Written evidence submitted by the Association of British Pharmaceutical Industry (ABPI) Vaccine Group (PHP0025)

Introduction and Summary

ABPI Vaccine Group welcomes the Health Select Committee’s inquiry into public health post-2013 – structures, organisation, funding and delivery. The ABPI Vaccine Group is committed to advocating on behalf of the industry on all aspects of vaccination and the benefits it brings to the health of our nation. The Group aims to work in partnership with the public health community throughout the four nations of the UK to encourage the continued and further success of the national immunisation programmes.

Vaccination provides significant public health benefits in the UK and only clean water can rival vaccines at reducing infectious diseases and deaths. In 1948, the NHS only vaccinated against two diseases. Today, the NHS vaccinates against 24 diseases and there are currently over 300 preventative and therapeutic vaccines in research and development to tackle some of the toughest diseases threatening our health in the future. The UK’s Joint Committee on Vaccination and Immunisation (JCVI) recently identified the development of vaccines against group A and B streptococcus, respiratory syncytial virus, norovirus and c difficile, for example, as high priorities for the UK due to the increasing disease burden.

It is vital that the structures, organisation, funding and delivery of vaccination programmes provide optimum access to cost effective vaccines in England. One of the most significant challenges to the future success of the UK’s vaccination programme is that the process of introducing vaccines into the NHS is becoming increasingly difficult. Vaccine development is a complex, expensive and high-cost venture and developing a new vaccine takes on average 18.5 years and costs over £300 million. High R&D costs and intensive manufacturing processes combined with downward pressure on market prices and rebates through the PPRS scheme, make it increasingly difficult for many vaccine companies to recoup R&D costs before patent expiry, which then impacts on the development of future innovations.

There are a number of reviews of the appraisal methods and process for vaccines and medicines currently ongoing: the NICE Triannual review, the Accelerated Access Review, the DH appraisal alignment working group (AAWG) and the Review of Cost-Effectiveness Methodology for Immunisation Programmes and Procurements (CEMIPP) to name but a few. These reviews are all looking at the methodology and processes used across the various appraisal bodies.

The ABPI Vaccine Group believes it is critical that in undertaking these reviews, the Government considers three key questions in the context of vaccination:

1. How are vaccines different from medicines in their value characteristics?
2. Is anything different about vaccine appraisal when compared with medicines?
3. What considerations (methods and process) are important to ensure the expert assessment of vaccines by any appraisal body, which takes into account the special characteristics of vaccines and gives visibility to the appraisal process?

Only by adequately addressing these questions can we ensure that we have a system in the UK for appraising and procuring vaccines that is fair, transparent and accountable and ensures appropriate access to vaccination both now and in the future.

**Special Characteristics of Vaccines**

**How Vaccines are Different from Medicines in Their Value Characteristics**

1. In contrast to medicines, vaccines are given to “healthy individuals” to prevent disease. The immunised patient does not have to suffer impact of a disease on their quality of life and the health system may benefit due to the prevention of serious and costly complications.

2. Vaccines greatly reduce health inequalities because they are delivered at the population level and their benefit is largely unaffected by other potentially health diminishing factors. Disease is not equally distributed in the population and access to treatment is often not equitable.

3. Vaccines confer broader health and societal benefits due to the indirect protection of the un-vaccinated population (ie herd immunity – protecting individuals who have refused or are contraindicated for vaccination). Medicines have a direct benefit only.

4. By protecting against future risk of disease, vaccines provide an “insurance” benefit (i.e. peace of mind) which is realised not just from those who are vaccinated but also others in the population. Treatment follows disease onset or the occurrence of risk factors (which are often illness conditions themselves).

5. Implementation of a successful vaccination programme results in low to zero levels of a disease. Unlike medicines, vaccines can potentially eradicate a disease, providing benefit in terms of patient outcomes and healthcare savings long after the vaccination programme has ended.

**The appraisal and market entry of vaccines**

**Key Considerations for the appropriate appraisal of vaccines to the UK**

The ABPI Vaccine Group considers that the principles which are outlined below are critical for the appropriate appraisal of vaccines:

- Greater engagement and consistency in the process of decision-making and a more collaborative approach with Industry, which aligns with the Health Technology Appraisal (HTA) process adopted by NICE for medicines.
- Following implementation of a new vaccine programme, the value of the programme is currently somewhat informally evaluated through an ongoing process of surveillance data collection and analysis. The decision making framework must
therefore be pragmatic, appreciate the value of present vaccine programmes, recognise the value of ongoing surveillance and enable faster adoption of innovative vaccines.

