

Director-General Health and Chief Executive NHS Scotland  
Dr Kevin Woods

T: 0131-244 2410 F: 0131-244 2162  
E: [dghealth@scotland.gsi.gov.uk](mailto:dghealth@scotland.gsi.gov.uk)



NHS Board Chief Executives  
For information:  
Directors of Public Health  
Nurse Directors  
Medical Directors  
Directors of Pharmacy  
Directors of Human Resources  
H1N1 Vaccination Programme Strategic and Operational Leads  
COSLA  
ADES  
ADSW  
Scottish Care  
Care Commission  
SCG Coordinators



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13 October 2009

Dear Colleague

## **INFLUENZA A(H1N1) VACCINATION PROGRAMME**

Further to my letter of 13 August, I am writing to provide further information on the commencement of the vaccination programme and details of the arrangements which will support this.

We know from previous influenza pandemics that we must prepare for a possible second wave in the autumn or winter that could affect larger numbers of people and put significant pressure on the NHS. We now need to move forward into delivering an effective vaccination programme.

We have considered further advice on vaccine supply based on manufacturer's delivery schedules. Vaccine supply will be limited initially and Boards should be prepared to start implementing the programme with these initial small quantities from 21 October. Current vaccine delivery schedules indicate that all territorial NHS Boards and Special Health Boards could receive their first vaccine delivery by 20 October. This will ensure that frontline healthcare workers and vulnerable patients in acute services will have access to vaccine first. The Department of Health have advised they have taken delivery of initial vaccine from GSK and expect a further delivery tomorrow before they can confirm exact quantities of vaccine supply for Scotland. Further information will be provided to Boards as soon as it is available

however, please ensure that arrangements are in place for immediate turn around on receipt of the vaccine to enable it to reach all necessary locations should the programme begin from 21 October.

In relation to vaccine supply for primary care settings, we are aiming to issue one box to each GP practice over a three week period starting from 26 October – this is subject to anticipated vaccine deliveries. Further advice on this issue will be provided when more information on the manufacturer's delivery schedules is known. Board planners will require to work closely with GPs over the coming weeks to determine logistics for delivery.

During the initial stages of the programme Scotland's share of each delivery of vaccine will be allocated to NHS Boards on a central basis. As the programme develops and more information is available about the vaccine delivery schedule this position will be reviewed and consideration will be given to allowing NHS Boards to place orders with the national distributor.

Stocks will be delivered by the national distributor on a weekly basis into NHS Board Vaccine Holding Centres. This delivery will be made on the same day as Holding Centres receive other vaccines for the childhood immunisation programme.

Some uncertainty remains in relation to the number of doses of the vaccine that will be needed and completion of key work to allow the programme to start, including the Direct Enhanced Service; data requirements; and information materials. We will update you on these aspects in due course but in the meantime this letter aims to provide you with as much information as possible to allow planning to continue and to enable you to proceed quickly to implement the vaccination programme.

### **Planning to start the vaccination programme**

I am pleased to report that all Boards' delivery plans have now been subject to final review and plans now require urgent sign off by each Board. You may be aware that the Joint Committee on Vaccination and Immunisation (JCVI) met on 8 October to consider dosage requirements for those identified in the priority groups and to discuss vaccine issues for pregnant women and children. Ministers are considering these issues and further advice will follow shortly.

### **Data Issues**

All the GP software systems in Scotland will be modified to enable the scheduling of patients for H1N1 immunisation and to record and report vaccinations given. New Read codes have been agreed at UK level and will be available to practices through the October Read code release as soon as possible. Uptake reporting will be via aggregate automated data returns of non-identifiable data which will enable the monitoring and management of the immunisation programme over the coming months. A letter from CMO outlining the data management issues will be sent to practices this week and will provide a link to guidance for practices developed by SCIMP.

Data management for immunisation of the health and social care workforce is reliant on a range of systems at NHS Board level. These are all able to record vaccinations administered. Boards will report high level aggregate uptake figures for the health and social care workforce throughout the immunisation delivery period with more detailed information at the conclusion of the programme.

### **Vaccine Supplies and Licensing**

In relation to the licensing process for the vaccine, I am pleased to advise that both the GSK and Baxter vaccines have now been licensed by the European Commission.

