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Dear Colleague

SCOTTISH IMMUNISATION PROGRAMME CHILDHOOD FLU PROGRAMME - YEAR 2 IMPLEMENTATION 2014-15

1. The purpose of this letter is to provide details about the further implementation of the childhood flu programme which began in October 2013. Year 2 of the phased introduction of that programme will formally commence from 1 October 2014. A separate letter ([SGHD/CMO\(2014\)12](#)) provides details on the routine annual seasonal flu programme for adults aged 65 and over and adults with “at-risk” health conditions. Circular [PCA\(P\)\(2014\)1/PCA\(M\)\(2014\)6](#) has already detailed the vaccine supply arrangements in respect of adults only. This letter, therefore, only deals with flu immunisation for children, including those with “at-risk” health conditions.
2. From 1 October 2013 the phased introduction of the childhood flu programme began in Scotland and the rest of the UK following advice from the Joint Committee for Vaccination & Immunisation (JCVI). The JCVI statement is available at: <http://webarchive.nationalarchives.gov.uk/20130402145952/http://media.dh.gov.uk/network/261/files/2012/07/jcvi-statement-on-the-annual-influenza-vaccination-programme-25-july-2012.pdf>
3. The programme, when fully rolled out, will apply to all children aged 2 to 17. Children below the age of 2 continue to be eligible if they have “at risk” health conditions.
4. **An updated green book chapter is expected by the end of June 2014.** Once this has been published Health Protection Scotland (HPS) will produce an algorithm to support immunisers to select the appropriate flu vaccine for different ages, taking into account those who cannot have the nasal flu vaccine.

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For action

Chief Executives, NHS Boards
Medical Directors, NHS Boards
Directors of Nursing & Midwifery, NHS Boards
Directors of Pharmacy, NHS Boards
Directors of Public Health, NHS Boards
General Practitioners
Practice Nurses
School Nurses
Immunisation Co-ordinators
CPHMs
Scottish Prison Service
Scottish Ambulance Service
Occupational Health Leads

For information

Chairs, NHS Boards
Infectious Disease Consultants
Consultant Paediatricians
Consultant Physicians
Consultants in Dental Public Health
Dental Lead Officers
Health Protection Scotland
Chief Executive, NHS Health Scotland
NHS 24
Health Visitors
Scottish General Practitioners Committee
Local Authority Chief Executives and
Directors of Education
Proprietors of Independent Schools
Scottish Council of Independent Schools

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Programme Phasing

5. The programme is being phased in due to its scale and resource implications. In year one, all 2 and 3 year old children were offered vaccination by GPs in GP Practices; and NHS Boards vaccinated a selection of primary school aged children on a pilot basis, a combination of single primary school year cohorts in some NHS Board areas and a proportion of whole schools in other areas.
6. The phasing of the rollout of the childhood flu programme has now been adjusted to reflect the feedback from NHS Boards and experiences from year one. The scale of the programme (ultimately increasing annual flu vaccinations from around one million doses to around two million doses) is unprecedented. The programme in Scotland is now being phased in as follows, as agreed with Michael Matheson MSP, Minister for Public Health:
 - **Year 2 - Winter 14/15**
 - all pre-school children aged 2 to 5 years
 - all primary school children in Primary one to Primary 7
 - **Year 3 - Winter 15/16**
 - all pre-school children aged 2 to 5 years
 - all primary school children
 - possibly one secondary school cohort (Secondary one) depending on resources
 - **Year 4 - Winter 16/17**
 - all pre-school children aged 2 to 5 years
 - all primary school children
 - possibly one or 2 secondary school cohorts (Secondary one and Secondary 2) depending on resources
7. Further work will be undertaken with NHS Boards, the BMA and other stakeholders to consider the impact and resource issues for the longer term future of the programme.

