JOINT COMMITTEE ON VACCINATION AND IMMUNISATION

DRAFT MINUTES OF THE MEETING held on 17 June 2009

Skipton House, 80 London Road, London, SE1 8UG

Members

Professor Andrew Hall (Chair) Professor Judith Breuer Professor Jonathan Friedland Dr Jennifer Harries Mrs Pauline MacDonald Mrs Vivienne Parry Professor Claire-Anne Siegrist

Ex-Officio

Dr Claire Cameron - HPS Scotland Professor David Hill – NATHNAC Dr Syed Ahmed Professor Alan Emond Dr Anthony Harnden Dr Gabrielle Laing Mrs Anne McGowan Dr Andrew Riordan Dr Christopher Verity

Dr Paul Colville-Nash – MRC Dr Stephen Inglis – NIBSC

Welsh assembly Government Mrs Jenny Thorne

Scottish executive Dr Andrew Riley

Northern Ireland Dr Lorraine Doherty

Invited Observers

Wg CDR Andy Green – MoD Dr Sabine Reiter – Germany Dr Mary Ramsay – HPA

Department of Health

Professor David Salisbury CB Dr Dorian Kennedy Dr Stephen Robinson (minutes) Dr Peter Grove Mr John Henderson Dr Elaine Gadd Mrs Ray Smith Dr Emma Savage Dr Gayatri Manikkavasagan Mrs Lisa Vallente-Osborne **MHRA** Dr Philip Bryan Dr Darina O'Flannagan – Eire Professor Elizabeth Miller OBE – HPA Professor John Watson - HPA

> Ms Joanne Yarwood Mr Damian Bishop Mr Faris Aranki Dr John Licorish Miss Rebecca Butterfield Ms Lisa Hymas

Dr Mair Powell

I. ANNOUNCEMENTS AND WELCOME

1. The Chairman welcomed all those present including Professor Judith Breuer attending her first JCVI meeting. Apologies were received from Dr Ray Borrow, Dr Richard Roberts and Dr Paul Jackson.

II. MINUTES OF THE LAST MEETING HELD ON 18 FEBRUARY 2009

- 2. The following changes to the draft minutes were agreed:
 - a. Page four; point 6 (ii) should be amended to read 'The PCV 13-valent vaccine manufactured by Wyeth (which is likely to be licensed at the end of the fourth quarter 2009)'.
 - b. Page five; fourth paragraph should be amended to read current JCVI advice stands that at risk children should receive one dose of PPV after the second birthday and at least two months after the final dose of PCV.
 - c. Page thirteen; after the fifth bullet the Pace et al paper showed that priming with a tetanus toxoid-conjugated MenC vaccine seems to give a better response to Hib/MenC than a CRM-conjugated vaccine.

III. MATTERS ARISING

Postnatal MMR vaccination

- The infectious diseases in pregnancy screening programme board of the UK National Screening Committee asked the committee to advise if two doses of postnatal MMR vaccine are required for women who are identified as rubella susceptible through the infectious diseases in pregnancy screening programme.
- 4. The committee advised that the current Green Book recommendation applies and two doses of MMR vaccine should be given to those individuals that are not protected against measles, mumps and rubella. The committee noted that the need for two doses of MMR vaccine was also important due to the emergence of measles as a result of an increasing number of partially and non-immunised people, who are thus susceptible to measles and mumps.

Measles cases in the UK

- 5. The HPA updated the committee on the current measles epidemiology in the UK. The number of confirmed measles cases in England continues to increase, with over 600 cases this year up to the end of April. The two hundred and twenty six cases in April alone made this the largest monthly total since the current method of monitoring the disease was introduced in 1995. A large number of cases are now occurring outside London and outbreaks have been mainly in travelling communities, schools and nurseries.
- 6. Wales noted that they have had around 300 cases to date this year with around 30 hospitalisations. It is calculated that around 80,000 children in Wales in primary and secondary schools have an incomplete MMR

vaccination status. Wales continues to work to prevent further outbreaks by offering MMR vaccinations to those with no or partial immunisation histories.

- 7. The DH noted that work continues in England to catch-up those children who have no or partial MMR vaccination status. DH is monitoring vaccination uptake trends in England for children aged five to 18 using a sentinel surveillance system. Data is automatically extracted from 50 per cent of GP practices and shows that since September 2008 MMR vaccine uptake has continued to increase across all SHAs. The highest increase in uptake rates are in London and Yorkshire and the Humber although London vaccination rates for five to 18 year olds remain the lowest in the country.
- 8. Scotland reported that they have had no outbreaks of measles and that their MMR immunisation rates remain high.

