JOINT COMMITTEE ON VACCINATION AND IMMUNISATION

Minutes of the Meeting held on Friday 6 November 1992, in Room 63/64 Hannibal House, 10.30am.

PRESENT:

MEMBERS:

Professor A G M Campbell (Chairman)
Professor J E Banatvala
Dr M F H Bush
Professor G Collee
Professor A Geddes
Professor P Grob
Dr I Jones
Professor H P Lambert
Professor R Levinsky
Professor C Peckham
Dr D Reid
Dr G Schild
Dr J B Selkon
Sir Joseph Smith

SECRETARIAT:

Dr D M Salisbury, HP(M)1
Mr L T Wilson, HP(A)3B

INVITED TO ATTEND:

Dr N T Begg, CDSC
Dr K Calman, CMO
Dr B Cooke, HEA
Mr M Corr, HEA
Dr E Miller, CDSC

OGD REPRESENTATIVES, etc.:

Dr J Faithful Davies MoD
Dr A Greer, DHSS (NI)
Dr J Ludlow, Welsh Office
Dr T V O'Dwyer, Ministry of Health (Republic of Ireland)
Dr O A Thores, SOHHD

DEPARTMENT OF HEALTH:

Mr R M Freeman, HP(A)3B
Dr J Hilton, HP(M)1
Dr J Leese, HP(M)1
Mr P Hayes HP(A)3B
Mrs S Philogene, NUR
Miss J StJuste, HP(A)3B

1) **ANNOUNCEMENTS**

The Chairman welcomed the Chief Medical Officer, Dr Calman, to the meeting; Dr Calman was able to stay for most of the morning session.

The Chairman announced that Sir Joseph Smith, who was retiring from the Directorship of the Public Health Laboratory Service, was also retiring from JCVI. Sir Joseph was thanked for the contribution he had made to the work of the Committee. Dr Diana Walford would to be Sir Joseph's successor.

Apologies for absence were received from Professors Breckenridge, Miller and Crompton, from Dr MacFarlane and Mrs Roden; from Dr Trevitt (MRC), Dr Tamblyn (Canada), Dr Bartlett (PHLS) and Dr Rotblatt (MCA).

2) **MINUTES OF THE MEETING HELD ON 1 MAY 1992**

These were read and agreed as a true record with the following amendment:

> Paragraph 2, 4.2: Scotland had achieved "well over 90%" take-up overall.

3) **MATTERS ARISING**

There were none.

4) **HEALTH OF THE NATION: ORAL REPORT BY MR L T WILSON**

Although immunisation had not been adopted as a Key Area the White Paper had praised the high levels of immunisation up-take being achieved and had mentioned the new target of 95% immunisation uptake by 1995. Immunisation up-take achievements had also been mentioned in the debate in the House of Commons and in the Department's press release (tabled).

5) **"IMMUNISATION AGAINST INFECTIOUS DISEASE, 1992 EDITION": ORAL REPORT BY MR L T WILSON**

This had been published at the beginning of August and had been well received. It had been distributed by the Medical Mailing Company which appeared to be the best method of distribution at present. Officials were pleased with the quality of design and lay-out. The next edition would be in 1994.

6) **COVER REPORT AND IMMUNISATION STATISTICS: DRS NORMAN BEGG AND DAVID SALISBURY** **JCVI(92)20**

It was noted that the low up-take districts had improved greatly and that only one district was now below 80%; the schedule change had helped in this achievement. The lowest achieving district, Camberwell in SE Thames, had been visited by Dr Salisbury and they were making efforts to

rectify the data handling problems which were the main cause of the low figures.

In Wales pertussis up-take was not quite 90%; this was felt to have been affected by the recent problems with the MMR vaccine. Northern Ireland was pleased, but not complacent about, the levels of up-take being achieved. In Scotland the interim uptake figure for diphtheria/tetanus/polio was 94.5%; it was predicted that MMR and pertussis up-take would be over 90% by the end of 1992. In the Republic of Ireland the recent pertussis court case had had a considerable affect upon the up-take figures; damages in the court case were likely to be awarded within the next 2 weeks. It was suggested that professionals seemed to be more affected by vaccine damage scares than parents and this would need further consideration.

