JOINT COMMITTEE on VACCINATION and IMMUNISATION

Minute of the meeting held on 14 October 2009

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

Members

Professor Andrew Hall (Chair)

Dr Syed Ahmed

Dr Ray Borrow

Professor Judith Breuer

Professor Jonathan Friedland

Dr Anthony Harnden

Dr Jennifer Harries

Dr Paul Jackson

Dr Gabrielle Laing

Mrs Pauline MacDonald

Mrs Anne McGowan

Mrs Vivienne Parry

Dr Andrew Riordan

Dr Christopher Verity

Invited observers

Dr Mary Ramsay - HPA

Professor David Hill - NATHNAC

Dr Stephen Inglis - NIBSC

Dr Andrew Riley - Scottish executive

Colonel Philip Bolton - MoD

Dr Linda Diggle – Jersey

Dr Albert Jan van Hoek - HPA

Dr Mark Jit - HPA

Dr Susana Scott - LSHTM

DH

Professor David Salisbury CB

Dr Dorian Kennedy

Dr Tom Barlow

Dr Stephen Robinson (minutes)

Dr Emma Savage

Ms Joanne Yarwood

Dr Edward Waller

Mr John Henderson

Dr John Licorish

I. ANNOUNCEMENTS and WELCOME

1. The Chairman welcomed all those present. Apologies were received from Professor Alan Emond, Dr Richard Roberts, and Professor Claire-Anne Siegrist.

II. MATTERS ARISING

- The committee was informed that the wording presently in the Green Book relating to the vaccination of very premature babies might be leading some medical practitioners to misinterpret the advice and leading to some children being readmitted for immunisation when they had been discharged before the first immunisation was due.
- The committee advised that any child born prematurely but well enough to be discharged from hospital does not need to be re-admitted to hospital to be immunised. However, those babies born prematurely who are still in hospital when their first immunisation is due to take place should be immunised in hospital.

ACTION: The committee asked the secretariat to reword the paragraph to make this point clear and to communicate this change to the healthcare profession.

III. JCVI TERMS OF REFERENCE

4. The committee was informed that the secretariat would circulate a draft committee protocol and code of practice to members for comments in December. A revised protocol and code of practice would be discussed at the next scheduled JCVI meeting in February 2010.

IV. JCVI PROCESS

The committee was informed that the secretariat is drafting an options paper on committee openness. This paper would be circulated with the protocol and code of practice for discussion at the February 2010 meeting.

V. VACCINE COVERAGE

- 6. Vaccine coverage data for England, Scotland, Wales and Northern Ireland was provided.
- 7. The committee noted that latest quarterly figures (April to June 2009) for MMR uptake is encouraging and uptake of other childhood vaccines is high. However, the data for the selective hepatitis B programme are concerning with coverage for three doses of hepatitis B vaccine at 12 months of age at 75 per cent in a high-risk group. This is concerning as a failure to vaccinate all of this high risk population would lead to carriers and chronically infected individuals with infection acquired at birth leading to chronic infection in about 80 per cent of cases. The committee noted that a lack of or incomplete data was returned from around a quarter of PCTs.
- 8. **ACTION:** The chair will write to the DH to highlight the committee's concerns about the poor uptake of the hepatitis B vaccine.

- The committee noted that the vaccine uptake for all vaccines is very high in Scotland and that Welsh data on hepatitis B and BCG coverage is now being reported.
- 10. Members noted that it is possible that the advice from JCVI introducing flexibility into the childhood vaccination schedule at 12 and 13 months may influence vaccination coverage. If PCTs decided to implement a local programme where, Hib/MenC, PCV and MMR were routinely given at the same time, it is possible that this may lead to a local decrease in vaccine uptake should some parents be concerned about their children receiving all three vaccines at one appointment. Alternatively, it was possible this approach may increase uptake. DH noted that the advice had been issued to make clear that the vaccination programme had not changed; simply that flexibility had been introduced into the schedule.
- 11. **ACTION:** The committee asked DH to provide a research paper on the attitudes of parents to receiving these vaccines at the same time.