Key Messages

8. Flu is a serious infection and can spread easily between family members and friends. The childhood flu programme is an ambitious development aiming to protect children from flu, reduce levels of flu circulating in the community and reduce transmission to other vulnerable groups.
9. Once fully rolled out it is estimated that the childhood flu programme will prevent an **additional** 200 deaths per year from flu, 1,100 hospitalisations and 33,000 GP consultations. Overall it is estimated that the annual flu programme for all risk groups will therefore prevent:
 - **600 deaths per year;**
 - **3,100 hospitalisations; and**
 - **58,000 GP consultations.**

10. Children are 2 to 3 times more likely to be ill with flu than adults, having had less time to build up any immunity. Vaccinating children will provide them with the best available protection and will also help to protect their families and friends by reducing onward transmission of flu. The flu programme is a clear example of a successful preventative healthcare approach.

Children to be Vaccinated by GP Practices

Pre-school

Children aged under 2 years of age with “at-risk” conditions

11. GP Practices continue to be responsible for vaccinating “at-risk” children aged 6 months to less than 2 years. GP Practices should continue to make their usual arrangements for vaccinating those children, including call and recall.

All children aged 2 to 5 years including “at-risk” children in this age group

12. Within the 2014-15 programme, the birth cohorts for the pre-school children aged 2 to 5 years eligible for the flu vaccine are as follows:

- Aged 2 years: **all** children born on or after 2 September 2011 and on or before 1 September 2012;
- Aged 3 years: **all** children born on or after 2 September 2010 and on or before 1 September 2011;
- Aged 4 years: children born on or after 2 September 2009 and on or before 1 September 2010 who are not yet attending primary school.
- Aged 5 years: children born on or after 2 September 2008 and on or before 1 September 2009 who are not yet attending primary school.

13. Children born between 1 March 2009 and 28 February 2010 will normally enter Primary one in 2014/15.

14. The vaccination of these children will be carried out by GP Practices. GP Practices will receive a list of eligible pre-school children from SIRS. GP Practices can either mark the SIRS list or return a list of children vaccinated which includes their CHI numbers and addresses to SIRS.

15. There is no central invitation being issued for pre-school children this year. GPs are responsible for call and recall of those children including “at-risk” children in this age group. Materials to assist GPs in this process will be provided – see paragraph 43.

School Aged Children

Primary School Aged Children

16. NHS Boards are responsible for arrangements for vaccination of all primary school aged children this coming winter. Scottish Government policy is that all

children (including “at-risk” children) should be offered vaccination in school whether they require the nasal vaccine or an injectable vaccine. However, it is recognised that not all Boards may wish to vaccinate children in schools who require an injectable flu vaccine until the programme is more fully established (and some NHS Boards may need support with vaccinating “at-risk” children early in the flu season to avoid “at-risk” children waiting). **NHS Boards need to discuss and agree their own local arrangements with the Local Medical Committee (LCM).** Some NHS Boards may choose to offer a LES agreement this winter.

Secondary School Aged Children and Those Who Have Left School Up to Age 18 Years

17. GPs continue to be responsible for vaccinating all “at-risk” children who are not receiving vaccine in school this year. **This year this will include all “at-risk” children who have left primary school as those children are not yet included in the rollout of the childhood programme.** GPs should continue to make their usual arrangements for those children, including call and recall.
18. Children born between 1 March 2002 and 28 February 2003 will normally enter Secondary one in 2014/15.

Children to be Vaccinated by NHS Boards

19. This winter the vaccine will be offered to all primary school aged children (including “at-risk” children) in schools as agreed with NHS Boards.
20. As noted above, local arrangements may differ in relation to “at-risk” children at primary school as the programme is rolled out. This should be communicated to local GP Practices as early as possible once agreed with the LMC.
21. NHS Boards are only required to offer one vaccination slot in primary schools. This means that children absent from school on that day (for any reason) will not receive the vaccine. In addition, some children offered one dose of vaccine in primary school will require a second dose (see Annex A, paragraph 4).
22. In all of these circumstances, NHS Boards have been asked to ensure that adequate local arrangements are in place to offer an alternative opportunity for vaccination where this is possible. Specific arrangements should be made to ensure provision of alternative injectable vaccine in relation to faith concerns about pork gelatine. **NHS Boards should communicate local arrangements as early as possible to all those involved in running the programme. Arrangements that involve GP Practices need to be agreed with the LMC.**

Vaccine

23. The JCVI has recommended that a live attenuated nasal flu vaccine (LAIV) be used as the vaccine of choice for the extended childhood flu programme. There is currently only one LAIV available in the UK, Fluenz® Tetra (marketed by Astra Zeneca). This year Fluenz® Tetra (a quadrivalent live attenuated intranasal influenza vaccine) will be supplied in place of Fluenz®.