Dr Salisbury pointed out that the denominators for the Korner figures and the COVER figures were not the same; he planned to address this problem, and therefore reduce demands on health authorities for statistics, during the coming year.

7) INTRODUCTION OF Hib VACCINE

7.1 TIMETABLE TO 1 OCTOBER: ORAL REPORT BY DR DAVID SALISBURY

Dr Salisbury recapped the position regarding the introduction of the Hib vaccine as reported at the last Committee meeting in May and outlined developments since that date.

By mid-July the Medicines Control Agency had still been expressing concern about the data being received on one of the vaccines that had been used in the Gloucester study. At that date Merieux had a product license but had then said that it could only supply 3 million doses of vaccine in the first year and not the 5 million doses they had previously confirmed they could supply. Dr Salisbury and Mr Coleman, from the Childhood Vaccines Supply Unit, had met Merieux officials in Lyon and had pursuaded them to fulfil the requirements. The batch release time table and preliminary delivery schedules had been drawn-up; there had been no margins for batch release failure or problems with manufacture. However, following the subsequent identification of a change in the manufacturing process at Merieux a submission had then had to be made to the Committee on the Safety of Medicine (the specifications set out in the license were not being met). The CSM Biological Standards Sub-Committee accepted that having a tetanus inactivation period of 14 days as against the 28 days set out in the license was acceptable and a license variation was issued for the vaccine which had already been produced. Vaccine produced after the date of the submission would require the full 28 days inactivation period.

In August Lederle received their license and made a very forceful case for the Department to purchase their vaccine in addition to the Merieux. The Department agreed to buy Lederle for use in those children aged over 12 months who would require only one dose of Hib vaccine and as a cushion against any shortfall in the Merieux vaccine supply. Negotiations with Lederle proved difficult and this unexpected development did delay the issue of advice on vaccine supply and ordering.

7.2 VACCINATION AGAINST Hib DISEASE: BMJ 29 AUGUST 1992 JCVI(92)21

This article was noted.

7.3 HEA MATERIALS: ORAL REPORT BY MR MICHAEL CORR JCVI(92)22

The HEA had produced a 40 second TV advert (which was shown to the Committee), leaflets and press packs; parents and professionals had been consulted in the production of the materials. The main Hib advertising campaign was due to start in January and would run for 3 months. Northern Ireland had developed its own material ("Cheerful Charlie") whilst Scotland had used the HEA material.

The matter of adverse reporting on immunisation (as in the tabled Which? article) was discussed. It was agreed that defensive reactions were not the best approach. It was recognised that resistance to immunisation had shifted from parents in the C2, D and E classes to those in the B and C1 classes; it was necessary to address their concerns and provide answers to their questions. The CMO said that improved surveillance of possible concerns and more rapid contact with professionals in the field were needs which were difficult to meet but which were being looked at. Suggestions from Committee members were invited.

7.4 VACCINE SUPPLIES: TABLES 1, 2 AND FIGURE 3. HEALTH SERVICE GUIDELINES (92)39 JCVI(92)23

The tables showed that sufficient vaccine had been made available to meet the demands of the immunisation schedule despite any perceived shortage. Merieux had confirmed that manufacture was ahead of schedule (tabled paper). It was recognised that there had been some local problems where vaccine had been supplied in boxes of 10 doses when the need was for less. It was agreed that the 'Pulse' article (tabled) was unfounded.

In Scotland the vaccine distribution arrangements already in place had been succesfully used for Hib although the catch-up programme may have been pushed too much. In Northern Ireland distribution of the vaccine had been slow but demand great, following a haemophilus influenzae meningitis death. Hib had been introduced into the Republic of Ireland from 1 October also, but, because of

difficulties, had only been licensed for use at age 2, 4 and 6 months.

