NOTE OF MEETING ON 10 DECEMBER 1986 ON ASSESSMENT REPORTS: RESPONSIBILITIES AND PROCEDURES

Present :

Mr A G STewart
Dr D Jefferys
Dr R Mann
Dr P Adams
Mr A C Cartwright
Mr R Cox

1. Introduction

EEC Directive 83/570/EEC came into force on 1 November 1985 changed the existing 75/319/EEC Directive in relation to Chapter III, the Committee for Proprietary Medicinal Products. Article 13 now makes it mandatory for the competent national authorities to prepare an assessment report for any product containing a new active substance. The purpose of the meeting was to discuss arrangements for providing such assessment reports.

2. Incoming NAS Licence Applications previously licensed elsewhere in another EC Member State

The Preamble to 83/570/EEC states that the fact that a PL is in existence elsewhere in the EEC has to be given 'due consideration'. It is also stated that where one Member State wished to refuse a PL for a product licensed elsewhere in the EC, it should refer the matter to the CPMP for an opinion. It was noted that this suggestion was contained in the Preamble to 83/570/EEC and was not part of the Directive. It was agreed that CPMP would not normally be consulted in cases where the UK wished to take S.21(1) etc action on an NAS application licensed elsewhere.

It was noted that where an NAS application is received which has been licensed elsewhere that an assessment report should now be requested so that the previous licence can be given due consideration. It was noted that the report was likely to need translation and some extra costs could be involved with this aspect.

3. Multi-state procedure and incoming licence applications

NAS applications through the Multi-state procedure should involve consideration of assessment reports from the Member State who had licensed the product. Dr Jefferys reported that assessment reports had been requested for current Multi-state applications but had not been received. Unless such reports were available immediately they could not be used by assessors or by the UK sub-committees/CSM.

It was agreed that the attention of CPMP would need to be drawn to the need for assessment reports to be received in time for them to be used. If there were objections to grant of a licence raised, then the letter to the CPMP Secretarial setting these out would also mention if the assessment report had not been available.

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4. Procedures, requirements, deadlines

It was agreed that it would be useful to have a flow diagram (agreed after legal advice). Mr Cox agreed to draw this up and obtain legal clearance.

5. Contents of Assessment Reports

The assessment report on an NAS - from the UK would normally comprise the following elements:

5.1 Expert Report (where this was put to S.4 Committee in its entirety. If it was not put to the S.4 Committee, then the summary of the data from the professional assessors would be substituted).

5.2 Summary of S.4 Committee deliberations with an explanatory linking text.

5.3 Summary of any Appeal data.

5.4 The approved Summary of Product Characteristics.

5.5 Drug Analysis Printout (ADR).

5.6 Summary of Licence Variations.

5.7 An index to all of the above documentation.

This report for any product which had been on the market for a while might be very lengthy and might be difficult for others to read and understand. It would have been preferable for assessors to provide a shorter condensed document (equivalent to the FDA Summary Basis of Approval) but present staffing resources would not permit this.

6. Administrative Support and Oversight

It was agreed that a designated officer would be needed for this work of at least HEO rank as the Multi-State Licence Applications Liaison Officer. There were arguments for such an officer to be part either of MB6 or MB1, and Mr Hale and colleagues would be asked to consider what arrangements would be needed for this work.

The designated officer would be able to prepare the first draft of the report from the data on file and this would then be subjected to professional oversight. The designated officer would be the nominated Divisional Contact point, and responsible for transmission of such reports on request.

7. Confidentiality

Some questions were raised about the confidentiality of the assessment reports which might refer to data on other products etc. The Liaison Officer would need to be sensitive to this issue and of the need to consult professional staff where appropriate.

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It was felt desirable for a legal view to be sought on confidentiality of the assessment reports. These could be supplied to requesting countries to the Commission for both bilateral discussions and the Multi-State procedure, but should copies be sent to the industrial companies concerned? For some products there would be different licensees in different Member States and it might not be appropriate to supply copies of assessment reports without first checking with the company making the PL application.

The meeting felt that copies of the assessment report should not be sent to companies. Dr Jones would be asked to confirm the policy on this matter.

8. General

The new requirements for assessment reports would mean provision of extra administrative staffing and increased professional time. The new procedures should be kept under careful review.

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A C CARTWRIGHT
Room 1531 MT
Ext GRO-C

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