Post exposure prophylaxis for measles: revised guidance from the HPA

- 9. The HPA updated the committee on the revised guidance for use of human normal immunoglobulin (HNIG) in post-exposure prophylaxis for measles. Levels of maternally transmitted antibodies in infants born to mothers who were vaccinated against measles are lower than in those born to mothers who had a measles infection. Thus, antibodies in the infant decline to a level that is not protective at an earlier age. This is due to the change in epidemiology with fewer cases of measles to provide a natural boost and increasing numbers of vaccinated mothers. Considering this, the HPA has produced revised guidance that details the use of HNIG for infants up to six months of age and for HNIG and MMR for infants aged six months and older. The guidance includes taking into account the status of the mother in terms of her vaccination, birth date and previous exposure to measles and the birth date of the infant.
- 10. The committee welcomed the new guidance noting the added clarity but that there was effectively no change in policy. The committee confirmed the guidance in the Green Book that if the MMR vaccine is given before 12 months of age then a further two doses are required at 12/13 months of age and three years and four months to five years of age.

Letter from the Secretary of State for Health

11. JCVI received a letter from the Secretary of State for Health noting the tremendous role that vaccination has to play in protecting against infectious diseases. The committee was asked to consider the following vaccinations and provide recommendations that would be binding on the SofS under the new vaccination right where the recommendations were shown to be cost effective: rotavirus, varicella and herpes zoster, hepatitis B and respiratory syncytial virus (RSV).

IV. TERMS OF REFERENCE

- 12. DH provided the committee with a document outlining the revised terms of reference for JCVI. From 1 April 2009 new regulations place a duty on the Secretary of State for Health in England to accept and, so far as is reasonably practicable, make arrangements to secure the implementation of recommendations from the JCVI, where those recommendations:
 - relate to new provision for vaccination under a national vaccination programme or to changes to existing provision under such a programme;
 - are in response to a question referred to the JCVI by the Secretary of State;
 - are based on an assessment which demonstrates cost-effectiveness ; and
 - do not relate to vaccination in respect of travel or occupational health.
- 13. The committee's terms of reference will be amended to capture these regulations. Clarification will also be provided around declarations of interest. JCVI agreed to remove the 'ex officio' member status. Instead, individuals representing organisations will be invited as observers and can be included in discussions at the invitation of the Chair. When invited to participate in discussions, observers will be asked to declare any interests relating to their organisation or product under discussion.
- 14. JCVI welcomed the changes to the terms of reference and asked the secretariat to place the redrafted terms of reference on the JCVI website. The members' declarations of interest on the website should also be updated after each meeting to reflect the previous twelve-month period.
- 15. In addition, the committee asked for a protocol to be drafted setting out what is meant by cost-effectiveness, and the committees' interactions with the UK devolved administrations – the secretariat agreed to draft these for the October meeting after which they will be placed on the JCVI website.

V. JCVI PROCESS

- 16. At the February meeting, the committee asked the secretariat to draft a paper outlining how the committee could become more open. One proposal warmly accepted by the committee was that papers considered by the committee should be published after the meeting unless they should be appropriately withheld through freedom of information exemptions.
- 17. JCVI considered the options for holding open meetings including having a part closed and part open meeting or holding one public meeting a year. The committee also discussed increasing the lay membership on the committee from one member to two or three. The committee asked the secretariat to look at another option whereby the committee would hold a question and answer session after each meeting. The committee asked the secretariat to provide a further paper at the next meeting outlining how options could be implemented.