24. JCVI recommended Fluenz® Tetra as it has:

- higher efficacy in children, particularly after a single dose;
- the potential to provide coverage against circulating strains that have differed from those contained in the inactivated vaccine;
- higher acceptability with children, their parents and carers due to intranasal administration; and
- it may offer important longer-term immunological advantages to children by replicating natural exposure/infection to induce potentially better immune memory to influenza that may not arise from the annual use of inactivated vaccines.

25. Full details of vaccine use and vaccine uptake data collection are outlined in Annex A and Annex B.

Dosage and Schedule

26. Most children will receive one dose of Fluenz® Tetra vaccine. Only children who are in an “at-risk” group for flu, are under the age of 9 years, and have not previously received influenza vaccine, will require a second dose of flu vaccine at least 4 weeks after the first dose. NHS Boards should ensure adequate arrangements are in place locally for the second dose. It should be noted that any child in an “at-risk” category under 9 years of age who has previously received the monovalent H1N1 vaccine will only require one dose of influenza vaccine.

Pork Gelatine Content in Fluenz® Tetra

27. As you will be aware, Fluenz® Tetra contains porcine gelatine. The Scottish Government has relied on advice from the WHO (<http://www.immunize.org/concerns/porcine.pdf>) that the vaccine is still acceptable to Muslims. However, we know that some parents may not wish to consent to their child receiving Fluenz® Tetra on the grounds of faith or belief. In those circumstances, where the parent is not minded to consent to Fluenz® Tetra and understands that alternative injectable vaccines are up to 50% less effective in children, NHS Boards or GPs should ensure that they make the offer of an alternative injectable flu vaccine that does not contain porcine gelatine. This is only on grounds of faith or belief. Faith or belief, in the context of offering an alternative, is considered to be religious faith or belief. We do not think that an offer of an alternative needs to be made where parents refuse consent because of non-religious belief such as vegetarianism or veganism. Parents may of course refuse a vaccine for their children for many other reasons as vaccination is entirely voluntary, however, individuals refusing for other reasons should not be offered the alternative vaccine.

Vaccine Ordering: Fluenz® Tetra and Inactivated Flu Vaccine for children in whom Fluenz® Tetra is Unsuitable

28. **All flu vaccines for children (whether Fluenz® Tetra or other injectable vaccines) are now being ordered centrally by the Scottish Government.** Fluenz® Tetra is ordered by Public Health England (PHE) on our behalf as part of a UK wide contract. Injectable flu vaccines are ordered by NSS procurement in Scotland. **GP Practices, therefore, are no longer required to order flu vaccine for children through Community Pharmacies.**
29. GP Practices should place orders with vaccine holding centres in each NHS Board using the local ordering system for both Fluenz® Tetra and injectable flu vaccines. Practices must liaise closely with holding centres to ensure adequate vaccine supplies are guaranteed before organising vaccination clinics. Clinicians should refer to the Scottish Government Circular PCA(P) (2014)/1/PCA(M)(2014)6 , issued on 11 February 2014 in relation to the seasonal flu immunisation programme, which details the vaccine supply arrangements for 2014/15 for adults aged 65 and over or aged 18-64 with “at-risk” conditions.
30. **Fluenz® Tetra is now the vaccine of choice for the majority of children but for those children who are contraindicated for Fluenz® Tetra, inactivated influenza vaccines can be used after checking age restrictions in the relevant summary of product characteristics (SmPC). Please refer to Annex A for details of contraindications on the use of influenza vaccines.**

