

From the Chief Medical Officer, the Chief Nursing Officer and the Chief Pharmaceutical Officer

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- Monitor Independent Regulator of NHS Foundation Trusts

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#### Gateway reference number: 16066

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Dear Colleague

### **SEASONAL FLU IMMUNISATION PROGRAMME 2011/12**

This letter contains important information about the seasonal flu immunisation programme for winter 2011/12 and should be used to plan local seasonal flu immunisation programmes. The letter builds on information sent out in March which can be found at

www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH\_125091.

For ease of use the information is set out in the attached annexes as follows:

- Annex A Groups eligible for the seasonal flu vaccination for 2011/12
- Annex B Dosage, consent and patient leaflet
- Annex C Further advice on immunising pregnant women
- Annex D Frontline health and social care workers
- Annex E Improving uptake and data collections
- Annex F Vaccine virus strains and available vaccines
- Annex G Vaccine supply
- Annex H Contractual arrangements, service reviews and funding

The purpose of the seasonal flu immunisation programme is to offer protection to those who are most at risk of serious illness or death should they develop flu. As set out in the letter of 14 March 2011, we would be grateful for plans to be put in place locally to:

- reach or exceed 75% uptake for people aged 65 years and over as recommended by the WHO; and
- reach or exceed 75% uptake for people under age 65 with clinical conditions which put them more at risk from the effects of flu, and pregnant women, as recommended by the EU. A reasonable trajectory for increases in uptake in clinical risk groups and pregnant women might be 60% in 2011/12,

and 70% in 2012/13, so that an uptake of 75% can be reached or exceeded in 2013/14.

The table below illustrates the importance of vaccination of those in the clinical risk groups. It sets out the relative risk of death from flu last winter in individuals in the various clinical risk groups compared to those not in a clinical risk group<sup>1</sup>. The message is clear – increasing flu vaccine uptake in individuals in the clinical risk groups is important in reducing serious illness and death in these groups.

Table: Numbers, rates and relative risks with 95% lower and upper confidence intervals for seasonal flu clinical risk factors amongst confirmed influenza related fatalities aged 6 months to 64 years, England, 2010/2011. Provisional and preliminary data from the HPA up to 4 May 2011.

	Number of fatal flu cases (%)	Mortality rate per 100,000 population	Age- adjusted relative risk*	Lower RR 95% Cl	Upper RR 95% Cl
In a risk group	213 (59.8)	4.0	11.3	9.1	14.0
Not in any risk group	143 (40.2)	0.4	Baseline	Baseline	Baseline
Chronic renal disease	19 (5.3)	4.8	18.5	11.5	29.7
Chronic heart disease	32 (9.0)	3.7	10.7	7.3	15.7
Chronic respiratory disease	59 (16.6)	2.4	7.4	5.5	10.0
Chronic liver disease	32 (9.0)	15.8	48.2	32.8	70.6
Diabetes	26 (7.3)	2.2	5.8	3.8	8.9
Immunosuppression	71 19.9)	20.0	47.3	35.5	63.1
Chronic neurological disease (Exc. Stroke/TIA)	42 (11.8)	14.7	40.4	28.7	56.8
Total**	378	0.8			

<sup>&</sup>lt;sup>1</sup> Individuals can have more than one risk factor.

\* Mantel-Haenszel age-adjusted rate ratio (RR), with corresponding exact 95% CI were calculated for each risk group using the two available age groups (from six months up to 15 years and from 16 to 64 years)

\*\* Including 22 cases with no information on risk factors.

#### Poultry workers immunisation programme ceasing

The Joint Committee on Vaccination and Immunisation (JCVI) has advised that there is no longer any benefit in continuing the routine flu vaccination of poultry workers beyond the 2010/11 season. Based on the advice of the JCVI, the seasonal flu vaccination programme for poultry workers is being discontinued<sup>2</sup>.

Poultry workers are no longer considered a risk group for seasonal flu and no central stock of vaccine will be provided for this programme.

Finally, we would like to take this opportunity to thank those in the NHS for the planning that they have undertaken so far.