It was agreed that, although the introduction of the vaccine had gone well, there had been no room for errors, eg. a batch failure. This confirmed the 2 year implementation timetable agreed by JCVI. It was seen that an alternative suggestion of a one year implementation timetable would have been impossible. Much had been learnt from the exercise and the Chairman congratulated and thanked Dr Salisbury for all his work on the introduction of the new vaccine.

7.5 COMMUNICABLE DISEASE REPORT, 25 SEPTEMBER 1992; BPSU PROTOCOL FOR Hib IMMUNISATION FAILURE: DR NORMAN BEGG
JCVI(92)24

This had been the first exercise of its kind in the world. There had been some true cases of immunisation failure in the Oxford study (antibody levels and organism results were awaited) whilst 6 patients had acquired Hib disease within 10 days of immunisation, ie. before antibodies had developed.

7.6 Hib IN FINLAND: LANCET, 5 SEPTEMBER 1992 **JCVI(92)25**
EFFICACY OF HIB CONJUGATE VACCINE IN OXFORD REGION: LANCET, 3 OCTOBER 1992

These articles were noted.

8) MMR: REPLACEMENT OF URABE VACCINES
(This item was discussed after items 9, 10 and 12).

8.1 REPORT TO SUB-COMMITTEE ON SEAR/CSM: DR DAVID SALISBURY
JCVI(92)26

Dr Salisbury reminded members of the discussions and action agreed at the last JCVI meeting and outlined developments since then.

In July data from Nottingham and the other Public Health Laboratories had been received and the officials from the Nottingham PHL, CDSC, NIBSC and the vaccine manufacturers had met. In August, Department of Health officials met with MCA and the manufacturers. At the end of August SKB, acting on the advice of their lawyers, decided to stop producing vaccine and advise licensing authorities world wide accordingly; the Department had, therefore, to act quickly. On the 3 and 4 September the Chief Medical Officers of European Community countries were advised in confidence of the situation at a routine meeting. ARGOS/SEAR agreed on 4 September that no action would be taken to revoke the manufacturer's license as a change of purchasing policy was to be made by the Department; revoking the license would have caused a world-wide vaccine crisis. The Department requested an increased supply of vaccine from MSD (manufacturers of MMRII vaccine) from 200K to 800K doses per annum. This was initially agreed by Wellcome on behalf of

MSD but then demands for extra vaccine had arisen as the UK actions became public knowledge. Department of Health officials visited the MSD factory in Philadelphia and obtained agreement for supply of the additional amounts required by UK.

Regional and District Pharmacists were advised on 9 September to expect delivery of unrequisitioned supplies of MMRII; this information was leaked to the press by a pharmacist and was published on 15 September pre-empting the Department's plans for an orderly release of information, press releases etc.. A letter from CMO was issued on the same day and press releases provided. Further production delays on the part of MSD were resolved and, at the date of the JCVI meeting, 35K doses were being made available each week.

8.2 CMO LETTER (92)11 **JCVI(92)27**

8.3 LETTER TO REGIONAL AND DISTRICT IMMUNISATION CO-ORDINATORS **JCVI(92)28**

8.4 MUMPS MENINGITIS AND MMR VACCINE, LANCET, 29 SEPTEMBER 1992 **JCVI(92)29**

8.5 MENINGITIS ASSOCIATION WITH MMR VACCINES, WHO WER, 9 OCTOBER 1992 **JCVI(92)30**

The above papers were noted.

8.6 MMRII VACCINE SUPPLY **JCVI(92)31**

The Committee was advised that, since the 25 September, an extra 150K doses of vaccine had been issued to the NHS. The distribution of vaccine had been analysed (tabled paper); this had shown up regional inequalities which were unjustifiable. There had been complaints from the field of shortages but it was evident that the problem lay with the ordering and distribution arrangements within the NHS. Returns of the discontinued vaccines had shown that some doctors had had up to 5 months supply of vaccine in their fridges, including, in some cases, stock which had expired. These supply and distribution arrangements were being looked at.