VI. INFLUENZA

- 18. The Committee accepted the minutes of the influenza subgroup meeting that was held on the 17 March to discuss pandemic influenza but acknowledged that the situation has changed significantly since that meeting.
- 19. Previously JCVI had stated that the following groups should be targeted for pandemic influenza vaccination:
- health and social care workers,
- children under 16 years, and
- vulnerable groups such as those identified for seasonal influenza vaccination (people aged 65 years and over, and the clinical risk groups).
- 20. These priority groups had not been put in any particular order by JCVI.
- 21. The likely rate of H1N1 'swine flu' vaccine production means that vaccine will become available over the course of a year. The Committee was informed that if a vaccination campaign was to be implemented then groups would need to be prioritised taking into account the availability of H1N1 'swine flu' vaccine.
- 22. The Committee was asked, based on the current epidemiology to provide advice on:
- the criteria for determining at what point a vaccination programme should begin, and
- the prioritisation of the target groups for vaccination taking into consideration the risks and benefits of vaccination against the health risk from H1N1 'swine flu'.
- 23. The committee recognised that the H1N1 'swine flu' pandemic situation is constantly changing and that the recommendations they make are based on the current evidence. Any significant change in the situation would require JCVI to reassess its advice

Epidemiology

- 24. A paper was presented by the Health Protection Agency on the clinical picture and severity of 'swine flu' (influenza A H1N1v). The majority of cases of influenza A H1N1v are in the younger age groups with less than 5% of cases in those aged over 60. Around 50% of cases are in those younger than 18 years of age. Most cases have experienced mild disease typical of seasonal influenza. 2-3% of cases have been hospitalised and there has been one death to date in the UK. Nineteen cases had been hospitalised in the UK to 10 June 2009. They ranged in age from 14-62 years of age. The committee was also updated on information from other countries.
- 25. The low number of cases seen in the over sixties is thought to be due to different social mixing patterns in this age group leading to less exposure and previous exposure in this age group to a similar strain of H1N1 between 1918 and 1957 that circulated up to 1957.

26. The Health Protection Agency will be carrying out age-specific serological surveys and it was considered important to include antenatal sera in these studies if possible.

Modelling

27. Modelling of the current outbreak suggests that the attack rate is up to 30% with an R0 estimated to be 1.5 if there was no intervention. The case fatality rate is estimated to be between 0.1and 0.4% but could be up to 0.9%. The age-specific attack rates of the current outbreak appear to be similar to those seen in the 1957 pandemic. The modelling suggests that vaccinating children who are the main transmitters of the infection would have the greatest effect. The modelling also suggests that if the case fatality ratio is much higher in older people then we should vaccinate this age group; if the case fatality rate is similar across all age groups or increases with increasing age it is still better to vaccinate children to prevent the transmission of disease to the older age groups.

H1N1 'swine flu' Vaccines and Regulatory Approval

- 28. The MHRA updated the Committee on the situation regarding the licensure of H1N1 vaccines. In 2003 the EMEA established a route for the rapid licensure of pandemic vaccines when the WHO declared a pandemic i.e. phase six.
- 29. The EMEA is currently reviewing its position on the process and timetable for licensing the H1N1 vaccines. The MHRA is currently seeking clarification on whether clinical data will be required in addition to quality data.
- 30. Both GSK and Baxter are planning clinical trials of the new H1N1 vaccines. First clinical data on the new H1N1 vaccines will not be available until later in the year.
- 31. The Committee agreed that as clinical data for the H1N1 vaccines would not be available for some time, it would have to advise on the use of the H1N1 vaccines based on the available data from the H5N1 pandemic vaccines. The Committee agreed that the reactogenicity data for H5N1 vaccines would be applicable to the H1N1 vaccines with the antigen change only having a minor effect on reactogenicity.

Target Groups

32. The Committee agreed that the primary objective of the vaccination programme should be to reduce morbidity and mortality from the infection. It was considered that, if a second wave of infection occurred in Autumn, preventing transmission was not a feasible objective due to the limited number of doses initially available and attitudinal research, which suggests parents would be less likely to vaccinate their children for the benefit of other sectors of the population.

- 33. Based on the current available epidemiology the Committee advised that the following groups would be most at risk from 'swine flu' infection and should be prioritised for vaccination with H1N1 'swine flu' vaccine in the following order:
 - a. Individuals aged between six months and 65 years in the current seasonal clinical at-risk groups.
 - b. Pregnant women in their second and third trimester.
 - c. Health and social care workers directly involved in patient care in line with the current seasonal flu vaccination programme
 - d. All children aged from 3 years to 16 years of age
- 34. JCVI agreed that they would want to consider this list again before final decisions were made about the vaccination programme. The committee recognised that by the time it came to broadening the recommendation to all children aged three to 16 years there would be a significant amount of experience from vaccinating at risk children.

