Michael McMahon MSP
Convener
Public Petitions Committee
c/o Public Petitions Clerks
Room T3.40
The Scottish Parliament
Edinburgh
EH99 1SP
By Email: petitions@scottish.parliament.uk
07 January 2016

Ref CONSIDERATION OF PETITION PE1538

Calling on the Scottish Parliament to urge the Scottish Government to setup an advisory committee within NHS Scotland to provide advice on immunisation and vaccination policy.

Dear Michael,

Thank you for this opportunity to respond to this petition and the official report of the discussions that took place at the meeting of the Public Petitions Committee.

The Joint Committee on Vaccination and Immunisation (JCVI) is an independent Departmental Expert Committee and a statutory body, established in its current form in 1981.

The Chair and members of the JCVI are appointed through a process of fair an open competition. The Department of Health Public Appointments Team is responsible for the recruitment of members, and shortlisted candidates are interviewed by senior officials within the Department of Health and PHE. The process is designed to ensure that only the very best candidates are appointed to the JCVI.

As part of the recruitment process candidates are required to declare any potential conflicts of interest. Appointments are made on merit and in accordance with the principles of the Code of Practice for Scientific Advisory Committees and the Code of Practice issued by the Commissioner for Public Appointments. Any conflicts of interest declared by potential candidates will be taken into account during the recruitment process, with consideration as to whether such conflicts could limit their capacity to take part in the discussions and decision making of the committee.

The Code of Practice for the JCVI is a public document, and was agreed by the Department of Health in 2013. The Code of Practice sets out a clear conflicts of interest policy for members of JCVI which is in line with the Code of Practice for Scientific Advisory Committees, and the World Health Organisation guidance “National Immunization Technical Advisory Groups (NITAGs): Guidance for their

The JCVI Code of Practice is available online at: https://www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation#terms-of-reference.

A register of member’s conflicts of interest is held by the Secretariat and is published as an appendix to the minute of each meeting. At the time of writing the vast majority of members of the JCVI do not have any documented conflicts of interest. By handling conflicts held by members in accordance with the rules set out in the JCVI Code of Practice, it is ensured that the decision making of JCVI remains independent. Critically, where a member has a conflict which is both ‘personal’ (they receive direct financial gain from industry) and ‘specific’ to the subject for which advice is being formed (the financial gain is associated with the product being considered) the member will be excluded from the discussion and may not participate in any vote. Most of the advice provided by the committee is formulated by consensus. On exceptional occasions where consensus cannot be reached, decision making is undertaken by vote. There are very clear rules set out in the JCVI Code of Practice on who may or may not vote, in relation to conflicts of interest.

The petitioner makes a number of claims regarding the independence of the JCVI, and in particular raises questions around the independence of the Chair, Professor Andrew Pollard. Contrary to statements made by the petitioner Professor Pollard is fully able to independently chair the JCVI. Professor Pollard holds no ‘personal pecuniary’ conflicts of interest, and any ‘non-personal’ conflicts held by Professor Pollard are handled according to the rules set out in the JCVI Code of Practice, as is the case for all members. Detailed information on this is provided in Appendix A.

A number of other statements made by the petitioner are inaccurate and Appendix A to this letter also provides information aiming to correct such statements. A list of declarations of JCVI members from the most recent JCVI meeting held in October 2015 is provided in Appendix B. Appendix C provides a relevant excerpt from the JCVI Code of Practice regarding conflicts of interest.

Yours sincerely

Andrew Earnshaw
Secretary to the Joint Committee on Vaccination and Immunisation
Public Health England,
Wellington House,
133-155 Waterloo Road
London SE1 8UG
Email: jcvi@phe.gov.uk
CC: Professor Andrew Pollard Chair of JCVI

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2 The Role of National Advisory Committees in Supporting Evidence-Based Decision Making for National Immunisation Programs (2010). Vaccine 28:Supplement 1; A18–A25
Appendix A – Responses to specific issues raised by the petitioner

Conflicts of interest

1. Members must declare all their interests at the time of their appointment and must promptly notify the secretariat of any changes. Before or at the start of every meeting members will be asked to declare any changes to their interests. In addition, it is the responsibility of each member to indicate if they have an interest in any item of business on the agenda of a meeting of JCVI or a JCVI Sub-committee at the appropriate time. Where this happens the Chair will determine whether a member should take part in any discussion or decision on an issue.

2. Conflicts are registered as being either ‘personal pecuniary’ (including in relation to family members) or ‘non-personal pecuniary’. A personal pecuniary conflict relates to direct payment to the individual (or family member) or other benefit from a business or representative body relating to vaccines or any other product or service that could be under consideration by JCVI. Conflicts which are ‘non-personal pecuniary’ relate to payments made to an institution where the individual holds a senior position.