There was no vaccine at all available in Northern Ireland and the programme had been suspended there. In the Republic, although it had been known for many months that there were problems with some of the MMR brands, the withdrawal of the vaccine by SKB had been unexpected. The Irish CMO had decided to suspend the MMR programme until it was possible to obtain stocks of MMRII vaccine from the USA.

8.7 RISK OF ASEPTIC MENINGITIS AFTER MMR VACCINATION IN UK CHILDREN: DR ELIZABETH MILLER **JCVI(92)32**

The overall risk of this complication in the UK was 1 per 10,000 immunised children but, in Nottingham, this had increased to 1 in 4,000. Tests in Canada in 1989 had associated the Urabe vaccine with meningitis. The linking of laboratory records of CSE samples with district computer databases on immunisation had been very effective.

The Committee was told that all the countries which had had a choice had switched from Urabe to Jeryl Lynn; the UK data had been accepted by all these countries.

The immunogenicity data was not as clear cut as had previously appeared. No significant differences had been shown between the Schwarz and Moriten immunogenicity studies and it was agreed that the action which had been taken was correct.

8.8 ADVERSE DRUG REACTION REPORTS OF SENSORINEURAL HEARING LOSS FOLLOWING MMR IMMUNISATION: DR BARBARA STEWART. JCVI(92)33

This paper was noted.

8.9 FUTURE ADVERSE EVENT SURVEILLANCE: ORAL REPORT BY DR DAVID SALISBURY

Many lessons had been learnt from MMR. It was agreed that better surveillance was needed as well as a consideration of how adverse events were followed up. One district had CHCS data, PHL data and hospital data all linked to pick up any adverse event; this could be expanded nationally. The Committee endorsed this approach. The UK's quality of surveillance was unsurpassed but uniformity was necessary.

9) POLIOMYELITIS IN THE NETHERLANDS: COMMUNICABLE DISEASE REPORT, 9 OCTOBER 1992 JCVI(92)34

The cases of wild virus poliomyelitis in the Netherlands illustrated the dangers of having pockets of unimmunised individuals. Concern was expressed that the control of poliomyelitis in South America now seemed better than in Europe, especially in the East where immunisation programmes were now weak. The outbreak also illustrated the advantage of using OPV rather than IPV vaccine. It was agreed that poliomyelitis was an issue that needed consideration at a later date.

10) INFLUENZA: CMO LETTER (92)12 - INFLUENZA IMMUNISATION JCVI(92)35

The inclusion of Chronic Dialysis as an indicator for immunisation was questioned. A poster had been provided for GP surgeries.

11) DRAFT WHO EURO TARGETS JCVI(92)36

The European Regional Office of WHO had convened a small working group to consider the European immunisation targets. It was now appropriate for JCVI to consider whether the new targets should be recommended for acceptance by the UK Government.

There were many important points arising from the working group report. It acknowledged that the elimination of measles would be more difficult than was originally thought.

The new ambitious targets of no measles related deaths and only 1 case per 100,000 by the year 2000 would require immunisation uptake of 99% to break the transmission of disease. There were only minor modifications to the other outcome targets. The process targets had all been changed; new surveillance targets had been recommended.

The Committee agreed to recommend the new targets to the UK Health Departments.

12) **REPORT OF US ADVISORY COMMITTEE ON IMMUNISATION PRACTICES 21/22 OCTOBER 1992**
ORAL REPORT BY DR DAVID SALISBURY.

Dr Salisbury had attended this meeting; the meeting agenda was tabled.

The ACIP was addressing the same matters as JCVI. Of note was the report on the Merck Hib Conjugate Vaccine; this had not performed well. 2 million children had received the Merck Hib vaccine which had been shown to be sub-potent; this had shown the special difficulties of batch-testing Hib conjugate vaccine. The ACIP was also now considering the use of BCG vaccine, especially for the immunisation of health care workers.

13) **ANY OTHER BUSINESS**

There was none.

14) **FUTURE MEETINGS**

The dates for future meetings were confirmed: 7 May 1993 and 5 November 1993.