Monitoring Vaccine Uptake: Data Extraction

31. HPS will lead in monitoring vaccine uptake on behalf of the Scottish Government.
32. For pre-school children aged 2 to 5 years, this will be primarily managed by extracting uptake information from GP systems by age, sex and risk group. Estimated vaccine uptake rates on those vaccines given in GP Practices will be published on a weekly basis in the HPS weekly influenza report. Additionally, NHS Boards will be able to access specific uptake data down to individual practice level within their Board from the HPS seasonal influenza vaccine uptake microsite. The data made available will include vaccine uptake by week in the season 2014/15 and 2013/14 and 2012/13 for comparison.
33. For primary school aged children vaccinated in school, HPS will collate and publish in season aggregate level vaccine uptake figures provided by NHS Boards when they become available. End of season validation of uptake figures will be based on individual level uptake data from the child health system which will allow consolidation of school programme uptake figures with GP based vaccinations of primary school aged children.
34. The Scottish Clinical Information Management in Practice (SCIMP) website provides very good information and guidance on coding, recording of vaccinations and exceptions (e.g. where a vaccine is contraindicated), as well as links to relevant documents. Colleagues in primary care or within NHS Boards

with general queries about data extraction and coding, should refer to the SCIMP website in the first instance: <http://www.scimp.scot.nhs.uk/>

35. In achieving accurate uptake figures, it is important to ensure that the size of the populations “at-risk” – i.e. the denominators of the population who are to be offered vaccination – is accurately and consistently described and that mechanisms are put in place by GP Practices to ensure their validity.
36. **GP Practices are requested to send to Practitioner Services Division (PSD) a single figure for the total number of children (i.e. a denominator figure) who are in eligible groups within their practice area as part of their immunisation payment claim (Directed Enhanced Service). This information should be submitted by 31 March 2015.** These groups will be (a) 2 to 5 year old children (inclusive) not in any “at-risk” group and (b) 2 to 5 year old children (inclusive) in “at-risk” groups. (These will be the verified denominator figures for percentage uptake calculations and payment claims)
37. The denominator data will be used for statistical purposes and is important as this information allows HPS to validate the estimated uptake figures collected throughout the influenza season for those under the age of 65 in “at-risk” groups (which also includes the 2 to 5 year olds in the “at-risk” groups), and separately for those 2 to 5 year olds “at-risk”, and those not “at-risk”. A similar validation process is undertaken for those aged 65 years and over using the end of season PSD immunisation payment claims (Directed Enhanced Service).
38. For further information regarding the HPS vaccine uptake monitoring programme, please contact nss.hpsflu@nhs.net

Funding and GP Contractual Arrangements

39. The Scottish Government is meeting the vaccine purchase costs (including delivery to vaccine holding centres) and other central costs associated with the programme, and NHS Boards are meeting the service delivery costs including GP costs from their baseline resources.
40. The delivery of the extended programme will be via an extension of the existing Flu Directed Enhanced Service, and the Directions which provide the legal framework for Directed Enhanced Services in Scotland are being revised.
41. The minimum position outlined in the Directed Enhanced Service (DES) regarding payments to practices should normally apply, and any necessary variation for local circumstances should be agreed by NHS Board and Local Medical Committees (LMCs).

Communications and information for patients and health professionals

National Media Campaign

42. There was no national media campaign to support the childhood flu programme in year one as activity was directed at smaller numbers of children. This year there will be a national media campaign to support the programme including

radio, TV and newspapers. The campaign will be timed around the delivery of consent packs to parents (see below) for primary school children and to support the invitation of pre-school children to be vaccinated at their GP practice. The campaign is planned to run from August to October. A media Q&A will also be developed and made available.

To Support GP Practices

43. NHS Health Scotland is developing an information leaflet and poster for parents of pre-school children. **The materials provided to GP Practices this year will include a template invitation letter. Please note that GP Practices are responsible for inviting pre-school children for vaccination this year (this was handled centrally on a one-off basis last year). GP Practices must ensure that they call children for vaccination this year using the template letter provided or their own alternative letter.** The template letter and information leaflets will be made available during August 2014.
44. Posters will be distributed to key settings such as nurseries, GP Practices and pharmacies.