3. When conflicts of interest are considered at meetings this is done in relation to the subject matter under consideration, if a conflict relates directly to a product under consideration then it is considered ‘specific’, if the conflict relates to another product by the manufacturer of the product under consideration then it is considered non-specific’.

4. Conflicts are handled as follows:
   - personal and specific – the individual must absent themselves from any discussion and may not vote;
   - non-personal and specific – the individual may participate in the discussion but may not vote;
   - personal and non-specific – the individual may participate in the discussion but may not vote
   - non-personal and non-specific – the individual may participate in the discussion and also vote.

Conflicts of interest held by Professor Pollard

5. The role of the Chair necessitates that he/she cannot have any interests that may conflict with his or her responsibilities to JCVI, and the same applies for the Chairs of Sub-committees. Therefore, the JCVI Chair and Sub-committee Chairs cannot have interests that could conflict with the issues under consideration by the JCVI or Sub-committee, respectively. Upon appointment to the JCVI all relevant conflicts of Professor Pollard were declared and all held were non-personal. Professor Pollard would only have been appointed if it was agreed by the appointments panel that these would not affect his ability to Chair the JCVI.
6. Professor Pollard has not received any personal financial remuneration from vaccine manufacturers, and has received no travel support for attendance at scientific conferences for the last five years. Prior to his appointment as Chair of JCVI, Professor Pollard had undertaken clinical trials of various vaccines on behalf of Oxford University, which had been funded by vaccine manufacturers, including trials involving group B meningococcal vaccines. This information is in the public domain, was known to the appointments panel and was not considered an obstacle to his appointment. Indeed, his extensive knowledge of this area made him a suitable candidate for the role.

7. At the time of his appointment Professor Pollard indicated that he had been reassured by the Department of Health that the conflicts of interest he held would not impact on his ability to Chair the JCVI. However, as Professor Pollard was concerned about how the non-personal conflicts he held might be perceived, he decided that he would not take on any new vaccine-industry funded projects following his appointment. This was not a requirement of his appointment and at the time of writing Professor Pollard has not deviated from this commitment. Research projects with funding from vaccine manufacturers which had already been planned at the time of Professor Pollard’s appointment were honoured, and these were continued to completion.

Research initiated after Professor Pollard’s appointment

8. The petitioner referred to two clinical trials, with concerns that these started after Professor Pollard’s appointment to JCVI. One study funded by Pfizer which the petitioner referred to, began in November 2013 after Professor Pollard’s appointment. However, this was not a clinical trial, as implied, but an epidemiological study of pneumococcal bacteria in the noses of young children, had been in planning during the previous 12 months, and was taken on before Professor Pollard’s appointment. As an epidemiological study, this did not require any use of vaccine from any manufacturer. The November date refers to the formal initiation of the project and not the set up and development of the project.

9. The petitioner also refers to a trial funded by Novartis vaccines, “lodged” after the Bexsero decision. This is a clinical study investigating the cause of fever in babies vaccinated with Bexsero and is funded by the European Commission. Novartis supplied the vaccine for this study through an agreement, but have no control of the design, analysis or reporting of the study and are not responsible for funding the clinical trial. This project was planned and funded in 2011. The petitioner may be unaware of the processes involved in applying for funding for clinical research, planning of the research, ethical and regulatory approvals, clinical trial registration and running the trial which have long timescales even before the first volunteer is enrolled.

10. Professor Pollard’s declaration that no new industry funded projects have been initiated since his appointment is therefore correct.
Patents

11. Professor Pollard does not hold any patents for the meningococcal vaccine “Bexsero” and has never done so. Oxford University filed patents on meningococcal vaccines independently developed in Oxford, on which Professor Pollard was named. A decision was made in 2013 that these patents should be allowed to lapse. The February 2014 publication in “Clinical and Vaccine Immunology” which mentions these patents, and which is referred to by the petitioner, was no longer current by the time of its publication as these patents had already lapsed. It should be noted that declarations for different journals may require declarations to be made for different time periods (previous 3 or 5 years) and may therefore not be the same as the period covered by declarations for JCVI.

