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To: Immunisation Co-ordinators

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Copy: SHA Immunisation Leads
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Gateway Number: 12699

Dear Colleague

HPV vaccine Batch AHPVA043BB

This email is a follow up to my communication yesterday.

Preliminary results from the autopsy on the young girl from Coventry who sadly died after receiving HPV vaccine suggest that she had a rare and grave underlying medical condition that was likely to have caused her death. Indications are that it was most unlikely that the HPV vaccination was the cause of death. Further information is available at www.coventrypct.nhs.uk.

Before this information was known, GSK had voluntarily initiated a recall of Batch AHPVA043BB that I had asked to be quarantined. Further information can be found at www.mhra.gov.uk/NewsCentre/Pressreleases/CON057420. The company will advise you on the recall process.

Information on which PCTs have received deliveries of HPV vaccine from this batch, and the delivery points that it has been delivered to, is available on the Immform website (www.immform.dh.gov.uk).

We have been clear all along that there is no reason to suspend HPV immunisation and I strongly recommend that you continue with your HPV vaccination programme. If you do not have adequate supplies of alternative batches, please contact Movianto and order replacement vaccine and recommence your programme as soon as the vaccine arrives. Colleagues in neighbouring PCTs may have some available stock to help in the interim.

We have prepared some information materials that address some of the issues that have arisen in the last few days and these are below.

Thank you for all your efforts over this very difficult event.

Yours sincerely

Professor David M Salisbury CB FRCP FRCPCH FFPH
Director of Immunisation

HPV Q & A

This Q and A is provided by the Department of Health in response to the tragic death, on 28th September, of a girl in Coventry which occurred shortly after receiving a vaccine against Human papillomavirus.

What were the circumstances around the girl's death?

A teenage girl in Coventry, who had received her first dose of HPV vaccine (Cervarix[®]) as part of the catch-up programme, died on Monday 28th September following vaccination.

How has this been investigated?

A post mortem has been carried out. Preliminary results have revealed that sadly the girl had a rare but grave underlying medical condition which was likely to have caused her death. Indications are that it is most unlikely that the HPV vaccination was the cause of death.

Coventry PCT have put information on this case on their website at www.coventry.nhs.uk, which you may wish to check for further updates.

Is the HPV vaccination programme going to be suspended?

No. We recommend that where stocks of other batches of vaccine are available that the programme continues. The HPV vaccine helps to protect against cervical cancer that kills more than 1000 women every year.

How is the safety of this vaccine monitored?

The Medicines and Healthcare products Regulatory Agency (MHRA) collects information from doctors, other healthcare professionals and patients on suspected adverse reactions (unwanted or harmful reactions following administration of all medicines, including vaccines). These reports (which come through the 'Yellow Card' scheme) are monitored and serious reports are followed up. Action is taken if a possible problem is identified.

The information on adverse reactions is publicly available at www.mhra.gov.uk/hpvvaccine. HPV vaccine has shown a good safety profile, with most adverse reactions reported being minor, such as a sore arm.

Is a batch of vaccine being recalled?

Before the preliminary results of the post-mortem were known, the vaccine manufacturer, GSK, took the decision to voluntarily recall the batch of HPV vaccine that the girl had received. This was as a purely precautionary measure. Information on this is available at

www.mhra.gov.uk/NewsCentre/Pressreleases/CON057420

As this voluntary recall had already been announced, it will continue and we will replace the recalled vaccine as quickly as possible so the programme can continue.

What is the batch number?

The batch number is AHPVA043BB

About the Vaccine

The vaccine in question is against human papillomavirus (HPV) and protects young women against cervical cancer. It is produced by GlaxoSmithKline under the brand name Cervarix.

Q What is HPV?

HPV is a virus that infects the deepest layer of the skin or genital surfaces. There are over 100 different types of HPV, 13 of which are known to cause cervical cancer. The others are harmless or cause genital warts. The virus is transmitted through sexual contact and is very common, with over half of all women becoming infected at some point in their lifetime.

Q Why vaccinate against HPV?

The vaccination programme aims to prevent young women from developing cervical cancer. In the UK, about 3000 women are diagnosed with cervical cancer every year and about 1000 die from it.

Cervarix protects against HPV strains 16 and 18 which are responsible for over 70% of all cervical cancers in the UK.

Who is offered the HPV vaccine?