To Support NHS Boards

45. Packs of information will be distributed either direct or via the NHS Board to local schools to be sent home in school bags. These packs, which will be put together centrally and posted to Boards, will include a letter and information leaflet for parents of primary school children as well as a consent form. A post immunisation sheet, detailing possible side effects and a note for parents to be given to children directly following immunisation will also be made available to local immunisation teams.
46. To support the programme in schools, NHS Health Scotland is also producing a support pack that will include briefing sheets for education staff, stickers and a DVD that can be shown to children in advance of vaccination sessions. These packs will be delivered to all primary schools during August.
47. Information leaflets have been developed in consultation with parents, expert groups and NHS partners. Leaflets will also be available in a range of other languages to download from www.immunisationscotland.org.uk. NHS Health Scotland is happy to consider requests for other languages and formats. Please contact 0131 536 5500 or email nhs.healthscotland-alternativeformats@nhs.net
48. The public should be signposted to www.immunisationscotland.org.uk for up to date information on the programme.

Resources for health professionals

49. NHS Education for Scotland in partnership with HPS is producing a number of educational resources for registered and non registered healthcare practitioners. These will include updated training slides, a question and answer resource and a short video clip showing the administration of the Fluenz® Tetra vaccine (the video clip is available now). These resources will be available at

<http://www.nes.scot.nhs.uk/education-and-training/by-theme-initiative/public-health/health-protection/seasonal-flu.aspx> It is anticipated that these resources will be available by mid July 2014.

The Green Book

50. The Green Book, *Immunisation against Infectious Disease*, provides guidance for healthcare workers on administering the flu vaccine. PHE will publish an updated influenza chapter of the Green Book on the Gov.uk website shortly. The Green Book is available online at: <https://www.gov.uk/government/publications/green-book-the-complete-current-edition>

51. **An updated green book chapter is expected by the end of June 2014.**

Planning Activity

52. GP Practices and NHS Boards are encouraged to ensure that uptake of flu vaccine by all eligible children is as high as possible. This is important in order to maximise the health benefits that the extended programme is expected to bring. Colleagues are reminded of the importance of planning for vaccination early in the season, to ensure that as many of the eligible population as possible can be protected before influenza viruses begin circulating. **Our aim should be to get as many children as possible vaccinated before the end of November. GP Practices should particularly note their additional responsibility for the call and recall of pre-school children this year.**

53. It is also important that health visitors, school nurses and other relevant health professionals encourage flu vaccination, promote uptake of the vaccine and work closely with education professionals. The communications resources will assist you in this, as will the key messages included earlier in this letter.

Uptake Targets

54. Uptake targets for the purposes of management of year 2 of the programme have been agreed with both NHS Boards and the BMA. The targets take into account the recorded uptake figures from year one of the programme. These are aspirational but realistic targets that NHS Boards and GP Practices should seek to work towards. Uptake data will be gathered by HPS and monitored and assessed by the Scottish Immunisation Programme (SIP) groups and the Scottish Government Steering Group. Targets are as follows:

- Primary school children: an aspirational target of 75% (interim uptake for 2013/2014 - 67.2%), and in line with WHO recommendations for flu vaccine uptake.
- Pre-school children: an aspirational target of 70% for 2014/15 (interim uptake for 2013/14 – 50.7%), but no less than 60%, and working towards the WHO target of 75% in 2015/16.

55. Targets will be reviewed for year 3 of the programme.

Action

56. NHS Boards, including Primary Care Teams, and GP Practices are asked to note the arrangements outlined in this letter for year 2 of the phased introduction of the childhood flu programme.

57. We are very grateful for the ongoing and considerable support of all staff in working together to implement this significant and challenging new public health programme.