Jully ( CV

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<sup>2</sup> www.dh.gov.uk/prod\_consum\_dh/groups/dh\_digitalassets/@dh/@ab/documents/digitalasset/dh\_124596.pdf

### For further information, please contact:

www.info.doh.gov.uk/contactus.nsf/memo?openform

Tel: 020 7210 4850 (Office opening hours 08:30-17:30 Mon-Fri) Textphone: 020 7210 5025 (for people with impaired hearing)

Immunisation Branch Department of Health Wellington House 133-155 Waterloo Road London SE1 8UG

To doctors and practice nurses: for correction or changes of address, practice or name, please contact:

The Medical Mailing Company PO Box 60, Loughborough Leicestershire LE11 0WP Tel: Freephone 0800 626387

This letter is also available at:

www.dh.gov.uk/en/Publichealth/Immunisation/Officialimmunisationletters/index.htm

# Annex A – Groups eligible for the seasonal flu vaccine for 2011/12

The list of eligible patients who should be offered the seasonal flu vaccine has not changed since the 2010/11 season. The seasonal flu vaccine should be offered to the eligible groups set out in the table below, which continues overleaf.

Eligible groups	Further detail		
All patients aged 65 years and over			
Chronic respiratory disease aged six months or older	Asthma that requires continuous or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospital admission.		
	Chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema; bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD).		
	Children who have previously been admitted to hospital for lower respiratory tract disease.		
Chronic heart disease aged six months or older	Congenital heart disease, hypertension with cardiac complications, chronic heart failure, individuals requiring regular medication and/or follow-up for ischaemic heart disease.		
Chronic kidney disease aged six months or older	Chronic kidney disease at stage 3, 4 or 5, chronic kidney failure, nephrotic syndrome, kidney transplantation.		
Chronic liver disease aged six months or older	Cirrhosis, biliary artesia, chronic hepatitis		
Chronic neurological disease aged six months or older	Stroke, transient ischaemic attack (TIA). Conditions in which respiratory function may be compromised (e.g. polio syndrome sufferers).		
	Clinicians should consider on an individual basis the clinical needs of patients including individuals with cerebral palsy, multiple sclerosis and related or similar conditions; or hereditary and degenerative disease of the nervous system or muscles; or severe neurological disability.		
<b>Diabetes</b> aged six months or older	Type 1 diabetes, type 2 diabetes requiring insulin or oral hypoglycaemic drugs, diet controlled diabetes.		

Immunosuppression aged six months or older	Immunosuppression due to disease or treatment. Patients undergoing chemotherapy leading to immunosuppression. Asplenia or splenic dysfunction, HIV infection at all stages. Individuals treated with or likely to be treated with systemic steroids for more than a month at a dose equivalent to prednisolone at 20mg or more per day (any age) or for children under 20kg a dose of 1mg or more per kg per day. It is difficult to define at what level of immuno- suppression a patient could be considered to be at a greater risk of the serious consequences of flu and should be offered flu vaccination. This decision is best made on an individual basis and left to the patient's clinician. Some immunocompromised patients may have a suboptimal immunological response to the vaccine.
	Consideration should also be given to the vaccination of household contacts of immunocompromised individuals, i.e. individuals who expect to share living accommodation on most days over the winter and therefore for whom continuing close contact is unavoidable. This may include carers (see below).
Pregnant women	Pregnant women at any stage of pregnancy (first, second or third trimesters).
People living in long-stay residential care homes or other long-stay care facilities where rapid spread is likely to follow introduction of infection and cause high morbidity and mortality. This does not include, for instance, prisons, young offender institutions, or university halls of residence.	Vaccination is recommended.
Carers	Those who are in receipt of a carer's allowance, or those who are the main carer, or the carer of an elderly or disabled person whose welfare may be at risk if the carer falls ill.
	(Please note – this category refers to individual carers entitled to a free flu vaccine on the NHS, not professional health and social care workers who should be vaccinated by their employer as part of an occupational health programme.)

The list above is not exhaustive, and the medical practitioner should apply clinical judgement to take into account the risk of flu exacerbating any underlying disease that a patient may have, as well as the risk of serious illness from flu itself. Trivalent seasonal flu vaccine should be offered in such cases even if the individual is not in the clinical risk groups specified above.

Further guidance on the list of eligible groups and guidance on administering the seasonal flu vaccine, can be found in the updated influenza chapter of the Green Book: Immunisation against infectious disease <a href="http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\_079917">www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\_079917</a>

# Annex B – Dosage, consent, and patient leaflet

The dosages for flu vaccines are shown below and should be given according to the recommendations for use of the vaccines. Given that some flu vaccines are restricted for use in particular age groups, the Summary of Product Characteristics (SPC) for individual products should always be referred to when ordering vaccines for particular patients.