I include further technical information about the vaccine at **Annex A**. Much of the content will also be contained within the professional information materials being produced by the Department of Health (DH). However I hope you will find it useful in the meantime. In terms of other progress, arrangements to report suspected adverse reactions to H1N1 vaccines will be the same as arrangements for reporting adverse reactions to antivirals (Tamiflu and Relenza). MHRA has put in place a special web based reporting system – the Swine flu ADR Portal ([www.mhra.gov.uk/swineflu](http://www.mhra.gov.uk/swineflu)) based on the Yellow Card scheme.

You should also note that from 10 October the H1N1 vaccines will be included in the Vaccine Damage Payments Scheme. The Department for Works and Pensions are responsible for managing the Scheme and more information can be obtained from the website at <http://www.dwp.gov.uk>.

### **GP Contracts**

You will be aware that UK wide contract negotiations with General Practitioners were concluded on 14 September and arrangements for GP involvement in the vaccination programme are now in place. Frank Strang, Deputy Director of Primary Care Division wrote to you on 15 September to provide you with details of the agreement. The Direct Enhanced Service has now been received from the Department of Health and we are adapting this for use in Scotland. We will issue this to Boards later this week together with a more general guidance note. As per Frank Strang's communication of 9 October, I would encourage those Boards who have not yet engaged with GPs to do so in advance of the formal DES notice. I can also confirm that the cost of the GP contract arrangements will be met centrally by the Scottish Government.

In order to provide GP practices with key information about the vaccination programme, Health Protection Scotland have produced Q and A which was issued on 11 September. This document is now being updated on a regular basis by HPS and the latest version can be found on the Health Protection Scotland H1N1 Vaccination Programme microsite.

### **Vaccination of Health and Social Care Staff**

Further guidance was issued on 4 September setting out the definitions of health and social care professionals who should be offered vaccination in this first phase. This

guidance is attached at **Annex B**. I would urge you to encourage staff involved in frontline services to take the vaccination. The vaccination will both protect staff members from infection, and minimise the risk of vulnerable patients also becoming infected.

### **Programme Management and Governance**

The H1N1 Steering Group met for the third time on 14 September and considered strategic issues across the programme including the need for clarification around the decision making process both across the programme in Scotland, and also in liaison with the Department of Health and other UK devolved administrations. Other issues discussed were hard to reach groups for vaccination, data integration across the programme and the need for coherent communications. The Scottish Government and HPS have prepared papers on these issues that have been circulated to Board leads. If you would like further information about the Steering Group or wish to see copies of minutes from the meeting, please contact Syed Kerbalai at [syed.kerbalai@gsi.gov.uk](mailto:syed.kerbalai@gsi.gov.uk) or on 0131 244 5662.

Health Protection Scotland are continuing to coordinate the programme and have weekly meetings with Board leads. These meetings will continue as a forum for Boards to receive up to date information and to work with both HPS and Scottish Government in the development of local plans for delivery.

### **Communications and Information Materials**

Please see **Annex C** for further details on communications and information materials to support the programme.

### **Conclusion**

The success of the vaccination programme depends on the effective coordination of many people and organisations over the coming months and will require effective communications to be in place locally. I want to thank you for your co-operation and for all the work which has gone into preparing for the programme to date, which has put Scotland in a good state of readiness for commencement of the programme later this month.

We will provide further updates as and when further information becomes available. In the meantime, I would ask you to ensure arrangements are in place to proceed with the programme as outlined above and if you or any colleagues have any questions on the H1N1 vaccination programme, I would be grateful if you could contact Dona Milne, on 0131 244 2495 or at [dona.milne@scotland.gsi.gov.uk](mailto:dona.milne@scotland.gsi.gov.uk) .

Yours sincerely

A handwritten signature in black ink, appearing to read 'K Woods', written in a cursive style.

**KEVIN WOODS**

## **SCHEDULE OF ANNEXES**

**A Vaccine Information**

**B Influenza A (H1N1) Vaccination Programme: Definition of Priority Staff and Occupational Groups**

**C Update on Communications and Information Materials**

## VACCINE INFORMATION

The **GSK vaccine** (brand name Pandemrix) is a split virion, inactivated, adjuvanted vaccine. It is a monovalent vaccine containing 3.75µg of antigen. The antigen used is A/California/07/2009 (H1N1)v-like strain (X-179A), propagated in fertilised hens' eggs. The vaccine contains an adjuvant – AS03 – to help boost the immune response, and it contains thiomersal as a preservative.