Yours sincerely

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VACCINE USE IN CHILDREN

Use of Flu Vaccine for Children

1. The JCVI has advised that a single vaccine – the live attenuated nasal flu vaccine (Fluenz® Tetra marketed by AstraZeneca) that is authorised for children aged from 2 to under 18 years – should be the vaccine of choice for the extended programme. This is because it is more effective in children than other inactivated flu vaccines, it has a good safety profile in children aged 2 years and older and an established history of use in the United States. Furthermore, it may provide some cross protection against other flu strains that are not well matched to the vaccine strains.
2. A summary of the JCVI advice is available at: <http://webarchive.nationalarchives.gov.uk/20130402145952/http://media.dh.gov.uk/network/261/files/2012/07/jcvi-statement-on-the-annual-influenza-vaccination-programme-25-july-2012.pdf>
3. The vaccine being used in 2014/15 (Fluenz® Tetra) is a quadrivalent vaccine as it has 2 flu B strains and may be better matched and therefore may provide better protection against the circulating B strain(s).
4. The Marketing Authorisation holder's patient information leaflet provided with Fluenz® Tetra suggests children should be given 2 doses of this vaccine if they have not had flu vaccine before. However, the JCVI considers that the public health benefit would be greater if the quantity of Fluenz® Tetra that is available is offered as a single dose to more children. This is because a second dose of the vaccine provides only modest additional protection. Therefore, it would be better if more children received the benefit of the protection provided by at least one dose of the vaccine.
5. On this basis, the JCVI has advised that, when extending the flu immunisation programme to children, most children should be offered **a single dose** of the Fluenz® Tetra. However, children in "at-risk" groups aged 2 to less than 9 years who have not received flu vaccine before should be offered 2 doses of Fluenz® Tetra (given at least 4 weeks apart). It should be noted that if any child in an "at-risk" category under the age of 9 years, who has previously received the monovalent H1N1 vaccine, will only require one further dose of influenza vaccine.
6. Registered Healthcare Practitioners are reminded that in some circumstances the recommendations regarding vaccines given in the Green Book chapters may differ from those in the SmPC for a particular vaccine. When this occurs, the recommendations in the Green Book are based on current expert advice received from the JCVI and this advice should be followed.
7. The parents/guardians of any child in an "at-risk" category who has not received the vaccine at school or requires a second dose, should make an appointment at

their GP practice. The local agreed arrangements should be checked for “at-risk” children in the primary schools this year.

8. Experience from the first year of the programme has been very positive. Some parents did need reassurance about its effectiveness if they noticed their child’s nose dripping after the vaccine had been administered. However as the vaccine is absorbed very quickly, even if a child gets a runny nose, sneezes or blows their nose immediately after the spray, it is still likely to be effective.

Presentation

9. Fluenz® Tetra is supplied as a single use prefilled nasal applicator. The nasal applicator is ready to use. No reconstitution or dilution is required. The nasal suspension is colourless to pale yellow, clear to opalescent. Small white particles may be present.

Administration

10. Fluenz® Tetra is administered by the intranasal route and is supplied in an applicator that allows a divided dose to be administered in both nostrils. Neither divided dose needs to be repeated if the patient sneezes, or blows their nose following administration.
11. Fluenz® Tetra can be given at the same time as other vaccines including live vaccines. The recommendation for administering live vaccines at the same time or after an interval of 4 weeks only applies to injectable live vaccines and therefore not to Fluenz® Tetra.

Dosage

12. The dose of Fluenz® Tetra is 0.2ml, administered as a divided dose (0.1ml) in both nostrils. After administering half of the dose (0.1ml) in one nostril the other half should be administered in the other nostril immediately or shortly after.

Contraindications and Precautions

13. Fluenz® Tetra should not be given to children less than 2 years of age or in individuals aged 18 years and above.
14. Fluenz® Tetra should not be given to those who have had a confirmed anaphylactic reaction to a previous dose of flu vaccine or any component of the vaccine.
15. Fluenz® Tetra should not be given to children or adolescents who are clinically severely immunodeficient due to conditions or immunosuppressive therapy such as: acute and chronic leukaemias; lymphoma; HIV infection not on highly active antiretroviral therapy (HAART); cellular immune deficiencies; and high dose corticosteroids. It is not contraindicated for use in children or adolescents with HIV infection receiving stable antiretroviral therapy; or who are receiving topical/inhaled corticosteroids or low-dose systemic corticosteroids or those

receiving corticosteroids as replacement therapy, e.g. for adrenal insufficiency. It is contraindicated in children and adolescents younger than 18 years of age receiving salicylate therapy because of the association of Reye's syndrome with salicylates and wild-type influenza infection.