VI. INFLUENZA

12. A draft Green Book chapter on pandemic influenza A (H1N1v)2009 [Swine Flu] was provided to members for comment. The Green Book chapter, incorporating members' comments, will be available before the start of the immunisation campaign.

VII. VARICELLA

- 13. The committee was provided with a summary of the advice from the varicella subgroup that met in March 2009 to consider the evidence together on:
 - burden of disease:
 - the vaccines, including safety, efficacy and duration of protection;
 - limitations of the data; and
 - the potential impact of varicella vaccination and/or herpes zoster vaccination.
- 14. The Chair of the Subgroup summarised the Subgroup's advice. With respect to the varicella vaccine, the subgroup did not identify any safety issues relating to the vaccine. During the subgroup's consideration, there had been a change to the license of the varicella vaccine for children from a one-dose to a two-dose schedule that had necessitated a reanalysis of the cost-effectiveness.
- 15. The committee was informed that the subgroup did not advise that a combined varicella (chickenpox) and herpes zoster (shingles) vaccination programme should be implemented for the following reasons:

- it is not cost-effective in the short-term;
- an increase in the incidence of herpes zoster cases as a result of childhood varicella vaccination is likely to occur;
- a potential increase in varicella among adults is also likely if there is low vaccine coverage
- it is not guaranteed that varicella vaccination will protect against herpes zoster in later life due to re-infection. With poor uptake levels, re-infection would be common. The protection against herpes zoster is a key factor in making varicella vaccination cost-effective and therefore re-infection would have an effect on the cost-effectiveness of vaccination.
- 16. The subgroup advised that herpes zoster vaccination should be introduced to people aged 70 years and over. This age group was proposed as the duration of protection, based on current data, is estimated to be 7.5 years and infection is more severe and the burden of illness is greater in this age group.
- 17. The subgroup advised that further modelling work on an adolescent varicella vaccination programme should be done.
- 18. The committee discussed the subgroup's advice and the conclusions, noting that a modelling study showed that a routine childhood varicella-vaccination programme is not cost effective. A key assumption made in the modelling was vaccination of children against varicella leads to an increase in herpes-zoster disease in adults for the first 40 to 60 years of a programme. This was assumed because adult immunity would no longer be boosted from exposure to children infected by varicella, based on observational data including a case-control study. If the programme was to go on infinitely, then in the long-term, it could be cost-effective. However, there are no data on the longevity of varicella vaccine-induced immunity and therefore the need for booster doses later on is not known. Although data on the potential impact of a childhood programme on disease in later life are limited, the committee view was that it is reasonable to assume that herpes zoster cases would increase in the short to medium term if a childhood varicella vaccination programme were introduced.
- 19. The committee noted that in the UK varicella and herpes zoster viruses are not notifiable diseases except in Scotland where varicella is notifiable. More data are needed to ascertain accurately disease burden and any impact that vaccination programmes might have. The committee agreed that it would be preferable if surveillance systems were in place for all vaccine preventable diseases. It was noted that a consultation of draft Health Protection (Notification) regulations had been issued

ACTION: JCVI chair to write to HPA to highlight the need for surveillance systems to be put in place for all vaccine preventable diseases and to review the consultation of the draft Health Protection (Notification) regulations.