Bexsero decision

12. It is important to clarify that JCVI was consistently of the view throughout the course of its deliberations that this vaccine could be of benefit to the health of children in the UK. As well as considering whether a new vaccine is likely to be safe and effective, it is a key role of JCVI to consider whether use of the vaccine in the UK would be cost-effective. The deliberations of JCVI were made in relation to several meetings of the meningococcal subcommittee, chaired by Dr Andrew Riordan. The decision made to recommend the use of the vaccine in 2014 stemmed from an independent academic analysis of the cost-effectiveness of the vaccine. The analysis was based on a mathematical model which when considered in 2013 indicated that it would not be cost-effective to use the vaccine in the UK. The considerations of JCVI were published in an interim statement, which was put out for stakeholder consultation. Following consideration of the consultation responses and the advice of the Meningococcal sub-committee JCVI requested amendments to the analysis. The final analysis, again provided by an independent academic modelling group, considered by JCVI indicated that use of the vaccine could be cost-effective if the vaccine was purchased at a price significantly lower than the vaccine ‘list-price’. The analyses considered by JCVI were peer reviewed independently from the JCVI and were also scrutinised by analysts from the Department of Health. It was this final analysis that led to JCVI recommending use of the vaccine in the UK, with the caveat that the vaccine would need to be purchased at a price substantially lower than the list price.

European Medicine Agency (EMA) declaration

13. Contrary to what the petitioner indicates the EMA declaration for Professor Pollard is correct. The next update to this is due on 31/12/2015

Ebola vaccines

14. Professor Pollard is involved in two studies of Ebola vaccines neither of which is funded by industry and are not considered as conflicts. One trial which is testing the GSK-made vaccine is funded by the Wellcome Trust and the other which tests the Janssen-made vaccine is funded by the European Commission.
Invitations to industry representatives to sub-committees meetings

15. Vaccine manufacturers are not allowed to have direct access to the JCVI’s decision-making process and are not invited to the main JCVI meetings. The option of inviting industry representatives was discussed at the June 2014 JCVI meeting with the aim of providing the opportunity for industry to share information and for a subcommittee, and its invited experts, to put questions on specific issues under consideration direct to industry representatives. It should be noted that this is an option for a Subcommittee and not a right of the manufacturer. Such an invite to industry representatives is only considered where such an invite would be considered useful because of the issues under review.

16. For any engagement with industry it should also be made clear that a subcommittee is not the JCVI but reports up to JCVI and meetings should not be used as a way to push an agenda to the JCVI. This process is currently being trialled, and under the current arrangements industry may only present information that has been requested by the subcommittee. Industry representatives are only allowed to provide a factual presentation and to answer questions, they are then asked to leave and are not party to the discussions undertaken on the information provided.

17. JCVI has strict rules around this process and it is the members that decide what information they are interested in and the questions that are to put to the manufacturer. The rules of engagement between the subcommittees and manufacturers have been formalised in a document which has been shared with manufacturers and will shortly be published on the JCVI website.

Consideration of removal of vaccines from immunisation schedules

18. Contrary to what the petitioner has stated, JCVI has considered changes to UK vaccine programmes involving either the removal of a vaccine or removal of doses or changing programmes to target smaller populations. The National Schools BCG programme was stopped in September 2005 and now only groups considered at high risk receive the BCG vaccine. One of the doses for the meningococcal group C vaccine has been removed from the childhood schedule and another is planned which will mean the schedule will have gone from 3 doses to one for infants. The HPV Schools programme has changed from a 3 dose to a two dose schedule. JCVI has also considered whether the routine use of PPV 23 pneumococcal vaccine in the UK should continue on two separate occasions in recent years.

Statutory basis of JCVI

19. JCVI is an independent Departmental Expert Committee and a statutory body. It was stated at the hearing that “in England the law says that the Secretary of State should do what the JCVI tells him to do”. This is a gross over simplification of the statutory arrangement between JCVI and the Secretary of State for Health. An accurate description of the responsibilities of the Secretary of State with regards to JCVI recommendations is set out in the JCVI Code of Practice and provided below for information.

“Since 1 April 2009 the Health Protection (Vaccination) Regulations 2009 place a duty on the Secretary of State for Health in England to ensure, so far
as is reasonably practicable, that the recommendations of JCVI are implemented, where those recommendations:

a) relate to new provision for vaccination under a national vaccination programme or to changes to existing provision under such a programme and

b) are made by JCVI (and not therefore a Sub-committee of JCVI) and

c) are in response to a question referred to the JCVI by the Secretary of State and

b) are based on an assessment which demonstrates cost-effectiveness and

e) do not relate to vaccination in respect of travel or occupational health.

This duty ceases to apply in relation to a recommendation where JCVI withdraws that recommendation.”

Safety of vaccines

20. Vaccine safety is continually evaluated by the Medicines and Healthcare products Regulatory Agency (MHRA) as part of its statutory function in the regulation of medicinal products across the UK. MHRA takes advice from the independent Commission on Human Medicines (CHM) in its decision-making. MHRA has strict processes for dealing with any potential conflict of interest of its staff, as does CHM for its membership. MHRA also works within a European regulatory framework co-ordinated by the European Medicines Agency (EMA), which abides by similar rules concerning potential conflicts of interests of staff and expert advice. In its evaluation and decision-making on the safety (and cost-benefit) of a national immunisation programme, the JCVI will take into account any safety evaluation/recommendation undertaken separately and independently by MHRA or EMA, or other national and international sources.