16. Fluenz® Tetra should not be given to children with egg allergy.
17. Fluenz® Tetra is not recommended for children with active wheezing at the time of vaccination or severe asthma (BTS SIGN step four or above) because of limited safety data in these groups.
18. There is a potential for transmission of live attenuated influenza virus in Fluenz® Tetra to very severely immunocompromised contacts (e.g. bone marrow transplant patients requiring isolation) for one to 2 weeks following vaccination. Where close contact with very severely immunocompromised patients (for example household members) is likely or unavoidable, appropriate alternative inactivated influenza vaccines should be considered.
19. The advice in contraindications and precautions sections in the Green Book influenza chapter should be referred to: <https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19>
20. For the small proportion of children for whom Fluenz® Tetra is contraindicated, a suitable inactivated injectable flu vaccine should be considered:-
 - If these children are aged less than 9 years and have not received flu vaccine before, 2 doses of the injected inactivated vaccine should be offered (given at least 4 weeks apart).
 - Children aged from 3 years for whom Fluenz® Tetra is not suitable should be offered **quadrivalent inactivated vaccine**. The quadrivalent vaccine has 2 influenza B strains and may be better matched and therefore may provide better protection against the circulating B strain(s) than trivalent inactivated influenza vaccines.
 - Children aged from 6 months to under 2 years in “at-risk” groups who are not included in the extension programme should be offered a **trivalent inactivated vaccine** licensed for their age.
 - Children from age 2 years to under 3 years for whom Fluenz® Tetra is not suitable should be offered a **trivalent inactivated vaccine** licensed for their age.
 - Young people at secondary school and those who have left school up to age 18 in “at-risk” groups who are not included in the extension programme should be offered **quadrivalent inactivated vaccine**.

21. Some inactivated flu vaccines are restricted to use in particular age groups. Practitioners must be familiar and refer to the marketing authorisation holder's SPC for the particular brand when administering vaccines.
22. More detailed information on the characteristics of the available vaccines, including age indications and ovalbumin (egg) content can be found in the Seasonal Flu chapter of the Green Book.

Storage

23. Vaccines should be stored in the original packaging at +2°C to +8°C and protected from light. All vaccines may be sensitive to some extent to heat and cold. Heat speeds up the decline in potency of most vaccines, thus reducing their shelf life. Do not freeze. Freezing may cause increased reactogenicity and loss of potency for some vaccines. It can also cause hairline cracks in the container, leading to contamination of the contents.
24. Please be aware that, before use, the Fluenz® Tetra vaccine may be taken out of the refrigerator, without being replaced, for a maximum period of 12 hours at a temperature not above 25°C. If the vaccine has not been used after this 12-hour period, it should be disposed of.
25. Fluenz® Tetra has a shorter shelf life (18 weeks) than other influenza vaccines and some of this may have passed the expiry date by the time the vaccine has been supplied to you. The expiry date on the nasal spray applicator should always be checked before use. Vaccine has been ordered to cover the period over which historically the flu vaccine has been used, extending from September to mid-December. It is likely that **all the Fluenz® Tetra will have expired by the end of December 2014**. In light of this it will be important to ensure that efforts are made to vaccinate children before the Christmas holidays.

Vaccine Stock Management

26. Please ensure sufficient fridge space is available for the new vaccine. Each site holding vaccine is asked to review current stocks of all vaccines. No more than 2 to 4 weeks of stock is recommended, and higher stock levels should be reduced to this level. A review of available fridge space will be necessary to ensure adequate storage capacity at the start of the programme.
27. Effective management of vaccines throughout the supply chain is essential to reduce vaccine wastage, including the use of appropriate cool boxes/bags for transporting the vaccine during home visits. Local protocols should be in place to reduce vaccine wastage to a minimum. Even small percentage reductions in vaccine wastage will have a major impact on the financing of vaccine supplies.