- 20. The committee noted the subgroup's advice that a herpes zoster vaccination programme should be implemented for older people aged 70 years and over. The committee agreed that before it could make a recommendation, it would need to review a written reply from the authors of the cost-effective modelling to the comments made by peer reviewers that was not available to them at the meeting. The vaccination age was influenced by assumptions made about the minimum duration of vaccine effectiveness in the absence of long-term data. Should data become available that suggest the duration of vaccine effectiveness is appreciably longer then it may be cost-effective to vaccinate people less than 70 years of age. In addition, the committee asked for additional modelling information to establish what age vaccination is no longer cost-effective and inform decisions about a specific cost-effective cohort for a catch-up programme.
- 21. The committee agreed with the subgroup advice that further modelling work should be undertaken to determine if an adolescent varicella vaccination programme would be cost-effective.
 - **ACTION:** the committee asked the secretariat to arrange for further modelling work to be completed on adolescent varicella-vaccination.
- 22. The subgroup had agreed with advice from the National Screening Committee that there is insufficient evidence to recommend the introduction of routine antenatal screening for Varicella Zoster Virus susceptibility, in the context of the current primary prevention strategy of targeted immunisation to high-risk groups. The committee also concurred with this advice.
- 23. The committee agreed with the varicella subgroup advice that there is insufficient evidence to advise the use of varicella vaccine in children on immunosuppressive treatment. HIV infected individuals with moderate immune suppression can be vaccinated using a single varicella vaccine subject to clarification of the definition of moderate immune suppression indicated by a specific CD4 count.

VIII. HAEMOPHILUS INFLUENZAE TYPE B (HIB)

- 24. The committee was provided with a paper outlining the cases of Hib diseases following the various Hib campaigns including:
 - the booster campaign, conducted during 2003;
 - the routine booster of Menitorix®, introduced in October 2006; and
 - the pre-school catch-up dose (for children born between March 2003 and August 2005).
- 25. The committee noted that the overall number of cases of Hib disease has declined each year since the booster campaign was started in 2003. There were only four Hib cases in children aged 1-4 years in 2008/09: by far the lowest number ever recorded in this age group. Total cases in children eligible for Menitorix® have remained constant during 2007/08 and 2008/09 and so far, none of the England and Wales cases confirmed as Hib infection by the HPA has received a booster dose of Menitorix®.
- 26. The committee was informed that current surveillance suggests that control of Hib has been re-established and that the current schedule is highly effective at providing direct protection, at least up to the age of 4-5 years. Early indications suggest that the most recent Hib pre-school programme has also helped to

- improve control of Hib further. Overall control of Hib, as indicated by cases in adults, is now excellent.
- 27. The committee was also informed about the estimated effect on Hib disease should a combined vaccine that included Hepatitis B protection (Infanrix-Hexa®) be used in the routine programme instead of Pediacel®. The estimates were based upon two published case control studies comparing protection from Infanrix® Hib with DTwP-Hib.
- 28. It is estimated that an additional five to twelve excess cases of invasive Hib disease per birth cohort could occur if the currently used Pediacel® was replaced with Infanrix-Hexa®.
- 29. The committee noted that this report was helpful in considering agenda item IX the cost-effectiveness of introduction of a universal hepatitis B vaccine programme.

IX. HEPATITIS B

- 30. The committee was presented with a paper, peer review comments and a response from the authors on the introduction of a hepatitis B vaccine programme. The authors of the paper concluded that at current vaccine prices neither a universal infant programme, universal adolescent programme nor selective infant vaccination programme (i.e. one targeting geographically intermediate/high risk ethnic populations similar to that in place for BCG) would be considered cost-effective in the UK.
- 31. The committee considered the peer review comments and noted the difficulty in costing the treatment of chronic hepatitis B infections. The committee also noted that the majority of cases in the UK originate abroad and therefore, a universal programme would not prevent infection in those who migrated to the UK from high incidence countries.
- 32. The committee agreed that at this point in time it could not recommend the use of hepatitis B vaccines in a universal infant, universal adolescent or selective infant vaccination programme. The committee noted that improvements need to be made to the current programme to immunise more at risk infants who are born to mothers who are hepatitis B positive.
- 33. The committee also noted that a universal infant programme may be costeffective if a multivalent vaccine containing HepB was used however, they would not recommended it at this point as this could lead to an increase in Hib cases.
- 34. The committee would consider the benefits of a universal infant programme if a multivalent vaccine became available that offered the same protection against Hib that is currently offered by Pediacel® in addition to an effective hepatitis B component.