The **Baxter vaccine** (brand name Celvapan) is a whole virion, inactivated, vero cell derived vaccine containing 7.5 µg of antigen. The antigen used in the Baxter vaccine is the wild-type A/California/07/2009 H1N1 strain. The whole virion is inactivated both by formaldehyde and UV-irradiation. It does not contain an adjuvant or thiomersal.

### Product Dimensions

#### GSK Vaccine - Pandemrix

Pandemrix vaccine will be presented in a box of 50 multi-dose vials of 2.5ml suspension and two boxes containing 25 2.5ml vials of adjuvant. Each 5.0 ml of reconstituted vaccine should provide 10 0.5ml doses. Each pack should provide 500 doses.

The pack size for the 500 dose pack of GSK vaccine is 260mm x 113mm x 97mm. This is about the size of a small shoe box.

#### Baxter Vaccine - Celvapan

Celvapan vaccine will be presented in a pack of 20 multi-dose vials of 5ml suspension per pack. Each 5ml vial should provide 10 0.5ml doses, with each pack providing 200 doses.

The pack size for the 200 dose pack of Baxter vaccine is 206mm x 166mm x 55mm. This is about the size of a box of chocolates.

### Contraindications

JCVI has advised that individuals with a confirmed history of anaphylactic reaction to egg, which is a very rare condition, should not be offered the GSK swine flu vaccine (Pandemrix). Individuals with a confirmed anaphylactic reaction to egg should be offered the Baxter vaccine, when available.

A Green Book chapter on pandemic influenza, which is currently being drafted, will reflect JCVI advice and is likely to read as follows:

There are very few individuals who cannot receive the swine flu vaccine.

The vaccines should not be given to those who have had:

- A confirmed anaphylactic reaction to a previous dose of the vaccine, or
- A confirmed anaphylactic reaction to any component of the vaccine.

The GSK product should not be given to those who have had:

- A confirmed anaphylactic reaction to egg products as the vaccines are prepared in hens' eggs.

### **GSK vaccine - Pandemrix**

The following information on the GSK vaccine Pandemrix has been recommended by the Committee for Medicinal Products for Human Use (CHMP) :The SPC lists the following contraindications and precautions for use:

History of an anaphylactic (i.e. life-threatening) reaction to any of the constituents or trace residues (egg and chicken protein, ovalbumin, formaldehyde, gentamicin sulphate and sodium deoxycholate) of this vaccine.

Caution is needed when administering this vaccine to persons with a known hypersensitivity (other than anaphylactic reaction) to the active substances(s) to any of the excipients, to thiomersal and to residues (egg and chicken protein, ovalbumin, formaldehyde, gentamicin sulphate and sodium deoxycholate).

The excipients in Pandemrix are:

Suspension vial  
Polysorbate 80  
Octoxynol 10  
Thiomersal  
Sodium chloride  
Disodium hydrogen phosphate  
Potassium dihydrogen phosphate  
Potassium chloride  
Magnesium chloride  
Water for injections

Adjuvant vial:  
Sodium chloride  
Disodium hydrogen phosphate  
Potassium dihydrogen phosphate  
Potassium chloride  
Water for injections

Adjuvant:  
Squalene  
DL- $\alpha$ -tocopherol  
Polysorbate 80

The draft Summary of Product Characteristics (SPC) can be found at <http://www.emea.europa.eu/humandocs/PDFs/EPAR/pandemrix/Pandemrix-PU-17-en.pdf>

### **Baxter vaccine - Celvapan**

More information on the Baxter vaccine Celvapan is available from the SPC for the 'mock-up' H5N1 vaccine (upon which the pandemic vaccine is based). The SPCs lists the following contraindications and precautions for use:

History of an anaphylactic reaction to any of the constituents or trace residues (e.g. formaldehyde, benzonase, sucrose) of this vaccine.

Caution is needed when administering this vaccine to persons with a known hypersensitivity (other than anaphylactic reaction) to the active substances(s) to any of the excipients and to trace residues e.g. formaldehyde, benzonase, sucrose.

The excipients in Celvapan are trometamol, sodium chloride, water for injections, polysorbate 80.

The full Summary of Product Characteristics can be viewed at [www.emea.europa.eu/humandocs/Humans/EPAR/celvapan/celvapan.htm](http://www.emea.europa.eu/humandocs/Humans/EPAR/celvapan/celvapan.htm) (Click on the 'en' option for the English version of the documents).