### Dosage for trivalent seasonal flu vaccines

Age	Dose
Children aged from 6 months to under 13 years	Unless specified otherwise (see note below*), a single injection of 0.5ml repeated 4 to 6 weeks later if receiving seasonal flu vaccine for the first time. Some seasonal flu vaccines are not licensed for young children.
Adults and children aged 13 years and over	A single injection of 0.5ml for intramuscular injected vaccines. For intradermal vaccine, Intanza® - a single injection of 0.1ml of Intanza® 15µg in those aged 60 years and older or 0.1ml of Intanza® 9µg in those aged 18 to under 60 years. Neither Intanza® formulation is licensed for use in those aged under 18 years.

\*Some seasonal flu vaccine SPCs indicate that young children can be given either a 0.25ml or 0.5ml dose. The Joint Committee on Vaccination and Immunisation has advised that unless a specific dose is indicated on the SPC, a 0.5ml dose should be given to infants aged six months or older and young children because there is evidence that this dose is effective in young children (Heinonen *et al.,* 2010)<sup>3</sup>.

### **Consent**

Health professionals should ensure that appropriate information and advice about the flu vaccine is given to each person who attends an immunisation session, and that the person's consent is obtained. Individuals coming for immunisation should be given a reasonable opportunity to discuss any concerns before being immunised.

For further information on consent, please see Chapter 2 of *Immunisation against infectious disease* (the 'Green Book')<sup>4</sup>.

<sup>&</sup>lt;sup>3</sup> Heinonen S, Silvennoinen H, Lehtinen P et al. (2011) Effectiveness of inactivated influenza vaccine in children aged 9 months to 3 years: an observational cohort study. Lancet Infect Dis. 11: 23-29.

<sup>&</sup>lt;sup>4</sup> www.dh.gov.uk/prod\_consum\_dh/groups/dh\_digitalassets/@dh/@en/documents/digitalasset/dh\_063591.pdf

# Publicity and information materials

An updated patient leaflet will be available from the Department of Health website ahead of the start of the seasonal flu immunisation programme.

## Annex C – Further advice on immunising pregnant women

### Rationale and target groups

There is good evidence that pregnant women are at increased risk from complications if they contract flu and particularly from the H1N1v strain. **All pregnant women** are recommended to receive the seasonal flu vaccine irrespective of their stage of pregnancy in the 2011/12 flu season.

A review of studies on the safety of flu vaccine in pregnancy concluded that inactivated flu vaccine can be safely and effectively administered during any trimester of pregnancy and that no study to date has demonstrated an increased risk of either maternal complications or adverse fetal outcomes associated with inactivated influenza (Tamma *et al.*, 2009)<sup>5</sup>. A number of studies show that seasonal flu vaccination during pregnancy provides passive immunity against flu to infants in the first few months of life (Benowitz *et al*, 2010; Eick *et al*, 2010; Zaman *et al*, 2008)<sup>6</sup>.

#### When to stop offering the vaccine to pregnant women

Seasonal flu vaccination is usually carried out between October and January and it would be unusual to carry on vaccinating after that date. However, clinicians should apply clinical judgement to assess the needs of an individual patient, taking into account the level of flu-like illness in their community and the fact that the immune response following flu vaccination takes about two weeks to develop fully.

### Data review and data recording

Uptake of vaccine by pregnant women, along with other groups, will be monitored. GPs will need to check their patient database throughout the flu season in order to identify women who are not pregnant at the start of the immunisation programme but become pregnant during the winter.

PCTs should explore ways of linking midwifery services with GP practices so midwives can raise awareness of the seasonal flu vaccine among pregnant women and could administer the flu vaccine at ante-natal classes. If arrangements are put in place where midwives administer the flu vaccine, it is important that the patient's GP practice is informed so their records can be updated accordingly, and included in vaccine uptake data collections.

<sup>&</sup>lt;sup>5</sup> Tamma PD, Ault KA, del Rio C, Steinhoff MC et al. (2009) Safety of influenza vaccination during pregnancy. Am. J. Obstet. Gynecol. 201(6): 547-52.