X. TRAVEL VACCINES

- 35. The committee was provided with a summary of the advice from Travel subgroup that met on 8 October 2009.
- 36. The travel subgroup met to provide advice to JCVI on three issues relating to

travel immunisation:

- Japanese encephalitis vaccines;
- Meningococcal ACWY vaccines; and
- Changes to the cholera chapter in Immunisation against Infectious Diseases Green Book'
- 37. A member of the subgroup summarised the subgroup's advice. On the use of the licensed Japanese encephalitis (JE) vaccine IXIARO® the subgroup advised that:
 - The licensed JE vaccine IXIARO® should be used for individuals aged 18 years and over.
 - The subgroup noted that since the primary course of IXIARO® is two
 doses of vaccine, given one month apart, this vaccine is not able to offer
 protection to travellers who need to leave before the second dose can be
 administered.
 - The unlicensed Green Cross vaccine should continue to be used for children over one year and up to and including those aged 17 years of age until paediatric data on a safe dose of IXIARO® are available. The subgroup will reassess paediatric use of this vaccine when completed studies are available that address safety, dose and method of administration. The subgroup noted that IXIARO® has been licensed from the age of 17 years in the US, and individual prescribers may wish to consider the use of a full dose of IXIARO® in older teenage children 'off label'.
 - No data on the length of protection more than 12 months after vaccination were available, and so no definite recommendation could be made about booster doses. Vaccinated individuals should be advised to seek medical advice three years post vaccination, by which time more data will be available.
 - There are no data available of the ability of IXIARO® to boost pre-existing
 immunity in individuals previously vaccinated with JE-Vax or Green Cross
 vaccine. Until data are available, individuals previously vaccinated with
 JE-Vax or Green Cross vaccine should be immunised with a primary
 course of IXIARO®.

ACTION: The secretariat was asked to contact Novartis and ascertain if the company has additional data or when these data will become available, to address:

- the duration of immunity up to three years post vaccination;
- the ability of IXIARO® to boost immunity of individuals previously vaccinated with JE-Vax or Green Cross Vaccine: and
- paediatric use including dosage and vaccine safety.
- 38. The subgroup also advised that the Green Book be amended to include these changes to JE vaccination. The changes should include separating vaccination for children and adults and the risks and benefits of vaccination with IXIARO® and Green Cross Vaccine. The subgroup also advised that the section on 'Travellers and those going to reside abroad' should be revised to describe the key factors that should be considered when making a risk assessment to decide on vaccination against Japanese Encephalitis. To assist in this, the websites of

- the two travel vaccine information providers Travax and NaTHNaC should be provided.
- 39. The subgroup also advised on the use of the MenACWY conjugate vaccine Menveo® when it is licensed and the use of the currently licensed MenACWY polysaccharide vaccine. The subgroup advised that:
 - There should be no alteration to the current Green Book indications for the use of MenACWY vaccines for travel.
 - There is good evidence for the efficacy of both the polysaccharide vaccine and Menveo® in individuals aged 11 years and older. When Menveo® is licensed, both vaccines can be used in individuals aged 11 years and older, but individuals should be advised that that Menveo® is likely to provide longer lasting immunity.
 - When licensed, Menveo® should be used for children under five years of age 'off label', as the benefits of protection outweigh the risks of vaccination. Polysaccharide vaccine has limited immunogenicity in this age group and in children under the age of two, it has been shown to produce antibody hypo-responsiveness. Data on Menveo® demonstrates that this vaccine is safe and immunogenic in children.
 - When licensed, Menveo® can be used for children aged five and up to 10 years of age 'off label'. Polysaccharide vaccine can also be used in this age group, but individuals should be advised that that Menveo® is likely to provide longer lasting immunity.
 - In preference, Menveo® vaccine should not be administered at the same time as other conjugate vaccines (for example, the conjugates Hib/MenC and PCV that are administered at 12 -13 months) until further data are available on concomitant administration of these vaccines. This advice is not based on safety concerns, but because data on the effect on immunogenicity if these vaccines are administered together are limited. However, if this results in a young child not receiving MenACWY conjugate before travelling to a risk area then conjugate vaccines should be given at the same time, as the benefit of vaccination outweighs the theoretical risk of a negative effect on immunogenicity when the two conjugates given together.
 - When Menveo® is licensed, a revised Green Book chapter should be produced to reflect the indications listed above and also to include references to the websites of the two travel vaccine information-providers Travax and NaTHNaC.
- 40. The subgroup had been presented with a letter from MASTA (a private provider of travel vaccines and travel health advice) highlighting text in the Green Book chapter on cholera that MASTA believed is inaccurate. The subgroup considered the points made by MASTA and advised that some changes of fact be made to the Green Book chapter, including up-dating figures on disease incidence and clarifying disease severity. No changes were recommended in the indications for the use of cholera vaccine.