[discussions of the priority groups listed above took place on June 17 2009. These have now been superseded by subsequent meetings of JCVI and SAGE and should not be quoted as the definitive groups]

- 35. The Committee advised that if supplies permitted, the GSK vaccine should be used in children as no paediatric data are available for the Baxter H5N1 vaccine. The committee needs to consider further whether fever prophylaxis is required in children.
- 36. The Committee also needs to consider further what dose of the antigen in the GSK vaccine should be given to children from the age of six months. The data from the H5N1 trials showed that children over three years who received the full adult dose had a good immune response but there is increased reactogenicity. Reactogenicity was reduced with half a dose of antigen and adjuvant but immunogenicity was also lower. The committee noted that there were no data for children aged under three years and therefore, only children aged under three years but over six months in clinical risk groups indicated for influenza should receive the GSK vaccine as the benefits would outweigh the risks of vaccine at least three weeks apart.
- 37. The committee was asked if future recommendations for the use of the H1N1 vaccine in the UK could be based on the available H5N1 data. The committee noted that in terms of relative immunogenicity between the two pandemic vaccine products, the data cannot be extrapolated. A head-to-head study was being planned to look at the two vaccine products but the committee noted that the study has limited value because the results are unlikely to be available in time to inform policy. Safety data from the use of the adjuvant in the H5N1 GSK vaccine was relevant to the H1N1 vaccine as this was the same.

- There are no data available on the co-administration of H1N1 'swine flu' vaccines with seasonal influenza vaccine. However, evidence from immunological studies on non-adjuvanted vaccines suggested that it was theoretically possible that seasonal influenza vaccine may interfere with the immune response to the H1N1 'swine flu' vaccine if given at the same time as the first dose of H1N1 'swine flu' vaccine, as this was a novel antigen. The immune response to both vaccines if the seasonal flu vaccine was given at the same time as the second dose of H1N1 'swine flu' vaccine would be similar. Based on the greater antigenic distance between H1N1/2009 and previous seasonal strains and the fact that the H1N1 'swine flu' vaccine will be adjuvanted, the issue of giving the pandemic vaccine and seasonal flu vaccines together on the first dose may not be an issue. The committee advised that the seasonal influenza vaccine could be co-administered with H1N1 pandemic vaccine. The committee advised that the risk of interference was small for vaccines other than seasonal influenza (e.g. HPV) and these could be co-administered.
- 39. The Committee also considered a paper on influenza in enclosed institutions. There is currently no evidence of clustering of cases in enclosed institutions or that infection is more severe in these settings. Therefore, there is no reason to target particularly these groups for vaccination and only individuals that fall into the target groups outlined above should receive the vaccine.
- 40. The Advisory Committee on Dangerous Pathogens (ACDP) met last week to discuss the novel influenza H1N1 and the implications for pig and poultry workers. ACDP advised the committee to consider H1N1 vaccination for poultry workers as a precautionary public health measure to guard against the potential risk of the emergence of a new influenza strain, if re-assortment of influenza viruses were to occur in a person co-infected with both human and avian influenza viruses. The ACDP also advised that ACDP has previously advised that there was no need to offer pig workers seasonal influenza vaccination as a precautionary public health measure. There is little evidence to suggest that pigs have a role to play in the transmission of influenza to humans. Though it is known that the H1 and H3 strains of human influenza are circulating in the UK pig herd, the risk of re-assortment of swine and human influenza viruses in a human is considered to be very low. Since this was last discussed in 2006, the situation has not altered, and therefore ACDP reiterated their advice that seasonal influenza vaccination need not be routinely offered to pig workers.
- 41. The JCVI endorsed this advice and advised that seasonal and H1N1 'swine flu' vaccine should be offered to poultry workers but the vaccination of poultry workers with H1N1 vaccine was considered a low priority. The Committee also agreed that pig workers should not be offered seasonal or H1N1 'swine flu' vaccine unless they fell into one of the recommended at risk groups.

42. The Committee agreed that the only reason not to start a pandemic influenza vaccination programme is if no H1N1 virus was circulating in the UK or other countries. Monitoring developments in the Southern Hemisphere over the next few weeks, where H1N1 infection rates are currently very high, is crucial.