### **OTHER COMMON QUESTIONS**

#### **How many doses of vaccine will be needed to give protection?**

Advice has been sought from JCVI on the dosing schedule and this will be shared with colleagues as soon as it is available.

#### **Swine flu vaccines and Guillain-Barré syndrome (GBS)**

Guillain-Barré syndrome is a rare but serious disease of the peripheral nervous system. Influenza-like illness has been shown to be associated with an increased risk of GBS. A recent study showed that the risk of GBS was about seventeen times higher in the period following infection with a flu-like illness compared to the usual risk of GBS (Stowe et al., 2009).

In 1976, the swine influenza vaccines used in the United States were associated with an increased risk of GBS. It is thought that one extra case of GBS occurred with every 100,000 doses of the vaccine (Schonberger et al., 1979). The exact reason why the 1976 vaccine increased the risk of GBS remains unknown. Many studies have since looked at whether other influenza vaccines used since 1976 carry a risk of GBS and no robust evidence of a causal link has been found (Stratton et al., 2004). An epidemiological study of seasonal flu vaccines recently used in the UK found no risk of GBS (Stowe et al., 2009).

There is no evidence to suggest that either the GSK or Baxter swine flu vaccine, or seasonal flu vaccine, will carry an excess risk of GBS. As with any new vaccine, we will have robust systems in place to identify any serious side effects.

Schonberger LB et al., Guillain-Barre syndrome following vaccination in the national influenza immunization program, United States, 1976-1977. Am J Epidemiol 110(2):105-123.

Stratton K et al., (eds). (2004) Immunization Safety Review. Influenza Vaccines and Neurological Complications. Washington: The National Academies Press

Stowe J et al., Investigation of the temporal association of Guillain-Barre syndrome with influenza vaccine and influenza like illness using the United Kingdom General Practice Research Database. Am J Epidemiol 169(3):382-8.

### **Thiomersal**

Further information on thiomersal in the GSK vaccine will be provided as soon as it is available.

The UK Commission on Human Medicines (CHM) keeps the safety of vaccines, including other thiomersal containing vaccines, under continual review. The view of the CHM remains that there is no evidence of neurodevelopmental adverse effects caused by levels of thiomersal in vaccines. The only evidence of harm due to thiomersal is a small risk of hypersensitivity reactions (that typically include skin rashes or local swelling at the site of injection). The CHM advises that the balance of risks and benefits of thiomersal-containing vaccines is overwhelmingly positive. Further information is available at [www.mhra.gov.uk](http://www.mhra.gov.uk) (search for 'thiomersal').

### **Porcine product**

Some porcine products are used in the manufacturing process of the Baxter vaccine; however there are no detectable traces of these products in the vaccine itself.

The GSK vaccine does not contain porcine products.

Previous advice regarding faith communities and vaccines containing porcine products can be accessed at <http://www.immunisation.nhs.uk/Library/Search?stags=&terms=porcine>

## **Influenza A (H1N1) Vaccination Programme: Definition of Priority Staff and Occupational Groups**

### **1. Introduction**

On 13 August 2009 the Scottish Government announced details of the priority groups for the Influenza A (H1N1) vaccination programme. These include priority staff and occupational groups to be vaccinated alongside the clinical priority groups.

These staff and occupational groups comprise frontline health and social care workers as they are at increased risk of infection and of transmitting that infection to susceptible patients. Frontline health workers eligible for this vaccination programme are those eligible for seasonal influenza vaccine, as detailed in the Green Book.

The following definitions for these staff have been agreed:

- **Healthcare workers with direct patient contact**
- **Social care staff who are employed to provide personal care to children and adults, both in care homes and in the community**

These groups have been included alongside the first set of clinical priority groups because they are at increased personal risk of infection and of transmitting that infection to susceptible patients; and because this will help to maintain the resilience of the NHS.

Further information of the definition of healthcare workers and social care workers for the H1N1 vaccination programme is outlined below. The purpose of this guidance is to support local planning for the delivery of the vaccination programme within NHS Boards. Any further consideration of priority groups will be taken by NHS Boards.

### **2. Definition of Frontline Health Care Worker for the H1N1 vaccination programme**

Chapter 12 of the Green Book covers immunisation of healthcare and laboratory staff and sets out which healthcare workers should be routinely offered a vaccination against seasonal influenza as an occupational health vaccine (pages 85-87) i.e. those staff involved in direct patient care. It also sets out those that would not be expected to be offered this vaccine routinely.