41. The committee endorsed the advice of the subgroup and asked the secretariat to take forward all the actions identified by the subgroup.

XI. RESPIRATORY SYNCYTIAL VIRUS (RSV)

- 42. The committee was reminded that it had discussed the use of Palivizumab® monoclonal antibody in June 2009 in light of a health technology assessment that was considered by the RSV subgroup.
- 43. The committee had asked the secretariat to arrange for additional analysis in the HTA looking at subgroups of children with chronic heart diseases and chronic lung disease and other subgroups such as:
 - age less than six weeks at the start of the RSV season,
 - male gender,
 - multiple births,
 - exposure to passive smoke,
 - lack or minimal breast feeding,
 - overcrowding in the family home,
 - parental education, and
 - family history of atopy'
- 44. The committee was presented with a preliminary HTA paper that had not been peer-reviewed. The committee noted that the new analysis resulted in recommendation on cost-effective administration of the vaccine that were complex and therefore an algorithm would need to be developed to apply them. Moreover, no data on the confidence intervals of cost effective values has been provided. The chair thanked the National Institute of Health Research and the HTA authors for producing a report so quickly.
- 45. **ACTION:** The committee agreed that once the HTA paper had been peer reviewed it should be considered in depth by the RSV subgroup together with the authors. The Subgroup should report back its advice to JCVI for its February meeting.

XII. Q FEVER

- 46. The committee was informed that a vaccine for Q fever is available and the Advisory Committee on Dangerous Pathogens (ACDP) had asked the JCVI to consider the suitability of this vaccination for use in high-risk occupational groups.
- 47. The committee was presented with a paper from the Health Protection Agency analysing the epidemiology and burden of disease of Q fever in the UK. Q fever is not a notifiable disease in the UK and surveillance of Q fever across the UK is based on voluntary laboratory reporting of *C. burnetii* to the respective surveillance centres in England and Wales, Scotland and Northern Ireland. Since routine laboratory reporting does not distinguish between acute, chronic and past infection, it is assumed that the majority of infections are acute. The reports only provide limited epidemiological information, as many data fields are not completed when the cases are reported.
- 48. It was noted that during the period 1999-2008, using a combination of routine laboratory reporting supplemented with reference laboratory cases, there were

