

DATE OF SUMMARY: JANUARY 2001

**SUMMARY OF THE MEETING OF THE COMMITTEE ON SAFETY OF MEDICINES
SUB-COMMITTEE ON BIOLOGICALS HELD ON 1st NOVEMBER 2000**

Committee Members

Present

Professor G W Duff (Chairman)
Dr M E Bruce
Professor C Bucke
Dr F G H Hill
Professor D J Jeffries
Professor N A Mitchison
Professor R A North
Professor S H Ralston
Dr G C Schild

Professional Staff of MCA

Principal Assessor

Dr L Tsang

Supporting Specific Items

Licensing Division

Mr D Jones
Dr J Lawrence
Dr R Shivji
Dr J Warren

Apologies

Professor D H Calam
Professor M W J Ferguson
Professor P R Lowenstein

Others

Dr J Cook MCA/L
Dr T Improta-Brears MCA/L
Mr G Inwards MCA/L
Dr G Kondowe MCA/L
Dr A Nicholson Acting Director, Licensing
Dr T Pepper MCA/L
Dr P Richardson MCA/L
Dr F Rotblat MCA/L
Dr K Jones Chief Executive, MCA
Dr A Thomas MCA/L

Secretary

Mr L M Williams

**NOTE: MCA STAFF MAY BE PRESENT FOR ALL OR PART OF THE MEETING
OR FOR SPECIFIC AGENDA ITEMS**

1. APOLOGIES AND ANNOUNCEMENTS

- 1.1 The Chairman reminded the Sub-Committee that the papers and proceedings were confidential and should not be disclosed. Members were also reminded to declare their personal specific, personal non-specific, non-personal specific and non-personal non-specific interests in all agenda items.
- 1.2 The Chairman received apologies from Professors Calam, Ferguson and Lowenstein for the day.

1.3 The Chairman welcomed Dr Teresa Improta-Brears who had recently joined the Agency.

2. **MINUTES OF THE MEETING HELD ON 6th SEPTEMBER 2000**

The minutes were signed and agreed as a true record of the meeting.

3. **MATTERS ARISING FROM LAST MEETING**

None.

4. **NEW PRODUCTS**

The Sub-Committee considered nine applications. Members had no interests to declare - [see note 1 below]

5. **PAPER - Poliomyelitis Vaccine**

The Sub-Committee considered a paper concerned with the supply of poliomyelitis vaccine and made recommendations to the CSM. Interests were declared - [see note 2 below]

6. **PAPER - Sourcing Of Plasma – Derived Medicinal Products**

The Sub-Committee was informed that the observation as published by Houston *et al*, using an experimental model to vCJD, was consistent with the results obtained in rodents. The Sub-Committee concurred that there was a signal that infection could be transmitted even at sub-clinical stage of the disease. The Sub-Committee considered that the precautionary measures recommended by the CSM in 1998 should be extended to products manufactured from plasma sourced from countries with more than one confirmed case of vCJD. The Sub-Committee also agreed that consideration should be given to extending the precautionary measures to plasma products derived from countries with BSE. However, this recommendation would require careful consideration to avoid disruption in supplies of essential life-saving products. A further review is therefore required particularly with regard to how the source plasma from different countries are pooled.

Following a review of the sourcing of plasma products currently licensed in the UK and a discussion in of the recent report in 'The Lancet' describing transmission of BSE by blood, the Sub-Committee recommended that:

- the precautionary measures currently in place for UK source plasma be extended to include medicinal products with source plasma derived from countries with one or more confirmed cases of vCJD.
- consideration should be given in this recommendation to including products from countries with BSE. Further information should be obtained from fractionators regarding the pooling of plasma sourced from different countries to ensure that such a measure would not disrupt product supply.

7. **ANY OTHER BUSINESS**

None.

8. **DATE AND TIME OF NEXT MEETING**

The next meeting will take place on **Monday 8th January 2001 at 10.30am.**

Michael agrees OK

Note 1: information about these applications is being withheld on the grounds that this advice remains confidential as at the date of this summary and publication would be premature while regulatory action continues. The advice will be published in due course. Exemption 10 of the Code of Practice on Access to Government Information applies

Note 2: information about this item is being withheld on the grounds that advice remains confidential as at the date of this summary and publication would be premature while regulatory action continues. The advice will be published in due course. Exemption 10 of the Code of Practice on Access to Government Information applies