Safety monitoring

- 43. MHRA and HPA provided a paper setting out the pharmacovigilance strategy for pandemic influenza vaccines. Passive surveillance is in place through a web-based pandemic ADR reporting portal. This will run in parallel to the existing yellow card system. GSK and Baxter have agreed to collaborate on a prospective cohort study. The protocol for this study is currently being developed.
- 44. Previous experience of a swine flu vaccine in the US several decades ago was associated with an increased risk of Guillain-Barre Syndrome. A number of explanations exist for why this occurred including the contamination of eggs used to manufacture the vaccine. Since that time, the use of influenza vaccine has not been associated with Guillain-Barre Syndrome but having an influenza like illness is a known risk factor. The committee thought that the pharmacovigilance could be improved by contacting the Association of British Neurologists and asking if all cases of Guillain-Barre Syndrome could be reported to capture any effects due to either swine flu or any vaccineassociated cases.

VII. RESPIRATORY SYNCYTIAL VIRUS (RSV)

- 45. The committee was informed of the advice from the RSV subgroup. After reviewing all the available evidence, the subgroup advised that the recommendations made in 2004 for the use of palivizumab should be changed to reflect the recommendations in the Health Technology Assessment (HTA; 12;36 titled 'Immunoprophylaxis against RSV with Palivizumab in children').
- 46. The subgroup advised that, based on cost effectiveness, palivizumab should be considered for the prevention of RSV in;
 - Children who have chronic lung disease (specifically, oxygen dependency for at least 28 days from birth) who have the following risk factors:
 - infants under three months old at the start of the RSV season who were born at 30 weeks gestational age or less,
 - infants under six months old at the start of the RSV season who were born at 26 weeks gestational age or less.
 - Children who have chronic lung disease (specifically, oxygen dependency for at least 28 days from birth), and who also have a sibling in day care or school including:
 - infants under three months old at the start of the RSV season who were born at 35 weeks gestational age or less,
 - \circ $\,$ infants under six months old at the start of the RSV season who $\,$

born at 30 weeks gestational age or less,

- infants under nine months old at the start of the RSV season who are born at 26 weeks gestational age or less.
- Infants who have haemodynamically significant, acyanotic congenital heart disease and are less than six months old, subject to this being confirmed as cost effective by the HTA.
- Children who have severe combined immunodeficiency syndrome (SCID) until they are 'immune reconstituted'. This was not covered by the HTA and is based on expert clinical advice. All children with this condition (around 25 per year in the UK) are treated in one of two centres.
- 47. Prophylaxis against RSV using palivizumab is not a cost-effective strategy for preterm infants and children who have congenital heart disease except for the groups above.
- 48. The subgroup advised that five injections of palivizumab should be administered during the RSV season, starting in October.
- 49. Some members of JCVI expressed concern that the recommendations may be hard to implement and the recommendation could be simplified and not include the different age stratifications for children who have chronic lung disease and who have a sibling in day care or in school. It was noted that having a sibling in day care or school increased the likelihood that a child who has chronic lung disease could be infected by RSV – hence the reason for it being included. The chair informed the committee that any change from the cost-effective advice would mean that the committee could not recommend the vaccination – only provide advice – and therefore this would not be covered under the 'vaccination right'. The secretariat was asked to work with members of the committee to produce an algorithm that could be used to explain the recommendation.
- 50. The committee was informed that the secretariat was working with the Health Technology Assessment, Science Support Directorate to ascertain if additional work could be undertaken as the JCVI RSV subgroup noted that in children who have haemodynamically significant acyanotic congenital heart disease this group was not age-stratified in the analysis and that palivizumab prophylaxis was close to the cost-effective threshold. It was noted that by age stratifying this group, there may be some infants for whom palivizumab is a cost effective treatment; for example, infants below the age of six months. The committee would address RSV again before October so that if a recommendation were made, it would be in time for the next RSV season.