### **3. Staff involved in direct patient care**

This includes staff who have regular clinical contact with patients and who are directly involved in patient care. This includes doctors, dentists, midwives and nurses, paramedics and ambulance drivers, occupational therapists, physiotherapists and radiographers. Students and trainees in these disciplines and volunteers who are working with patients must also be included.

In addition to these groups it is recognised that community pharmacists providing face to face consultations have a key role to play during the pandemic and as such should be considered for H1N1 vaccination if they have regular clinical contact with patients and are directly involved in patient care. NHS 24 staff will also be offered the vaccine given their role in underpinning out of hours services and maintaining the delivery of existing health services to patients in Scotland.

#### **4. Non-clinical staff in healthcare settings**

This includes non-clinical ancillary staff who may have social contact with patients but are not directly involved in patient care. This group includes receptionists, ward clerks, porters and cleaners and it is a group for which seasonal influenza vaccination is not routinely recommended. This group will not be vaccinated as a priority against H1N1 unless NHS Boards decide to do so following local risk assessment.

#### **5. Staff providing healthcare in non healthcare settings**

The following groups will be offered the H1N1 vaccine:

- Prison officers and staff in other secure institutions who are providing informal healthcare
- Staff providing informal healthcare in schools for children with special needs

Offshore doctors who work on oil and gas platforms and helicopter pilots who transport them and patients should also be treated as healthcare workers.

#### **6. Definition of Frontline Social Care Worker for H1N1 vaccination programme**

The definition of social care workers is “**social care staff who are employed to provide personal care to children and adults, both in care homes and in the community**”.

The Government has agreed the following definition, that “personal care” means:

- physical assistance given to a person in connection with:
  - eating or drinking (including the administration of parenteral nutrition)
  - toileting (including in relation to the process of menstruation)
  - washing or bathing
  - dressing
  - oral care, or
  - the care of skin, hair and nails (with the exception of nail care provided by chiropodist or podiatrist)or
- the prompting, together with supervision, of a person, in relation to the performance of any of the activities listed in paragraph (a) where that person is unable to make a decision for themselves in relation to performing such an activity without such prompting and supervision

Some examples of staff who should be included in this definition are:

- Care home staff in residential/nursing homes who provide personal care to residents
- Domiciliary care workers employed by agencies who provide personal care to service users in their own homes
- Personal assistants – staff employed to provide personal care to a single service user
- Students and trainees in these disciplines

And examples of people who would not be included are:

- Social workers
- Informal carers – family members and/or friends
- Non care staff in residential/nursing homes
- Housing staff – those who work in managing sheltered and similar housing
- Staff working in child or adult safeguarding
- Foster carers

Further groups may be added as further advice becomes available and could be prioritised within the second phase of the vaccination programme.

H1N1 Vaccination Team  
Public Health Division  
Scottish Government

## **Update on Communications and Information Materials**

### **Communications**

A Communications Strategy for the programme has been developed by Scottish Government in consultation with key partners across the vaccination programme and has been issued to Board H1N1 leads.

It is essential that all agencies and partners involved across the programme are provided with key information in order to respond to requests from the media. A Core Script Q&A document has been produced by the Department of Health as a resource for use by all four nations. This will be particularly useful for Health Boards, Scottish Government, Health Protection Scotland and other agencies to ensure consistency of response to interested parties in the vaccination programme. This will require to be revised in light of JCVI recommendations however we hope to issue this to you by the end of this week.

### **Information materials**

We are continuing to work with the Department of Health to develop a range of information materials to support the programme. These materials are now almost complete. This will include materials for both the public and professionals. Materials for health professionals will include a new Green Book chapter; factsheet in Q&A format; Training DVD and slideset; maternity services guidance (still in development at present); Patient Group Direction and a patient call-up letter template (to be included in the CMO letter). These materials will be finalised very soon and be made available to Board leads via an online resource. A toolkit for Boards will also be produced which will include a range of information materials that can be adapted and used locally.

For the public, a public information leaflet; vaccination record/appointment card and posters for display in GP practices have been developed. We hope to distribute all materials to Boards starting from next week and are working with the DH to distribute these on a UK wide basis.

