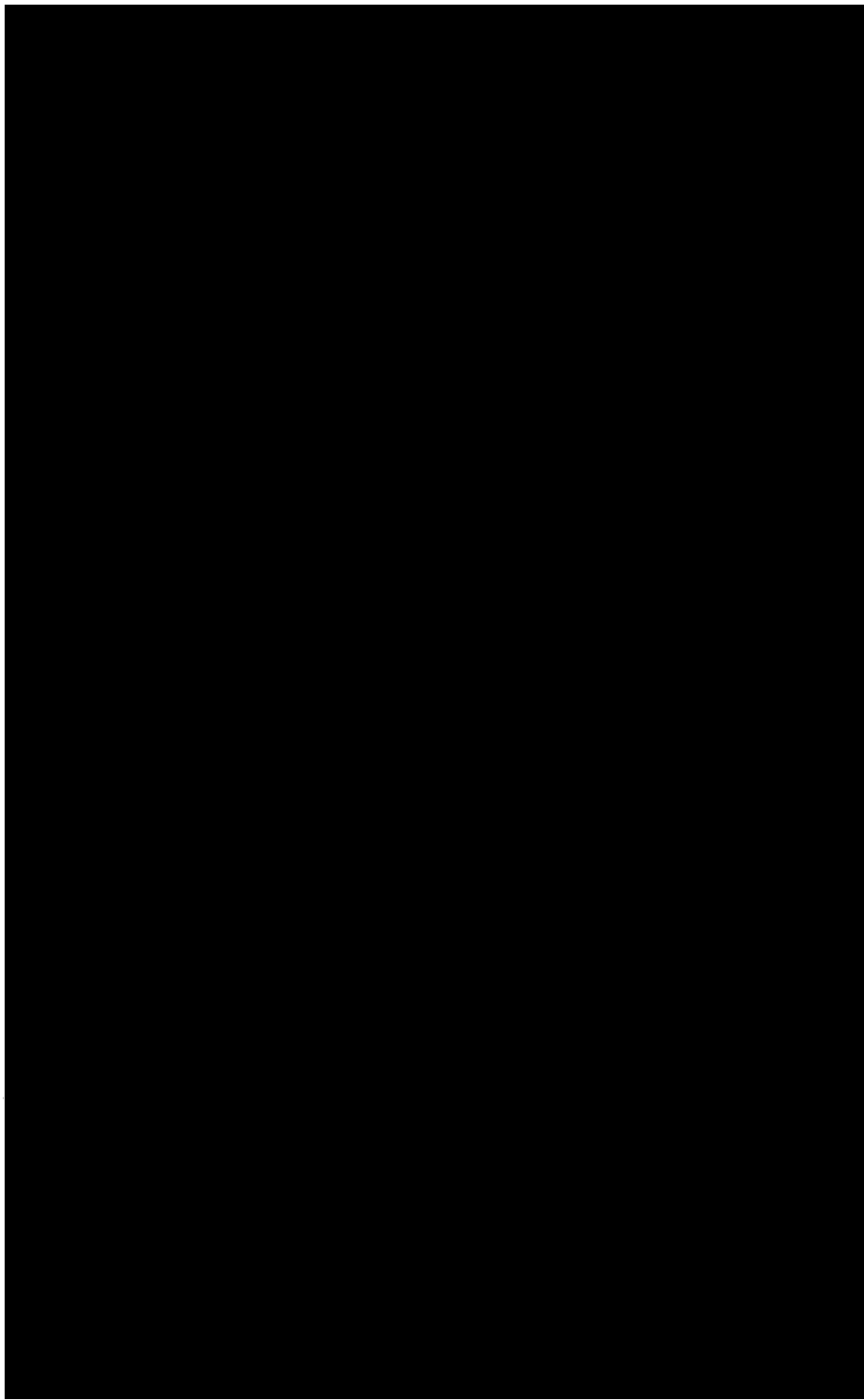
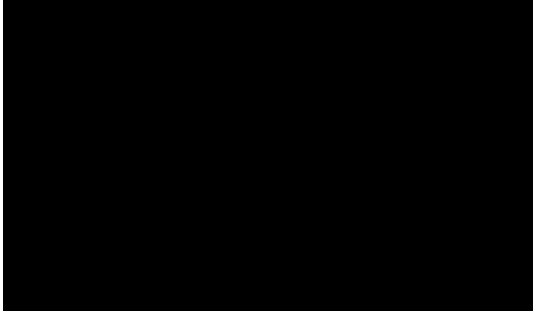












PL/0623/0001  
PL/0623/0002

Pharmacy Products UK Ltd

Labazene Tablets  
" Solution

(Anti-Convulsant)

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

The Sub-Committee recommends that a decision on these products should be deferred pending discussion with the applicants as to whether they would be prepared to conduct clinical trials comparing the product with phenytoin, since evidence of efficacy and safety in the clinical studies is inadequate.

Remarks

Further toxicological and teratological data is also required.

Main Committee (January 1972)

The Committee agreed that a decision on these products should be deferred pending discussion with the applicants as to whether they would be prepared to conduct clinical trials comparing the product with phenytoin, since evidence of efficacy and safety in the clinical studies is inadequate.

Subject to the applicant being willing to undertake a clinical trial on the lines indicated, then issue of a certificate could be recommended without further reference to the Committee.

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

On the evidence before them the Sub-Committee are unable to advise the grant of product licences for these preparations for the purposes indicated in the application since the animal toxicology, including teratology provided is inadequate, and the data which has been presented gives ground for concern in view of the expected long term administration of the drug.

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

Tablets - PL/0623/0001

On the evidence before them the Sub-Committee recommend the grant of a product licence for one year for this preparation for the purposes indicated in the application provided that promotion is limited to hospitals and other centres specialising in the treatment of epilepsy, and subject to all patients being monitored for therapeutic efficacy and safety.

Solution - PL/0623/0002

The Sub-Committee recommend that a decision on this product should be deferred pending the outcome of discussions between the Sub-Committee on Chemistry and Pharmacy and the applicant on the question of the "dropper" for use with this preparation.

(continued on page <sup>18</sup> 37a)

PL/0623/0001  
PL/0623/0002

Pharmacy Products UK Ltd

Labazene Tablets  
" Solution

(Anti-Convulsant)

Main Committee (June 1972)

Tablets - PL/0623/0001

On the evidence before them the Committee advise the grant of a product licence for one year for this preparation for the purposes indicated in the application, provided that promotion is limited to hospitals and other centres specialising in the treatment of epilepsy, and subject to all patients being monitored for therapeutic efficacy and safety. 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.

Solution - PL/0623/0002

The Committee noted that the applicant did not wish to proceed at this time with the Solution.

COMMITTEE ON SAFETY OF MEDICINES

Minor applications for Clinical Trial Certificates and Product Licences