VIII. BCG

- 51. The Chief Medical Officer had received correspondence asking whether the children of parents who foster other children from countries with high incidences of tuberculosis (TB) should be offered BCG vaccine. The example given was for unaccompanied asylum children from countries with a high annual incidence of TB being fostered in the UK. DH asked the BCG subgroup via correspondence should children living in the same household as the fostered child be offered BCG vaccine?
- 52. The advice of the subgroup was that the current recommendations in the Green Book should not be changed. There were several reasons for this decision including:
 - a. The current guidance from JCVI and from NICE states that the adopted/fostered child should be screened as a new entrant to the UK. If tuberculin negative without having prior BCG, the adopted child should be vaccinated with BCG because of its country of birth and initial residence. If the adopted child is tuberculin positive and confirmed by Interferon Gamma Release Assay (IGRA), it should have chemoprophylaxis. It is important that this advice be followed to reduce the risk of TB.
 - b. The rationale for offering BCG to the children from high incidence groups is to protect them against the early forms of TB. It is not primarily about protecting others from the risk of infection in the event that the child coming from a high incidence country has TB.
 - c. Despite coming from a high incidence country, the likelihood that such a child would develop TB (particularly if they have received BCG) is still very low and, if they did develop disease, the likelihood that as a child they would pose a significant infection risk to the other children in their foster house must also be small.
- 53. The committee endorsed the advice from the subgroup that the current Green Book recommendation should not be changed.

IX. Hib/MenC, PCV, and MMR

- 54. The HPA presented a paper on the safety and immunogenicity of administering Hib/MenC conjugate vaccine, 7-valent pneumococcal vaccine and measles mumps and rubella vaccine at the same time. The study showed that there was both excellent safety and immunogencity results confirming that the three vaccines could be co-administered. Before this study, there was limited evidence on the immunogenicity of administering the 7-valent PCV and Hib/MenC vaccines together.
- 55. The committee noted that the data could be applied to other PCV conjugate vaccines that were CRM conjugated.

56. The committee welcomed the paper and noted that there is no need to change the schedule but this information provides additional flexibility if all three vaccines or the two conjugate vaccines need to be co-administered.

X. IMMUNISATION OF PREMATURE INFANTS

- 57. The secretariat informed the committee that the current Green Book advice that 'there is no evidence that premature babies are at increased risk of adverse reactions from vaccines' was no longer fully applicable.
- 58. The EMEA's Committee for Medicinal Products for Human Use (CHMP), supported by its Pharmacovigilance and Vaccine Working Parties (PhVWP/VWP), reviewed the evidence of an association between infant immunisations and the risk of apnoea in 2007. This was largely stimulated by worldwide passive reporting data and supported by studies and reviews by the European Vaccine Manufacturers (EVM). This review led to publication, during 2008/9, of a core warning in the product information for all vaccines authorised in the EU that may be used in pre-term infants. The committee was asked if the Green Book advice should be amended accordingly.
- 59. The committee agreed that the wording in the Green Book should be changed and recommended the following wording taking into account the wording of the core warning in the product SPCs.
- 60. 'The occurrence of apnoea following vaccination is especially increased in infants who were born very prematurely. The potential risk of apnoea and the need for respiratory monitoring for 48-72 h should be considered when administering the primary immunisation series to infants who were born very prematurely (born ≤ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity.

The first immunisation of a child born very prematurely should be administered in hospital. If the child reacts to the first immunisation, they should return to hospital for their second immunisation.

As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed.'

XI. VACCINE SAFETY REPORT

- 61. The MHRA updated the committee on the UK suspected adverse reactions (ADRs) associated with routine and/or commonly used vaccines reported to the MHRA/CHM via the yellow Card Scheme during the period of 1st January 2008 to 31st December 2008. It was noted that a report of a suspected adverse reaction (ADR) to MHRA/CHM does not necessarily mean that it has been caused by the vaccine.
- 62. There were around six to ten reports per 100,000 immunised and the rates of adverse reactions remain low and over the past three years have decreased.

- 63. There was an increase in ADRs reported for DTPaP/IPV + Hib in 2008 compared with 2006 and 2007. The increase in ADRs can be partially explained by the increased exposure to the vaccines as a pre-school booster from the end of 2007. Limb swelling was the most reported serious reaction, which is a recognised phenomenon with a fourth dose of a DTaP vaccine.
- 64. Reports of MMR adverse reactions also slightly increased in 2008 however this may be in part due to the increase number of doses being administered in the catch-up programme.
- 65. Overall, the types of serious reactions reported in 2008 were broadly similar to those reported in the previous year; the committee was pleased to note that there were no significant new safety issues identified during 2008.
- 66. The committee was also informed of the safety data on human papillomavirus vaccines Gardasil® and the vaccine used in the national programme – Cervarix®. The MHRA has in place a proactive pharmacovigilance strategy to monitor the safety of Cervarix vaccine as it is used in the UK. Part of this includes comparing background age and sexspecific incidence rates (before the vaccine was introduced) of a wide range of medical conditions (those which may naturally occur in adolescent females and be temporally associated with vaccination) with rates reported via the Yellow Card Scheme. These analyses are adjusted for various levels of possible under-reporting through the Scheme. The MHRA noted that no new safety issues have been identified and that suspected adverse reactions received by the MHRA are published on its website at www.mhra.gov.uk/HPVvaccine
- 67. The committee noted that the human papillomavirus vaccine had an excellent safety profile.