We plan to send each Board and GP practice 500 leaflets, four empty belly posters, four generic posters and 500 appointment cards all with a covering letter. In addition we plan to send 500 leaflets, four empty belly posters and four generic posters to Community Pharmacists. Boards, GP practices and Community Pharmacists will be able to order additional copies if they need to from Prologue (who are managing distribution on a UK wide basis).

NGO's, Care Homes for the Elderly, Citizen Advice Bureaux and Scottish Library and Information Council will also receive a pack containing two A4 posters and five leaflets.

In addition, a UK advertising publicity campaign is being developed. The campaign will seek to raise awareness and encourage the public, particularly those in the initial

priority groups, to ensure they are vaccinated against H1N1. This is likely to include publicity via media channels and PR.

Given that the timing of the programme co-incides with the annual seasonal flu programme and other health campaigns such as those for winter planning, meningitis and respiratory hand hygiene, an overall timetable detailing key messages from each campaign, proposed communication channels and timelines has been drawn together and is attached below. This document was issued to Boards earlier this month but has now been updated.

## Influenza – Overall Time Plan – Autumn/Winter 2009

<b>Campaign</b>	<b>Key messages for public</b>	<b>Channels*</b>	<b>Media*</b>	<b>Timings*</b>
Seasonal Flu Vaccination	Ask your GP for a seasonal flu vaccination now. If you are over 65 or have a chronic illness you are more at risk of serious illnesses such as bronchitis and pneumonia if you catch season flu.	<ul style="list-style-type: none"> <li>• Poster</li> <li>• Leaflets</li> <li>• PR</li> <li>• Digital</li> <li>• Media Relations</li> </ul>	<ul style="list-style-type: none"> <li>• GP's, libraries, etc</li> <li>• As above</li> <li>• Various weekly titles</li> <li>• Key stakeholder websites</li> <li>• Launch</li> </ul>	w/c 5 <sup>th</sup> October
H1N1 Vaccination*	If you're in one of the priority groups get your swine flu vaccination now.	<ul style="list-style-type: none"> <li>• Press</li> <li>• Radio</li> <li>• Partnerships</li> <li>• Digital</li> <li>• Factsheet</li> <li>• Leaflet</li> <li>• Appointment card</li> <li>• Invitation letter</li> <li>• PR</li> <li>• Media Relations</li> </ul>	<ul style="list-style-type: none"> <li>• National and regional titles inc freesheets</li> <li>• All radio stations</li> <li>• 3<sup>rd</sup> party Orgs</li> <li>• Blogging, social networks, advertorial, contextual search</li> <li>• Press inserts, mailing</li> </ul>	Public campaign from early November.  All to be available from 21 October.
Respiratory	If you could see flu germs, you'd see how	<ul style="list-style-type: none"> <li>• Press</li> </ul>	<ul style="list-style-type: none"> <li>• Commuter titles</li> </ul>	w/c 26 <sup>th</sup> Oct

and Hand Hygiene	quickly they spread.	<ul style="list-style-type: none"> <li>• TV</li> <li>• PR</li> <li>• NHS/Voluntary orgs</li> <li>• Partnerships</li> </ul>	<ul style="list-style-type: none"> <li>• National press</li> <li>• BME press</li> <li>• News channels etc</li> <li>• Online toolkit</li> <li>• Tesco, Morrisons etc</li> </ul>	
National Pandemic Flu Service	There is a different way for people to seek treatment and advice about swine flu.	TBC	TBC	TBC
NHSScotland <i>Be Ready for Winter</i>	<p>Be prepared:</p> <ul style="list-style-type: none"> <li>• Re-stock your winter medicine cabinet</li> <li>• Use your local pharmacy</li> <li>• Make sure you have your repeat prescription</li> <li>• Know when your GP surgery will be open.</li> </ul>	<ul style="list-style-type: none"> <li>• TV</li> <li>• Radio</li> <li>• Outdoor</li> <li>• Press</li> <li>• Search</li> <li>• PR</li> <li>• Poster</li> <li>• Leaflet</li> </ul>	<ul style="list-style-type: none"> <li>• TV - ITV Scot, GMTV, Channel 4, Channel 5</li> <li>• Radio – commercial in Scotland and community radio</li> <li>• Outdoor – pharmacies; proximity to pharmacy/super market; ferry port, ferry panels</li> <li>• Press – Sun, Daily Record, Metro</li> </ul>	w/c 9 Nov '09 to w/c 4 Jan '10