- 1126 new diagnoses of Q fever in the UK. The overall UK mean annual incidence was 0.18 cases/100,000 population/year (range 0.10–0.34), with higher rates in Northern Ireland than in England & Wales and Scotland during the same period. It was not possible to estimate the contribution from occupational exposure, and of the recent UK outbreaks, only an outbreak at a Scottish meat processing plant had an occupational link.
- 49. The committee also considered a paper outlining the pre-licensure safety data and post-marketing safety data of Q-vax. This showed that non-immune subjects very commonly have local tenderness (48%) and erythema (33%) at the vaccination site. Local induration or oedema is uncommon (<1%). General symptoms occur commonly in about 10% of vaccinees and may include mild influenza-like symptoms such as headache (9%), fever [>38.5C] (0.2%), chills and minor sweating.
- 50. There are also two more significant adverse reactions among the estimated more than 130 000 individuals vaccinated from 1989–2004. The first is an intensified local reaction at the injection site, which may occur shortly after inoculation in individuals sensitised immunologically by previous infection or repeated vaccination. Rarely, an immune abscess develops and requires excision and drainage. The acute reactions may be accompanied by short-term systemic symptoms resembling the post Q fever fatigue syndrome. The introduction of the pre-vaccination skin test at NIH/NIAID Rocky Mountain Laboratory later combined with antibody testing in Australia, has largely eliminated reactions due to previous immune sensitisation.'
- 51. The second, much less frequent, pattern has been reported in people who were skin and antibody test negative at the time of vaccination who did not have any immediate reaction. Some 1 to 8 months after vaccination, some vaccinees, predominately women, developed an indurated lesion at the inoculation site. At the time when the indurated lesion developed, the original skin test site often was positive, presumably indicating a late developing cellular immune response. These lesions were not fluctuant and did not progress to an abscess. Most gradually declined in size and resolved over some months without treatment. A few lesions were biopsied or excised and showed accumulations of macrophages and lymphocytes'
- 52. The committee concluded that at this time, given the lack of data on occupational exposure and risk of infection, and the adverse reaction profile of Q-vax, that it could not recommend Q-fever vaccination.

XIII. HORIZON SCANNING

53. The committee was provided with a horizon scanning paper prepared by the secretariat that outlined vaccine development and the likely time to licensure. The report was based on information collected from a number of sources including vaccine manufacturers' websites, peer-reviewed publications and clinical trials listed on www.clinicaltrials.gov. A new process for improving the process of horizon scanning to allow better forward planning of committee business was proposed. During March-April 2010 organisations that are developing vaccines (e.g. pharmaceutical companies, medical research funders) will be asked to submit a short summary (a proforma will be developed) on their vaccine developments including:

- Disease(s) that vaccine is being developed to protect against (including any new multiple antigen vaccines).
- Stage of vaccine development i.e. preclinical or clinical stage.
- Forecasted date to submission to licensing authorities.
- 54. This process is likely to lead to first-hand and more timely information from those developing vaccines. The horizon scanning paper will then be included in the agenda of the June JCVI meeting and the process would be kept under review.
- 55. The committee discussed the purpose of the horizon scanning and concluded it needed to inform:
 - new or review existing surveillance for diseases for which vaccines are being developed;
 - new sub-committees to consider the evidence;
 - commissioning timely cost-effective modelling;

XIV. HUMAN PAPILLOMAVIRUS

- 56. The committee was presented with a paper outlining the safety of the HPV vaccine, the uptake in England and a review of the literature since the committee last looked at this vaccine.
- 57. The most recent safety report from the MHRA on suspected adverse reactions was provided for information.
- 58. JCVI noted the studies that have been published since it last considered HPV vaccines. Several studies have looked at the cross protection offered by Cervarix® and Gardasil®. Both vaccines show some cross-protection against HPV types other than HPV-16 and -18 with the Cervarix® study being sufficiently powered to show cross protection against individual strains associated with HPV-31, HPV-33 and HPV-45.
- 59. The committee also noted that a head-to-head comparison study funded by GSK showed that Cervarix® produced higher levels of serum antibodies compared with Gardasil®. At this stage, it is not clear what effect this higher antibody response may have on the long-term effectiveness against cervical intraepithelial neoplasias and cancer.
- 60. The committee noted that research had shown that Gardasil® and Cervarix® are also capable of producing HPV16 and 18 antibodies in boys and men. Neither vaccine is currently licensed for boys or men. The committee was reminded that the cost-effective modelling considered by JCVI when it made its decision on HPV vaccines showed that at the current high rates of vaccine uptake in girls it is not cost effective to vaccinate boys as significant herd immunity is likely.

