To: General Practitioners
NHS Trusts – Medical Director
NHS Foundation Trusts – Medical Director
PCT Medical Directors
PCT Immunisation Co-ordinators
SHA Immunisation Leads
Chief Pharmacists/Pharmaceutical Advisers of PCTs
Practice Nurses
All Pharmacists

cc: SHA Directors of Public Health
Consultants in Communicable Disease Control
Regional Directors of Public Health
Royal College of Physicians
Royal College of General Practitioners
British Medical Association

Gateway reference number: 16896

25 November 2011

Dear Colleague

HPV immunisation programme – change of supply to Gardasil® from September 2012

I am writing to inform you that following a competitive tendering exercise the Department of Health (DH) will be providing the human papillomavirus (HPV) vaccine Gardasil® for the national HPV immunisation programme for girls in school year 8 (aged 12 to 13 years) from September 2012.

What does this change mean for the programme?
For the current academic year (September 2011 to July 2012), there is no change to the programme. Cervarix remains the vaccine being offered for the HPV vaccination programme.

Most girls should already have received their first and possibly second doses of the HPV vaccine Cervarix®. Such girls should complete their HPV vaccination course with Cervarix® (the vaccine with which they started the course). Girls who have yet to receive their first dose of HPV vaccine should also be offered Cervarix®.

It is important that as many girls as possible complete the course of all three doses of Cervarix® vaccine before the end of this academic year in order to ensure they are fully vaccinated.

From the beginning of the next academic year (September, 2012), the DH will provide Gardasil® for the national programme. From September 2012, therefore, all eligible girls (see below) should start and complete their courses of HPV vaccinations using Gardasil®.

There will be some girls who have missed one or two doses of their HPV vaccination course from the 2011/12 academic year. These girls should complete their vaccination course with Cervarix® where possible. PCTs should retain any 'in date' stocks of Cervarix® after the end of the 2011/12 academic year to enable them to carry out 'mop up' of girls who have started Cervarix® courses.

A new version of the HPV chapter of the Green Book will be produced that provides guidance on the use of Gardasil®, including the scheduling of the course of vaccinations.

Eligibility for the vaccine

There is no change to the eligibility criteria for the programme. All 12- to13-year-old girls (school year 8) should continue to be offered the vaccine as part of the routine HPV vaccination programme. PCTs should have in place programmes that are directed to achieving the highest possible uptake.

Girls and young women outside of the routine cohort

Girls and young women remain eligible to receive the HPV vaccine as part of the national programme up to the age of 18 years (i.e. up to the day before their eighteenth birthday). PCTs should already have arrangements in place so that any girls, who are under the age of 18 but did not receive the vaccine when scheduled, or have not completed the course of all three doses, can be offered the vaccine.

Any girl falling into this category, who starts the HPV course before September 2012, should complete the course with three doses of Cervarix®. Any girl starting the course after 1 September 2012 should be vaccinated using Gardasil®. If a girl starts the course with Cervarix®, they should finish the course with the same vaccine.

Women aged 18 years or over, and boys of any age, are not covered by the national programme.

Why has the vaccine been changed?

In line with the previously announced policy of reviewing the provision of HPV vaccine after three years, the DH has recently conducted a procurement exercise through competitive tendering for the further supply of HPV vaccine: a three-year contract has been awarded to Sanofi Pasteur MSD for supply of Gardasil®. Gardasil® protects against two strains of HPV that cause over 70% of cervical cancer in England and a further two strains that cause around 90% of genital warts. Gardasil® will be provided for the HPV vaccination programme from September 2012. Until then, Cervarix will continue to be provided.

The procurement process has been undertaken in accordance with the requirements of the Public Contracts Regulations 2006 (the Regulations). The Regulations require the contracting authority to state the criteria that it will use to identify the successful bidder. DH had constructed a fair scoring system designed to measure the merits of the available products, promote competition and achieve value for money.

The criteria for the evaluation of the clinical element of this procurement exercise have been updated since the 2008 procurement exercise for the supply of HPV vaccine. This followed an updated cost effectiveness analysis of HPV vaccines that has been carried out by the Health Protection Agency and which was issued to all tenderers as part of the procurement process. This updated analysis was published recently.[1] The evaluation criteria for the current procurement do not reflect any change in Government priorities and DH believes that the award criteria would have permitted any eligible supplier to win the contract to supply HPV vaccine to the DH.

Funding

Funding for administering the HPV programme in 2012/13 will be allocated as part of the PCT allocation. There will be no separate funding.

Service arrangements

There are no changes to service arrangements; PCTs are responsible for the implementation of the HPV immunisation programme in the most expeditious way to achieve the highest possible coverage. PCTs will decide how to offer vaccination to the routine cohort in 2012/13 and provide the vaccine to those girls up to the age of 18 who have not been vaccinated previously. PCTs will need to make arrangements for girls who miss scheduled immunisations.

There will need to be clear communication with parents, girls and schools/colleges, and robust arrangements will be needed to obtain consent for immunisation. Guidance on consent has been provided in my previous letter of 2 May 2008. (www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_085625).

PCTs who have PGDs in place for the administration of the vaccines will wish to amend these in light of the change of supply of the vaccine. No new national template will be issued.