The routine HPV vaccine programme was introduced in September 2008 for girls aged 12-13 years (school year 8). A catch-up programme also started in September 2008 and offers the vaccine to other older girls up to the age of 18:

- Girls/young women aged 17 – 18 years (school year 13) born between 1 September 1990 to 31 August 1991 inclusive, were offered the vaccine in the 2008/09 school year.
- Girls/young women aged 14-18 years (school years 10, 11, 12 and 13 if in education) born between 1 September 1991 and 31 August 1995 inclusive, will be offered the vaccine from autumn 2009.

Primary Care Trusts are responsible for the delivery of the vaccination programme in their local area. A schools-based programme has been recommended for the routine vaccination programme (12-13 year olds), as vaccination will be delivered most efficiently through schools. Vaccination is voluntary, not mandatory.

By what process was the vaccination programme introduced?

Q Who recommended the HPV vaccination programme?

The Joint Committee on Vaccination and Immunisation (JCVI), which provides independent expert advice to ministers on vaccination, examined a wide range of evidence before making its recommendation on HPV vaccines. More information is available at <http://www.dh.gov.uk/ab/jcvi/index.htm>

Q Which vaccine will be used in the national programme?

Two vaccines against HPV are licensed for use in the UK; Cervarix and Gardasil. Cervarix is the vaccine used for the national HPV vaccination programme.

Q Where else is Cervarix used?

Cervarix has been approved for use in more than 100 countries around the world and in all the 27 European Union states.

More than 1.4 million doses of Cervarix have been given in the UK and over 9 million doses distributed worldwide in total.

Q How and why was Cervarix selected for the programme?

The two HPV vaccines licensed in the UK - Cervarix[®] and Gardasil[®] - both protect against HPV strains 16 and 18 that cause over 70% of cervical cancers in the UK. The national HPV vaccination programme uses Cervarix as it is the vaccine that offers the NHS best overall value.

Safety

Q Was Cervarix[®] tested prior to being granted a license for use?

Yes. Like all vaccines, the safety and effectiveness of Cervarix[®] was tested rigorously in clinical trials. These data were reviewed by the European Medicine Agency's Committee for Medicinal Products for Human Use before a license was granted for its use in Europe.

Q Is vaccine safety monitored?

Yes. The Medicines and Healthcare products Regulatory Agency collects information from doctors, other healthcare professionals and patients on suspected adverse reactions (unwanted or harmful reactions following administration of a medicine, including vaccines) through the Yellow Card scheme. These reports (yellow cards) are recorded and are regularly reviewed with appropriate investigation and action taken if a possible problem is identified.

There is also a legal requirement for pharmaceutical companies to report serious and suspected adverse events to Medicines and Healthcare Products Regulatory Agency.

Q What are the known side effects of Cervarix[®]

The known side effects listed in the Cervarix[®] patient information leaflet are:

Very common (side effects which may occur in more than 1 per 10 doses of vaccine):

- pain or discomfort at the injection site
- redness or swelling at the injection site
- headache
- aching muscles, muscle tenderness or weakness (not caused by exercise)
- tiredness

Common (side effects which may occur in less than 1 per 10 but more than 1 per 100 doses of vaccine):

- gastrointestinal symptoms including nausea, vomiting, diarrhoea and abdominal pain
- itching, red skin rash, hives (urticaria)
- joint pain
- fever ($\geq 38^{\circ}\text{C}$)

Uncommon (side effects which may occur in less than 1 per 100 but more than 1 per 1,000 doses of vaccine):

- upper respiratory tract infection (infection of the nose, throat or trachea)
- dizziness
- other injection site reactions such as hard lump, tingling or numbness.

Q How many doses of *Cervarix*[®] have been used since it was licensed and what is its safety record?

About 9 million doses have been used worldwide.

In the UK, more than 1.4 million doses have been administered since September 2008 when the HPV immunisation programme started.

The Medicines and Healthcare Products Regulatory Agency has received 2,137 yellow card reports and has detailed 4,657 suspected adverse reactions relating to *Cervarix*[®] covering the period 14 April 2008 – 23 September 2009. The vast majority have related to either to recognised side effects listed in the product information or were due to the injection process and not the vaccine itself. For the isolated cases of other medical conditions reported, the available evidence does not suggest that vaccine caused the condition.

Where can parents and girls go for additional information?

Further information is available on the NHS immunisation website (www.immunisation.nhs.uk/hpv), which is regularly updated.