<sup>&</sup>lt;sup>6</sup> Benowitz I, Esposito DB, Gracey KD et al (2010) Influenza vaccine given to pregnant women reduces hospitalization due to influenza in their infants. Clin Infect Dis. 51: 1355-1361.

<sup>&</sup>lt;sup>7</sup> Eick AA, Uyeki TM, Klimov A, et al (2010) Maternal Influenza Vaccination and Effect on Influenza Virus Infection in Young Infants. Arch Pediatr Adolesc Med. 165: 104-111.

<sup>&</sup>lt;sup>8</sup> Zaman K, Roy E , Arifeen SE et al (2008) Effectiveness of maternal influenza immunisation in mothers and infants. N Engl J Med. 359: 1555-1564.

## Annex D – Frontline health and social care workers

Employers are responsible for ensuring that arrangements are in place for the vaccination of their frontline health and social care workers. Flu outbreaks can arise in health and social care settings with both staff and their patients/clients being affected when flu is circulating in the community. It is important that health professionals protect themselves by having the flu vaccine, and, in doing so, they reduce the risk of spreading flu to their family members. Uptake of the seasonal flu vaccine in frontline healthcare workers had reached 34.7% at the end of February 2011. This is still too low. This compares with 40.4% uptake of the H1N1 monovalent vaccine in healthcare workers achieved during the flu pandemic of 2009. Some PCTs and Acute Trusts achieved high coverage levels in excess of 70% for pandemic flu vaccine during the 2009/10 pandemic vaccination programme, showing that high levels can be reached<sup>9</sup>.

Vaccination of healthcare workers against flu significantly lowers rates of flu-like illness, hospitalisation and mortality in the elderly in healthcare settings<sup>10 11 12 13</sup>. Vaccination of staff in social care settings may provide similar benefits. Flu immunisation of frontline health and social care staff may reduce the transmission of infection to vulnerable patients, some of whom may have impaired immunity that may not respond well to immunisation.

Vaccination of frontline workers also helps reduce the level of sickness absences which will contribute to keeping the NHS and care services running. This is particularly important when responding to winter pressures.

### Vaccine uptake data collection of healthcare workers

All commissioning PCTs should report uptake of flu vaccine of their staff, including staff in GP practices.

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www.dh.gov.uk/prod\_consum\_dh/groups/dh\_digitalassets/@dh/@en/@ps/documents/digitalasset/dh\_121015.pdf

<sup>&</sup>lt;sup>10</sup> Potter, J., Stott, D.J., Roberts, M.A., Elder, A.G., O'Donnell, B., Knight, P.V. and Carman W.F. The Influenza Vaccination of Health Care Workers in Long-Term-Care Hospitals reduces the Mortality of Elderly Patients. *Journal of Infectious Diseases* 1997;175:1-6

<sup>&</sup>lt;sup>11</sup> Carman, W.F., Elder, A.G., Wallace, L.A., McAulay, K., Walker, A., Murray, G.D., Stott, D.J. Effects of Influenza Vaccination of Healthcare Workers on Mortality of Elderly People in Long Term Care: a randomised control trial. *The Lancet* 2000; 355:93-97

<sup>&</sup>lt;sup>12</sup> Hayward, A.C., Harling, R., Wetten, S., Johnson, A.M., Munro, S., Smedley, J., Murad, S. and Watson, J.M. Effectiveness of an influenza vaccine programme for care home staff to prevent death, morbidity, and health service use among residents: cluster randomised controlled trial. *British Medical Journal* 2006; doi:10.1136/bmj.39010.581354.55 (published 1 December 2006)

<sup>&</sup>lt;sup>13</sup> Lemaitre, M., Meret, T., Rothan-Tondeur, M., Belmin, J., Lejonc, J., Luquel, L., Piette, F., Salom, M., Verny, M., Vetel, J., Veyssier, P. and Carrat, F. Effect of Influenza Vaccination of Nursing Home Staff on Mortality of Residents: a cluster randomised trial. *Journal of American Geriatric Society* 2009; 57:1580-1586

Approval for a mandatory collection will be sought from the Review of Central Returns (ROCR). Guidance about specific immunisation programmes and uptake data collections are published at www.dh.gov.uk/en/Publichealth/Immunisation/DH 119387

PCTs should use their own tried and tested methods of collecting information from GP practices. There is also a GP data entry tool available on the ImmForm website. It is important to note that this GP data entry tool is not a route for GP practices to submit data directly to the Department of Health and thus bypass PCTs; this application is not monitored by the Department and no data are extracted from it by the Department. This data entry tool is one of many different options for PCTs to collect staff flu vaccination data from GP practices.