XV. ARTICLES FOR INFORMATION

61. The committee discussed the process and purpose of articles provided to it for information. The committee would like to be made aware of:

- papers relating to the safety of vaccines used in the UK immunisation programmes.
- studies presenting potentially controversial results
- papers that contradicted current advice
- papers that may impact on the current recommendations
- 62. The chair also encouraged committee members and observers to send papers to the secretariat that they considered relevant for other members interest.
- 63. The following articles were provided for members information:
 - Vinogradova Y, Hippisley-Cox J, and Coupland C. (2009) Identification of new risk factors for pneumonia: population-based case-control study. Br J Gen Pract. October e329-338.
 - Hak E, Sanders EA, Verheij TJ et al. (2008) Rationale and design of CAPITA: a RCT of 13-valent conjugated pneumococcal vaccine efficacy among older adults. Neth J Med 66(9): 378-83.
 - Sandhu B, Steer C, Golding J et al. (2009) The early stool patterns of young children with autistic spectrum disorder. Arch Dis Child **94**(7): 497-500.

XVI. ANY OTHER BUSINESS

- 64. The Chair noted that Dr Verity was almost at the end of his second term of office and thanked him for his time and contributions to the committee.
- 65. The secretariat noted that new data are available on the herd immunity in relation to rotavirus vaccines from other countries including France, US, and Australia. These data could have an impact on the cost-effective modelling considered by JCVI and detailed in its statement.
- 66. **ACTION:** JCVI asked for the secretariat to provide this data for its February 2010 meeting.

XVII. DATES OF FUTURE MEETINGS

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

Annex

Declarations of Interest

Agenda Item 7

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

Syed Ahmed	Non-personal, specific (Sanofi Pasteur MSD), non-personal non-specific GSK	The member was allowed to answer direct questions from the chair but not participate in forming a recommendation
Ray Borrow	Personal, non-specific (GSK and Sanofi Pasteur MSD)	The member was allowed to participate in discussions but not participate in forming a recommendation
Judith Breuer	Non-personal, specific (Sanofi Pasteur MSD and GSK)	The member was allowed to answer direct questions from the chair but not participate in forming a recommendation
Pauline MacDonald	Non-personal, non-specific (Sanofi Pasteur MSD)	The member was allowed to participate in discussions and in forming a recommendation

Agenda Item 8 and 9

The following members declared interests in companies that manufacture Hib-containing and Hepatitis B-containing vaccines including GSK and Sanofi Pasteur MSD.

Syed Ahmed	Non-personal, non-specific (GSK and Sanofi Pasteur MSD)	The member was allowed to participate in discussions and in forming a recommendation
Ray Borrow	Personal, non-specific (GSK and Sanofi Pasteur MSD)	The member was allowed to participate in discussions but not participate in forming a recommendation
Judith Breuer	Personal, non-specific (Sanofi Pasteur MSD). Non-personal, non-specific (GSK and Sanofi Pasteur MSD)	The member was allowed to participate in discussions but not participate in forming a recommendation
Pauline MacDonald	Non Personal, non-specific (Sanofi Pasteur MSD)	The member was allowed to participate in discussions and in forming a recommendation

Agenda Item 10

The following members declared interests in companies that manufacture IXIARO® and Menveo® (Novartis) or supply Dukorol (MASTA).

Personal specific (Novartis),

Ray Borrow non-personal specific

(Novartis)

The member left the room for this

agenda item

Agenda Item 11

The following members declared interests in the company that manufactures Palivizumab® (MedImmune/AstraZeneca) or the UK distributers (Abbott).

Non-personal, specific Andrew Riordan (MedImmune, AstraZeneca,

Abbott)

The member was allowed to answer direct questions from the chair but not participate in forming a recommendation

Agenda Item 12

No members declared interests in the company that manufactures Q-vax (CSL).