21. The petitioner raises some unfounded safety concerns concerning the nasal influenza vaccine and human papillomavirus (HPV). For the record, there is no confirmed evidence of an association between the nasal flu vaccine and development of narcolepsy, and no evidence to suggest that HPV vaccine may be a cause of chronic illnesses. For the HPV vaccine in particular, a major European safety review has recently been completed and separate international reviews fully support the safety of HPV vaccine. JCVI also recently reviewed the safety of the HPV vaccine and concluded that it had no concerns about the safety of the HPV vaccine.
## Appendix

### Declaration of interests JCVI members October 2015

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<th><strong>Prof Andrew Pollard (Chair)</strong></th>
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Professor Pollard receives no personal payments from the manufacturers of vaccines

Since taking up his role with JCVI he no longer takes on research grants from industry sources. Grants already set up prior to appointment were from Pfizer (epidemiological studies of meningitis in children and nasopharyngeal carriage of pneumococci, MenB vaccine study in adolescents) and Okairos (RSV vaccine), and these past projects will end in 2015 or have already done so.

He is Director of the Oxford Vaccine Group in the Department of Paediatrics and has current research funding from the Wellcome Trust, The Bill and Melinda Gates Foundation, The Medical Research Council, the World Health Organisation, the National Institute for Health Research, the European Commission and the Global Alliance for Vaccines and Immunisation. He chairs the scientific advisory group on vaccines for the European Medicines Agency. Other investigators in the Department conduct research funded by vaccine manufacturers, currently GSK (RSV and Ebola vaccines), Novartis (MenB vaccine, study now ended), and the Department has received unrestricted educational grant funding from Novartis, GSK and Astra Zeneca.

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<th><strong>Prof Anthony Harnden</strong></th>
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Professor Harnden has no registered conflicts of interest.

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<th><strong>Dr Andrew Riordan (Deputy Chair)</strong></th>
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Dr Riordan receives no payments from the manufacturers of vaccines.

Dr Riordan has contributed to the development of an e-learning package on bacterial meningitis (supported by Novartis) for which he received no remuneration.

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<th><strong>Dr Peter Baxter</strong></th>
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Dr Peter Baxter has no registered conflicts of interest.
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<th><strong>Prof Adam Finn</strong></th>
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<td>Prof Finn receives no personal payments from the manufacturers of vaccines.</td>
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<td>He has undertaken consultancy/advisory work on behalf of the University of Bristol for Takeda (August 2014, Norovirus vaccine), GSK (October 2014, Rotavirus vaccine), SPMSD (October 2014, acellular pertussis containing vaccines).</td>
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<tr>
<td>He was principal/chief investigator for a vaccine research study sponsored by Pfizer (meningococcal group B vaccine, until January 2015).</td>
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<td>All funding is paid to the University of Bristol and/or University Hospitals Bristol NHS Foundation Trust.</td>
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<td>Professor Matt Keeling has no registered conflicts of interest.</td>
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<td>His team at the University of Warwick undertakes modelling on the impact and cost-effectiveness of HPV vaccination in adolescents.</td>
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| **Mr Chris Liffen** |
Mr Chris Liffen has no registered conflicts of interest

**Mrs Anne McGowan**

Anne McGowan has no registered conflicts of interest.

Mrs McGowan’s employer Public Health Wales develop educational materials with funding from Pfizer, Sanofi Pasteur MSD, Novartis, AstraZeneca and Wyeth.

**Prof Robert Read**

Professor Read has no registered conflicts of interest

**Prof Anthony Scott**

Professor Scott receives no payments from the manufacturers of vaccines.

Professor Scott is Director of the Vaccine Centre and the Director of the Health Protection Research Unit at the London school of Hygiene and Tropical Medicine, which receives funding from PATH for research into whole cell pneumococcal vaccines. Professor Scott is also a scientific advisor to PATH on whole cell pneumococcal vaccination.

**Prof Claire-Anne Siegrist**

Professor Siegrist receives no payments from the manufacturers of vaccines.

Professor Siegrist is the Head of the Vaccinology and Immunology Unit at the University Hospitals of Geneva, which receives funding from Sanofi Pasteur MSD for research into vaccine adjuvants, and independently undertakes research into the use of Prevenar 13®

**Dr Maggie Wearmouth**

Dr Wearmouth has no registered conflicts of interest