### Rationale and target groups

The updated Code of Practice on the prevention and control of infections and related guidance<sup>14</sup> reminds both NHS and social care bodies of their responsibilities. These are to ensure, so far as is reasonably practicable, that health and social care workers are free of, and are protected from exposure to infections that can be caught at work, and that all staff are suitably educated in the prevention and control of infections. This includes ensuring that occupational health policies and procedures in relation to the prevention and management of communicable diseases in healthcare workers, including immunisation, are in place.

Decisions on offering immunisation should be made on the basis of a local risk assessment as described in *Immunisation against infectious disease*<sup>15</sup>. Employers should make vaccines available free of charge to employees if a risk assessment indicates that it is needed.

The flu immunisation given to healthcare staff directly involved in patient care and social care workers who are employed to provide personal care acts as an adjunct to good infection prevention and control procedures. As well as reducing the risk to the patient/client of infection, the reduction of flu infection among staff, and reduced staff absenteeism, have also been documented. The importance of immunising healthcare workers was highlighted by the outbreak at the Royal Liverpool University Hospital in 2008 when flu spread rapidly through several wards infecting both patients and staff. The HPA confirmed that the infection was mainly spread by healthcare workers.

Trusts/employers will wish to ensure that health and social care staff directly involved in delivering care are encouraged to be immunised and that processes are in place to facilitate this.

<sup>&</sup>lt;sup>14</sup> www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\_122604

<sup>&</sup>lt;sup>15</sup> www.dh.gov.uk/prod consum dh/groups/dh digitalassets/@dh/@en/documents/digitalasset/dh 063632.pdf

Examples of staff who may be directly involved in delivering care include:

- clinicians, midwives and nurses, paramedics and ambulance drivers;
- occupational therapists, physiotherapists and radiographers;
- primary care providers such as GPs, practice nurses, district nurses and health visitors;
- social care staff working in care settings;
- pharmacists, both those working in the community and in other clinical settings.

Students and trainees in these disciplines and volunteers who are working with patients should also be included. This is not an exhaustive list and decisions to provide immunisation should be based on local assessment of likely risk and exposure to flu.

# Annex E – Improving vaccine uptake and data collection

In winter 2010/11 the estimated uptake of the seasonal flu vaccine in those aged 65 years and over reached 72.8% - still short of the WHO target of 75%. Uptake among people aged under 65 with clinical conditions which put them more at risk from the effects of flu reached 50.4%. Uptake among pregnant women reached 38%.



Figure 1: Seasonal influenza vaccine percentage uptake by year for England.

As in previous years, flu vaccine uptake collections will be managed using the ImmForm website. The Health Protection Agency (HPA) will coordinate the data collection on behalf of DH. The HPA will issue details of the collection requirements by the end of July 2011 and guidance on the data collection process by early September 2011. The email contact for flu queries concerning data collection content or process should be directed to influenza@hpa.org.uk

Queries concerning ImmForm login details and passwords should be directed to <u>immform@dh.gsi.gov.uk</u>

### Reducing the burden from data collections

Considerable efforts have been made to reduce the burden on GPs of data collection by increasing the number of automated returns that are extracted directly from GP IT systems. Over 70% of GP practices now benefit from using automated IT data returns for seasonal flu vaccine uptake. GP practices that are not able to submit automated returns should discuss their arrangements with their GP IT supplier.

### Data collections for 2011/12

Monthly data collections will take place over four months during the 2011/12 seasonal flu vaccination programme. Subject to ROCR approval the first data collection will be for vaccines administered by the end of October 2011 (data collected in November), with the subsequent collections monthly thereafter, with the final data collection for all vaccines administered by the end of January 2012 (data collected in February). These collections will enable performance to be reviewed at PCT level during the programme, with time to take action if needed, and for the uptake from the completed programme to be measured.