XII. COVERAGE DATA

68. Vaccine coverage data were provided. DTaP/IPV/Hib coverage in London remains low at around 83 per cent. The committee noted that this is a serious issue as there is the potential for transmission after an importation of polio. DH noted that there were ongoing discussion around vaccine uptake in London and this would be raised with NHS London Chief Executives.

XIII. ARTICLES FOR INFORMATION

69. The following articles were provided for members' information

- Report of the Director of Immunisation, April 2009
 <u>http://www.immunisation.nhs.uk/Library/News/Report of the Director of I</u>
 <u>mmunisation_April_2009</u>
- Manikkavasagan G and Ramsay M (2009) Protecting infants against measles in England and Wales: a review. Arch Dis Child.

• Campbell H, Borrow R, Salisbury D et al. (2009) Meningococcal C conjugate vaccine: The experience in England and Wales. Vaccine.

XIV. DATES OF FUTURE MEETINGS

Wednesday 14 October 2009 (confirmed) Wednesday 3 February 2010 (confirmed) Wednesday 16 June 2010 (confirmed) Wednesday 6 October 2010 (confirmed)

ANNEX: DECLARATIONS OF INTEREST

Agenda Item 3

The following members declared interests in companies that manufacture MMR vaccines including Sanofi Pasteur MSD and GSK.

Syed Ahmed: Non-personal, non-specific (GSK and Sanofi Pasteur MSD) Judith Breuer: Personal, non-specific (GSK and Sanofi Pasteur MSD) Pauline MacDonald: Non-Personal, non-specific (GSK and Sanofi Pasteur MSD) Claire-Anne Seigrist: Non-Personal, non-specific (Sanofi Pasteur MSD)

Agenda Item 6

The following members declared interests in companies that manufacture influenza and pandemic influenza vaccines including MASTA, Sanofi Pasteur MSD, Solvay, Wyeth, Novartis, GSK, and Baxter.

Syed Ahmed: Non-personal, non-specific (GSK, Wyeth, and Sanofi Pasteur MSD) Judith Breuer: Personal, non-specific (GSK and Sanofi Pasteur MSD) David Hill: Non-Personal, non-specific (MASTA) Pauline MacDonald: Non-Personal, non-specific (GSK and Sanofi Pasteur MSD) Claire-Anne Seigrist: Non-Personal, non-specific (Sanofi Pasteur MSD)

Agenda Item 7

The following member declared an interest in companies that manufacture palivizumab and are developing new vaccines against RSV: Abbot and MedImmune

Dr Andrew Riordan (Non-personal specific in MedImmune)

Agenda Item 8

Members did not have any interests to declare

Agenda Item 9

The following members declared interests in companies that manufacture Menitorix, Prevenar, and Priorix/MMR VaxPro: GSK, Wyeth, and Sanofi Pasteur MSD

Syed Ahmed: Non-personal, non-specific (GSK, Wyeth, and Sanofi Pasteur MSD) Judith Breuer: Personal, non-specific (GSK and Sanofi Pasteur MSD) David Hill: Non-Personal, non-specific (MASTA) Pauline MacDonald: Non-Personal, non-specific (GSK and Sanofi Pasteur MSD) Claire-Anne Seigrist: Non-Personal, non-specific (Sanofi Pasteur MSD)

Agenda Item 10

The following members declared interests in companies that manufacture the childhood vaccines: GSK, Wyeth, Novartis, Baxter and Sanofi Pasteur MSD,

Syed Ahmed: Non-personal, non-specific (GSK, Wyeth, and Sanofi Pasteur MSD) Judith Breuer: Personal, non-specific (GSK and Sanofi Pasteur MSD) David Hill: Non-Personal, non-specific (MASTA) Pauline MacDonald: Non-Personal, non-specific (GSK and Sanofi Pasteur MSD) Claire-Anne Seigrist: Non-Personal, non-specific (Sanofi Pasteur MSD)