JOINT SUB-COMMITTEE ON ADVERSE REACTIONS TO VACCINATION AND IMMUNISATION

Minutes of the meeting held on Tuesday 8 March 1988 at 10.30am in Room 1612, Market Towers

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| Present | Professor J Collee (Chairman) | |
| | Professor J E Banatvala | |
| | Dr N Cavanagh | |
| | Dr J Cameron Bowie | |
| | Dr P E M Fine | |
| | Professor D Hull | |
| | Professor D G McDevitt | |
| | Dr B W McGuiness | |
| | Professor S R Meadow | |
| | Professor D L Miller | |
| | Dr E Miller | |
| | Dr D Reid | |
| DHSS | Dr D M Salisbury | - Assessor |
| | Mr K Fowler | - Secretary |
| | Dr R Mann | |
| | Dr F Rotblat | |

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 announced that this was the last meeting of the Sub-Committee which would be attended by Dr Mann, the Medical Assessor of the CSM's Adverse Drug Reaction Section, because he would be retiring at the end of the month. The Chairman and members extended their thanks to Dr Mann for the work and advice he had given the Sub-Committee and wished him well in his retirement.

2. Apologies for Absence

Apologies had been received from Professor Breckenbridge, Sir John Badenoch and Dr Wallace.

3. Minutes of the last meeting

The minutes of the meeting held on Friday 2 October 1987 were signed by the Chairman as a true record of the meeting after adding Professor McDevitt's name to the list of apologies for absence.

4. Matters arising from the Minutes

4.1 Item 6.2 of the minutes of the July 1987 meeting - redraft of this paragraph (ARVI/88/1) was agreed by members and replaces the previous draft.

4.2 Item 7 (October 1987 minutes), paragraph 2 - reported about the CSM proposal for a pilot study to involve community pharmacists in the reporting of adverse drug reactions, which he thought would pick up information of the kind required.

4.3 Item 11 - the Chairman brought the attention of members to the date of the next meeting which will be Friday 2 September 1988.

5. Treatment of Anaphylaxis

The section on Anaphylaxis from the forthcoming edition of the Memorandum "Immunisation against Infectious Disease" had been made available to the Committee. The Anaphylaxis Section had been written to incorporate the recommendations of

The Committee recommended that this section should be made available to the British National Formulary who may wish to include it in subsequent editions.

6. Report of Yellow Card Data

There was considerable discussion of the information on reactions to vaccines during 1987. commented that this format of ~~this~~ the data was more appropriate for the Committee's needs, provided that the Committee's attention could be drawn to any important or unusual reactions. The frequency of adverse reactions to influenza vaccine was noted, perhaps reflecting the age and ill-health of the target recipients and JCVI may wish to consider the specificity of recommendations for appropriate groups. asked if information could be made available on the timing of convulsions in relation to immunisation. asked for information to be available in the future on reactions to plasma derived or recombinant hepatitis B vaccine. cautioned the Committee on interpretations or comparisons when there was a

significant degree of under-reporting. The figures were accepted as being useful for alerting ARVI ~~of~~ to evolving problems.

7. Adverse Reactions Surveillance

introduced his paper on adverse reaction surveillance as a spontaneously generated contribution which was not a criticism of present policies. He expressed anxieties that since the loss of public confidence in pertussis vaccine, the public had become far more critical of all vaccines. He recommended consideration of a monitoring system for vaccine reactions which would cope with any vaccine related adverse publicity. There was considerable discussion of this paper which received the widespread support of ARVI. The Committee agreed the following recommendations:-

(a) There was a need for good and adequate reporting of adverse drug reactions with control data where available.

(b) The Committee had reservations about patient generated data often involving event reporting, endorsed the need for doctor generated reporting and noted the resource implications of any new scheme. Existing facilities were acknowledged such as the Red Alert Scheme.

(c) The Committee suggested that a Working Group should be convened involving Dr Cameron Bowie, Dr Salisbury and the

ARVI secretariat who could co-opt other expert advisers to then provide advice for JCVI and CSM.

(d) The District Health Authority Immunisation Co-ordinators were identified as individuals who may have an important role in adverse reaction surveillance at district level and the possible involvement of CDSC/CDC was identified.

(e) paper will be submitted to JCVI as soon as possible.

8. Measles, Mumps, Rubella (MMR) Vaccines

(a) reported to the Committee on the steps which had been undertaken and were to be implemented in he near future for the introduction of MMR. The District Immunisation Co-ordinators had been identified as essential links in the dissemination of information to all those professionals involved in immunisation in each District. The Co-ordinators were all due to attend a meeting at DHSS on 15 March to discuss the implementation of MMR.

(b) spoke on the MMR trials which had been carried out using Health diaries on approximately 5,000 children in Fife, Somerset and North Hertfordshire. There had been no problem in introducing MMR into these districts and there had been a 90 per cent response from patients to

take part. The rate of convulsions in Somerset was two per 1,000, similar to the rate of convulsions after measles vaccine in the original MRC trial. Parotid swelling was noted ~~at~~ in approximately one per 100 children. The peak incidence of fever occurred eight to ten days after immunisation. Professor Hull spoke on the MMR trial in Nottingham and noted local concerns ~~of~~ about the potential infectivity of the mumps component of MMR to susceptible contacts. He was assured that the mumps vaccine virus is not transmissible.

(c) Five cases of mumps encephalitis following MMR have been reported from Canada. Four of these cases definitely followed the use of vaccine containing Urabe 9 mumps virus ~~containing vaccine~~, and the fifth probably did. This corresponded to a frequency of one per 100,000 doses and no sequelae had been reported in the sufferers. had discussed the incidence of mumps related complications from MMR with the Communicable Disease Center, Atlanta, whose data ~~was~~ were unfortunately only superficial on this issue. In the United States, Jeryl Lynn mumps virus is included in MMR but no data ~~was~~ were available on parotitis following MMR and many of the reported neurological complications were clearly related to the measles component. Two manufacturers have applied for Product Licences for the United Kingdom and both their vaccines contain Urabe 9 mumps virus. One manufacturer already had a Product Licence for vaccine containing Jeryl

Lynn mumps virus. After discussion, the Committee felt that the rate of adverse reactions to the mumps component of MMR from Canada was in keeping with that expected from live virus vaccine and endorsed the view that a study of the Jeryl Lynn containing vaccine should be carried out using the same health diaries as the present trial.

9. JCVI Memorandum

The rewriting of the 1988 edition of the Memorandum "Immunisation against Infectious Disease" had been completed and the material submitted to the printers. The publication was expected for mid-April. The Committee recommended that the Memorandum should have the widest possible distribution.

10. MMWR 36 Number 18 "Pertussis Immunisation"

This MMWR article had been distributed to Committee members for information. The ACIP had stated that a family history of convulsions should not be a contra-indication to vaccination with diphtheria and tetanus toxoids and pertussis (DTP) vaccine. In addition, the ACIP believed that antipyretic use in conjunction with DTP vaccination may be reasonable in children with personal or family history of convulsions.

11. Code of Conduct Disclosure of Interests

introduced this paper and explained the relevance of the proposed Code to Sub-Committee members. He briefly outlined the changes in the redrafted Code which members were being asked to consider, and which would be re-submitted to Ministers in due course. Some concern was expressed about the proposal to publish members' declared interests in the Committee's Annual Reports, and it was explained that this was the specific request of Ministers. invited any members who might have uncertainty about what they should personally declare to contact him or , the Secretary to the CSM.