NOT FOR PUBLICATION

COMMERCIAL IN CONFIDENCE

ARVI/87/3rd Meeting

COMMITTEE ON SAFETY OF MEDICINES/ JOINT COMMITTEE ON VACCINATION AND IMMUNISATION

JOINT SUB COMMITTEE ON ADVERSE REACTIONS TO VACCINES AND IMMUNISATION

Minutes of the meeting held on Friday 2 October 1987 at 10.30 am in Room 1611/1612 Market Towers

Present:

Professor J Collee (Chairman)
Sir J Badenoch
Dr N Cavanagh
Dr P Fine
Dr B McGuiness
Professor S R Meadow
Dr C Miller
Dr D Reid
Dr S Wallace

DHSS

Dr D Salisbury (Assessor
Mr K Fowler (Secretary)
Mr A Akinyele
Mr J McCracken
Dr R Mann
Dr F Rotblat
Dr A Scott

1. Confidentiality and Announcements

1.1 The Chairman reminded members that the proceedings, papers, and information before them were confidential and should not be disclosed.

1.2 The Chairman welcomed Dr Scott who had recently joined Medicines Division and was attending his first meeting of ARVI.

2. Apologies for absence

Apologies had been received from Professors Banatvala, Breckenridge, Hull, Miller and Dr Bowie.

3. Minutes of the last meeting

The minutes of the meeting held on 6 July had been circulated and members amendments were noted. They were signed by Professor Collee.

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4. Matters arising from the last minutes

The following items were discussed:

Item 6.2 It was felt that the second paragraph of this heading failed to reflect Professor Miller's views and Professor Miller has therefore been asked to submit a summary of Paper ARVI(87)8 relating to the NCES data discussed at the meeting on 3 October 1986.

Item 6.3 "Therefore" (para 2, line 5) to be deleted.

Item 6.4 JCVI's Revised Contra-indications to Pertussis Vaccine

Professor Collee reported that the discrepancy between JCVI recommendations and manufacturers product licenses had been discussed at CSM who had upheld JCVI's right to issue advice to the profession.

Sir John Badenoch reported that a meeting was shortly to be held with the Pharmaceutical Industry to find common ground on issues such as this. Dr Salisbury stated that DHSS Solicitors views of this discrepancy had been sought and had been advised that there was no obligation on JCVI's views to conform with the manufacturers product licenses when those views represented the advice of expert medical opinion.

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5. Working Group on Protocols for Treatment of Anaphylaxis

It was agreed that a Group would need to meet quickly to complete these recommendations for the Memorandum or alternatively, to distribute material by post. Dr McGuinness had already provided valuable material for this purpose and Dr Salisbury offered to send examples of the material on anaphylaxis to Professor Meadow.

6. Processing and use of data from the Register of Adverse Reactions

Dr Mann described the changes in data processing a d on quality control which would follow the introduction of new computing facilities. There would be fewer backlogs and the opportunityfor screening of individual reports.
The example printouts of reported reactions were explained and the anticipated future improvements discussed.

7. Suspected Adverse Reactions to Vaccines : Report on Yellow Cards

Dr Salisbury presented a paper which discussed some of the aspects of analysis of the Yellow Card data and identified other epidemiological information which could be considered in association with the adverse reaction reporting.
Sample printouts of summaries and analyses of reactions were available. Professor Collee reminded members that the role of ARVI was not to consider the minutiae of vaccine reactions and expressed a wish that there should be summary of data rather than discussion of excess material. Dr Reid

asked if analyses were possible according to manufacturer and Professor Meadow questioned the delays in reporting and coding. These points were answered by Dr Mann.

Sir John Badenoch commented that general practitioners should be aware of the need for specificity of vaccine and batch and Dr Mann agreed to investigate this.

8. Vaccination and Cot Deaths in Perspective

There was discussion by the Committee of the reports made available on this topic and Professor Meadow identified the need for the present information, that there did not appear to be a causal relationship between pertussis immunisation and SIDS, to be disseminated and suggested the Foundation for the Study of Sudden Infant Death could promote the present knowledge. Dr Fine noted that there was a methodological problem preventing the conclusion that pertussis vaccination was protective against sudden infant death syndrome as those risk factors for sudden infant death syndrome may overlap with the contra-indications for vaccine and this issue had not been dealt with in the submitted papers. Professor Meadow questioned what risks were common to contra-indications and SIDS and Dr Fine mentioned factors such as ill-health and socio-economic issues which inhibited pertussis immunisation.

9. Investigation of the effects of influenza vaccine on drug metabolism.

This paper and its conclusions were noted. Merieux plan to study the effects of theophyllinewith their influenza vaccine and then submit data.

10. Reactogenicity of Meningococcal A and C Vaccine in a population of United Kingdom school children

This paper was discussed and members noted that meningococcal vaccines still were without product licence. Dr Salisbury described the consequences of the outbreak of Group A meningococcal infection in Mecca, with cases in this country and a huge demand for vaccine. A CMO letter had been sent to all doctors advising them of the approprite use of meningococcal vaccine in September.

11. Dates of Meetings in 1988

It was agreed that the Sub Committee should meet on two occasions during 1988, on Tuesday 8 March, and Friday 2 September, and not as previously notified.