Recording of Vaccination Information

28. Accurate, accessible records of vaccinations given are important for keeping individual clinical records, monitoring immunisation uptake and facilitating the recall of recipients of vaccines, if required. Further advice on the information

which needs to be recorded (i.e. brand name, batch number, expiry date, etc) can be found in Chapter 4 of the Green Book (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/147915/Green-Book-Chapter-4.pdf)

Reporting of Adverse Reactions

29. The Medicine and Healthcare products Regulatory Agency (MHRA) monitors the safety of influenza vaccine. If a doctor, nurse, pharmacist or patient suspects that an adverse reaction to a flu vaccine has occurred, it should be reported using the Yellow Card spontaneous reporting scheme (www.yellowcard.gov.uk). Chapter 9 of the Green Book gives detailed guidance about which ADRs to report and how to do so. Additionally, Chapter 8 of the Green Book provides detailed advice on managing ADRs following immunisation.

Patient Group Directions

30. The requirement for Patient Group Directions is described in HDL(2001)7 available from http://www.sehd.scot.nhs.uk/mels/HDL2001_07.HTM. The use of PGDs for administration of vaccines is described in detail in chapter 5 of the Green Book, <http://media.dh.gov.uk/network/211/files/2012/07/Chapter-5.pdf>

31. A specimen Patient Group Direction (PGD) for administration of Fluenz® Tetra is under development and will be available shortly on the HPS website after the publication of the updated Green Book chapter.

Arrangements For Reimbursing Vaccine Costs

32. As previously notified the Scottish Government is meeting the vaccine purchase costs (including delivery to vaccine holding centres) associated with the programme. Expected vaccine costs are being calculated and the Scottish Government will arrange an allocation transfer for 90% of estimated vaccine costs to each NHS Board for the Fluenz® Tetra, Zostavax and Rotarix vaccines. This will cover the childhood flu programme for the flu season commencing on 1 October 2014; shingles vaccination incurred between 1 April 2014 and 31 March 2015; and rotavirus vaccination incurred between 1 April 2014 and 31 March 2015. An exercise will be carried out in January 2015 to review actual vaccine costs incurred by the NHS Boards to date and the remaining 10% of estimated costs will be allocated to cover the period to the end of the financial year.

Further Information

33. Further information will be available in the updated influenza chapter of the Green Book. It is important that the full Green Book guidance is always reviewed carefully in addition to the information in this letter. The Green Book is available at: <https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book>

VACCINE UPTAKE DATA COLLECTIONS

1. HPS will lead in monitoring vaccine uptake on behalf of the Scottish Government. As in previous seasons for GP delivered vaccinations, this will be primarily managed by automated extracts on uptake information from GP systems by age, sex and risk group. Estimated vaccine uptake rates on those vaccines given in GP surgeries will be published on a weekly basis in the HPS weekly influenza report. As in previous years, NHS Boards will be able to access specific uptake data down to individual practice level within their board from the HPS seasonal influenza vaccine uptake microsite. The data made available will include vaccine uptake by week in the season 2014/15 and 2013/14 for comparison, to allow NHS Boards to monitor the success of their strategy to increase uptake.
2. GPs will also be required to submit individual level data on 2 to 5 year olds vaccinated in the GP setting to SIRS. GP Practices will receive a list of eligible pre-school children from SIRS. GP Practices can either mark the SIRS list or return a list of children vaccinated which includes their CHI numbers and addresses to SIRS.
3. Throughout the season aggregate school level vaccine uptake data for primary school aged children will be collated at the Health Board level and submitted to HPS. This data will be reported when it becomes available.
4. Individual level data on vaccination as part of the primary school programme will be recorded through CHSP-School. A list of children vaccinated in the school setting will be made available to GPs after the end of the primary school pilots. GPs should update their patient records accordingly as soon as possible and before the end of March 2014, especially for children in “at-risk” groups.
5. At the end of the season vaccine uptake estimates based on the aggregate level automated GP system extracts will be validated against the GP claims for payment made to PSD (see Annex A, paragraph 36) as well as against the individual level vaccine uptake data recorded on SIRS and CHSP.