- The assessment and appraisal of vaccines should be undertaken by a group of individuals with appropriate expertise in vaccines. The ABPI Vaccine Group recognises and acknowledges the expertise within the Joint Committee on Vaccination and Immunisation (JCVI) and the subcommittees which it constitutes.

- The ABPI Vaccine Group recommends that any potential changes to the methods of vaccine value assessment should ensure the following:
  - Appropriate weight should be given to non-QALY benefits in the consideration of vaccine appraisal, such as carer QALYs and wider societal benefits.
  - Expert analysis using appropriate infectious disease modelling methods should be employed that consider the specificity of the infectious disease in question, associated public health challenges (such as epidemics) and the additional and very significant value of indirect protection provided by vaccines (herd protection).
  - Application of a maximum discount rate of 1.5% for benefits (given the disadvantage to vaccines associated with longer-term preventative benefit), as per NICE public health appraisal guidance. Further, there should be no application of an arbitrarily applied time-horizon cut-off.
  - The cost per QALY threshold should remain the same as that applied to all other medicines. The ABPI Vaccine Group does not support the lowering of the threshold for vaccines or medicines.
  - Removal of the overly stringent and unjustified 90% uncertainty rule so that there is alignment with the assessment undertaken for all other pharmaceutical products. This uncertainty rule is detrimental to the development of future innovative and potentially highly beneficial vaccine programmes.

- ABPI Vaccine Group believes that specific consideration and weighting needs to be given to vaccine innovation. The relevant company, supported by a panel of patients, clinicians and R&D specialists should be provided the opportunity to illustrate the innovative character of a vaccine.

Managed entry of vaccines into the market

Most vaccines that are to be made available on a National Immunisation Programme are procured centrally at a national level. As there may be some unresolved uncertainty on the impact of a new programme, procurement must therefore be carefully managed due to the scale. The inclusion of a vaccine in the National Immunisation Programme is monitored and controlled by means of surveillance data and price negotiations. This is unlike the evaluation of most medicines but is similar
to the method of evaluation proposed to NICE by the ABPI for medicines for rare diseases and cancer.

While the link between evaluation and procurement is not explicit in vaccines, the two are in effect linked. After an initial evaluation of a vaccine, when a vaccine is placed onto a national immunisation programme, a surveillance system is set up in order to measure the impact of the programme. Each tender process and negotiation thereafter could, if required, be an opportunity for re-evaluation of the value of the vaccine based on up-to-date data from often enhanced surveillance systems.

Managed entry is a feature of vaccines appraisal and the potential for ongoing assessment based on surveillance data supports the establishment of effective programmes. However, the process and pricing of vaccines should remain separate from the appraisal and should not be reflected in the technology appraisal or any conclusions that it reaches.

Engagement with appropriate stakeholder groups

Patient groups, clinical experts and the pharmaceutical industry are key stakeholders that can provide important perspectives and must therefore be consulted on the decisions that affect them directly. Furthermore, pharmaceutical companies include among their personnel international experts in the fields related to their products, including vaccines. The expertise of these individuals can only enhance the evaluation of new vaccines. Recent moves to greater engagement in the decision making by the JCVI are welcome and it is hoped that this will continue and even go further.

Conclusion

Our ultimate goal is to control, eliminate and eventually eradicate vaccine-preventable diseases. In order to fully maximise the potential of vaccines in the fight against ill health, vaccines must be affordable to healthcare systems around the world whilst at the same time ensuring that companies can recoup the R&D costs that allow them to continue to develop innovative vaccines. A fair, transparent and accountable system for the appraisal and procurement of vaccines is therefore critical to this success by helping to ensure that we have sustained investment in new vaccine technologies with the potential to save many more lives in the future whilst also giving people appropriate access to the vaccines of today. We recommend that those involved in the structures, organisation, funding and delivery of vaccination programmes are encouraged to seek greater engagement with the vaccines industry in order to support system wide alignment in this aim.

14 December 2015

Useful References


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1 ABPI Vaccine Group members: Abbvie, AstraZeneca, GSK, Mylan, Pfizer, Seqirus, Takeda
3 Department of Health Chief Medical Officer’s Annual Report 2007, Chapter 5
4 NHS Choices Website: Vaccination Schedule NHS Choices Website
6 IFPMA report: Innovation for a Healthier World p15
7 JCVI Minutes June 2014 and June 2015
8 IFPMA report: Delivery the Promise of the Decade of Vaccines p16
9 Pharmaceutical Pricing Regulation Scheme