During the data collection period, GP practices, PCTs and SHAs are able, through the ImmForm website, to:

- see their uptake rates by risk groups (PCTs can view data for all practices in their Trust area);
- compare themselves with other anonymous general practices/PCTs/SHAs;
- validate the data on point of entry and correct any errors before data submission;
- view data and export data into Excel, for further analysis;
- make use of automated data upload methods (depending on the IT systems used at practices);
- access previous years' data to compare with the current performance.

These tools can be used to facilitate the local and regional management of the seasonal flu vaccination programme.

### Monitoring on a weekly basis

Weekly uptake data will be collected from a group of GP practices that have fully automated extract and upload facilities provided by their IT suppliers. This scheme was implemented successfully for the previous two vaccination seasons and provides high quality data from over half of GP practices allowing national level monitoring of the vaccination programme. These data will be published in the HPA weekly flu report that is issued on their website throughout the flu season.

## Annex F – Vaccine virus strains and available vaccines

Flu viruses change continuously and the World Health Organization (WHO) monitors the epidemiology of flu viruses throughout the world. Each year it makes recommendations about the strains to be included in vaccines for the forthcoming winter<sup>16</sup>. The WHO has announced the flu strains that should be included in the 2011/12 trivalent seasonal influenza vaccine.

As last winter, H1N1v is likely to still be one of the flu strains that will circulate during the 2011/12 flu season and therefore the trivalent seasonal flu vaccine for the coming flu season will protect against this strain and two others that are considered most likely to circulate (an A/California/7/2009 (H1N1)-like virus, an A/Perth/16/2009 (H3N2)-like virus and a B/Brisbane/60/2008-like virus).

Last winter some patients expressed concerns regarding the inclusion of H1N1 'swine flu' in the trivalent vaccine. In the event, H1N1 was the prevalent virus that caused more than 450 deaths in England<sup>17</sup> and there were no vaccines produced without this strain in them. This will be the situation this year. Q&A will be made available on the DH website and the NHS Comms Link website, available to NHS Communicators, which GPs and practice nurses may find helpful in handling concerns about this year's vaccines.

The table overleaf sets out the vaccines that will be available for the 2011 seasonal flu immunisation programme.

<sup>&</sup>lt;sup>16</sup> www.who.int/csr/disease/influenza/recommendations\_2011\_12north/en/index.html

<sup>&</sup>lt;sup>17</sup> www.hpa.org.uk/web/HPAwebFile/HPAweb\_C/1296685778542

Vaccines available for the 2011/12 seasonal flu immunisation programme.

Supplier	Name of product	Vaccine Type	Age indications	Ovalbumin content	Contact details	
Abbott Healthcare (formerly Solvay Healthcare)	Influvac	Surface antigen, inactivated, sub-unit	From 6 months	No more than 0.1µg ovalbumin / 0.5ml dose	han 0.1µg 0.5ml dose µg ovalbumin / dose	
	Imuvac	Surface antigen, inactivated, sub-unit	From 6 months	No more than 1µg ovalbumin / 0.5ml dose		
Baxter Healthcare	PREFLUCEL	Split virion, inactivated, prepared in Vero cell cultures	From 18 years	No ovalbumin	01635 206265	
Crucell UK	Viroflu	Surface antigen, inactivated, virosome	From 6 months	No more than 0.5µg ovalbumin / 0.5ml dose	0844 800 3907	
GlaxoSmithKline	Fluarix	Split virion, inactivated virus	From 6 months	No more than 0.1µg ovalbumin / 0.5ml dose	0800 783 0470	
MASTA	Imuvac	Surface antigen, inactivated, sub-unit	From 6 months	No more than 1µg ovalbumin / 0.5ml dose	0113 238 7500 (option 1)	
Novartis Vaccines	Agrippal	Surface antigen	From 6 months	No more than 0.2µg ovalbumin / 0.5ml dose	08457 451 500	
	Fluvirin*	Surface antigen	From 4 years	No more than 1µg ovalbumin / 0.5ml dose	00407 401 000	
Pfizer Vaccines	CSL Inactivated influenza vaccine	Split virion Inactivated	From 5 years	No more than 0.02µg ovalbumin / 0.5ml dose	0800 080 4033	
	Enzira	Split virion Inactivated	From 5 years	No more than 0.02µg ovalbumin / 0.5ml dose	0000 009 4000	
Sanofi Pasteur MSD	Inactivated influenza vaccine	Split virion	From 6 months	No more than 0.024µg ovalbumin / 0.5ml dose		
	Intanza 9 µg	Intradermal, split virion	From 18 years to 59 years	No more than 0.024µg ovalbumin / 0.5ml dose	0800 085 5511	
	Intanza 15 µg	Intradermal, split virion	From 60 years	No more than 0.024µg ovalbumin / 0.5ml dose		

None of the flu vaccines for the 2011/12 season contain thiomersal as an added preservative.