Supply of HPV vaccine

It is likely that many PCTs will be holding small quantities of Cervarix® at the end of the 2011/12 academic year. These supplies should be retained whilst they have not reached their expiry date and should be used for 'mop up' of girls and young women who have started their HPV vaccination course with Cervarix®.

Further details on the supply and distribution of Gardasil® for the 2012/13 programme will be provided in spring 2012; however, orders should continue to be placed on Immform and will be delivered by Movianto.

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[1] Jit *et al*. (2011) Comparing bivalent and quadrivalent human papillomavirus vaccines: economic evaluation based on transmission model *BMJ*. 2011; 343: d5775. Published online 2011 September 27. doi:10.1136/bmj.d5775 www.ncbi.nlm.nih.gov/pmc/articles/PMC3181234/?tool=pubmed

Communications
All information and guidance to support the HPV programme will be updated to reflect the change to the vaccine supply from Cervarix® to Gardasil®.

New information materials will be available to order from the Department of Health Publications Orderline at www.orderline.dh.gov.uk, and from Prolog telephone, 0300 123 1002 during summer 2012**.**

Monitoring vaccine uptake
The monthly and annual surveys will continue for vaccinations of the routine cohort.

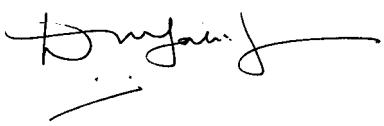
Local data management
My letter of 30 January 2009 (www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_094025) referred to the importance of local data management, which remains relevant, namely the need:

- for accurate data on the target population, to identify, schedule and recall individuals for vaccination;
- for accurate record keeping (preferably electronic);
- where appropriate, for engagement with local schools and colleges to access school/college rolls; and
- to ensure vaccination details are provided to GP practices and are recorded on GP practice systems.

Adding HPV vaccination status to future cervical screening record on the NHAIS (Exeter) System
It is vital to ensure that details of the vaccination of young women are added to their future cervical screening records on the NHAIS (Exeter) System. The process for doing this was outlined in my previous letter of 30 January 2009 (www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_094025). PCTs are strongly advised to specify the need for complete entry of data on HPV vaccinations onto ImmForm and Exeter in their commissioning arrangements.

I have attached a question and answer sheet to help you deal with questions that patients and their parents may ask about this change in vaccine.

Yours sincerely



Professor D M SALISBURY CB FRCP FRCPCH FFPHM
Director of Immunisation

Questions and answers sheet

Q. Why has DH policy changed?

A. DH policy has not changed. The primary aim of the HPV vaccination programme is to prevent cervical cancer, and the UK has one of the most successful HPV vaccination programmes in the world. This is very important in protecting women against cervical cancer and precancerous lesions that need treatment.

The aim of the procurement process is to measure the merits of the available vaccines, promote competition and achieve value for money for the health service.

Q. Is Cervarix vaccine inferior to Gardasil?

A. No. We have given five million doses of a licensed vaccine that has been shown to give good protection against HPV types16 and 18, which cause over 70 per cent of cervical cancer in the UK. We have one of the best HPV vaccination programmes in the world and we anticipate rates of cervical cancer to decline due to the success of this programme.

Q. What should we say to those who have already been vaccinated?

A. They did exactly the right thing in being vaccinated. As a result of their vaccination, they are significantly less likely to be infected by HPV types16 and 18 that cause over 70 per cent of cervical cancers in the UK – which is a fantastic outcome.

Q. What will we say to this year's cohort of girls?

A. Our plans will continue unchanged because we have already purchased vaccine for the year's HPV vaccination programme. They will be offered Cervarix®, the same vaccine that has been offered since the programme was introduced. We strongly recommend that young women take up the offer of the vaccine as part of the routine immunisation programme. It provides protection against HPV16 and 18 that cause over 70 per cent of cervical cancers in the UK.

The new contract is to buy vaccine for use from September 2012.

Q. Should those who received Cervarix® now be boosted or revaccinated with Gardasil®?

A. Cervarix® provides good protection against cervical cancer and boosters or revaccination after the initial three doses of Cervarix® are not required.

Q. Is there something wrong with Cervarix®?

A. No. Cervarix® has an excellent safety record established after use of more than five million doses in the UK over the past three years, with more doses used in other countries. No serious new safety issues have been found with Cervarix® since it was introduced in the UK in 2008, and it has been shown to provide good protection against cervical cancer.

Q. Is Gardasil® a new vaccine? Do we know how safe it is?

A. Gardasil® is not a new vaccine. It has been used extensively in other countries, such as the United States, and other countries in Europe, since it was first licensed in 2006. Tens of millions of doses have been given in other countries and its safety is well established.

Q. How will you monitor if there are any adverse reactions when Gardasil® starts to be used?

A. As with any vaccine or medicine newly introduced in the UK, the MHRA will closely monitor the safety of Gardasil®. Health professionals and those vaccinated will be asked to help us confirm the safety profile by reporting any suspected side effects, and the MHRA will regularly review any such reports using statistical and epidemiological techniques.

Q. My daughter has received three doses of Cervarix® but I want her to be vaccinated with Gardasil® as well so she is protected against genital warts.

A. The primary purpose of the national immunisation programme is to protect against cervical cancer. It would not be appropriate, therefore, as part of the NHS programme, to offer Gardasil® to those who have had a full course of Cervarix®