\*This vaccine states in its Summary of Product Characteristics (SPC) that it contains traces of thiomersal that are left over from the manufacturing process.

## Annex G – Vaccine supply

GPs remain responsible for ordering vaccine for their eligible populations, and final orders should now have been placed with manufacturers. GP practices should be planning to contact those patients in late September/early October as soon as their stocks of vaccine are in place.

### Central strategic reserve

Following the reports of localised vaccine shortages experienced last winter, this year the Department will retain a small central strategic reserve of trivalent seasonal flu vaccine to mitigate the impact of any shortages should they occur.

This stock of vaccine will not be available at the beginning of the flu season. Any isolated shortages should be managed locally, with local management addressing such shortages through the redistribution of existing stocks. This stock will only be issued if the Department determines that it is necessary to bridge a gap for which there have not been sufficient local supplies.

It is anticipated that in a normal flu season the strategic reserve will not be accessed by primary care and that this small reserve will be considered as an insurance against shortages in a more severe flu season when there has been exceptional demand for the vaccine.

#### Central procurement of seasonal flu vaccine

The Department published a consultation on the central procurement of seasonal flu vaccine today, 25 May 2011. This document asks for comments on the proposal that the Department of Health should procure all seasonal flu vaccine for the seasonal flu immunisation programme. You can find this document and submit a response at <a href="http://consultations.dh.gov.uk/">http://consultations.dh.gov.uk/</a> These proposals do not affect the 2011/12 flu immunisation season. The consultation closes on 17 August 2011.

## Annex H – Contractual arrangements, service reviews and funding

The arrangements, reviews and funding for the seasonal flu immunisation programme (administration of the trivalent seasonal vaccine) remain the same as in previous years. Under the Primary Medical Services (Directed Enhanced Service) Directions 2010, each PCT must operate or establish an Influenza and Pneumococcal Immunisation Scheme. The PCT may enter into arrangements with primary medical services' contractors or any other local provider, for example community pharmacies, to provide a flu immunisation service. Immunisation Coordinators should note the requirements in the DES and use these to assess the service provided by those GPs supplying the service. For a full list of the requirements placed on GP practices, please refer to section 10 of the DES, which can be downloaded<sup>18</sup>.

Some PCTs have had a low response rate from GP practices for data returns on vaccine uptake among their eligible patients. If PCTs have set up their local contracts under the DES according to the DES directions, the legal documents should have been drawn up in such a way as to incorporate direction 10(g):

'a requirement that the contractor supply its Primary Care Trust with such information as it may reasonably request for the purposes of monitoring the contractor's performance of its obligations under the plan<sup>'19</sup>.

PCTs will wish to check with their legal teams to ensure that the contracts for the seasonal flu immunisation programme are drafted in such a way as to ensure that GPs are obliged to provide the relevant data returns.

PCTs are reminded when commissioning services for vaccinations given in settings other than a GP practice (eg community pharmacies, antenatal clinics etc), it is important that the details of the vaccinations are provided to the patient's registered practice and are recorded on their electronic clinical record in a timely manner. This is important for clinical reasons (eg if there are any adverse events) and also means that these vaccinations will be included in the vaccine uptake data collections.

PCTs will recognise the need to assess the quality of their local flu immunisation services, drive towards continuous improvement, be responsive to patient needs, provide value for money and extend the reach of their immunisation programme to those who need it most. Patients who fail to attend for vaccination should be followed up and their needs reviewed. PCTs may want to consider putting targets and other performance measures into any Local Enhanced Service (LES) agreements that they set up.

The budget to reimburse contractors is provided as part of the PCT's Unified Allowances.

<sup>&</sup>lt;sup>18</sup> www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Directionsfromthesecretaryofstate/DH\_113692

<sup>&</sup>lt;sup>19</sup> www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Directionsfromthesecretaryofstate/DH 113692