Safeguarding public health

UK Suspected Adverse Reaction Analysis

Swine Flu (H1N1) Vaccines – Celvapan and Pandemrix

12 November 2009

This report provides an overview of all UK reports of suspected adverse reactions to the new swine flu (H1N1) vaccines (Celvapan and Pandemrix) received by MHRA between Monday 15th October 2009 and Thursday 5th November 2009 (inclusive)[1]. These reports have been voluntarily submitted to MHRA by UK healthcare professionals and members of the public via the MHRA's 'Swine Flu ADR Portal' (www.mhra.gov.uk/swineflu) and the Yellow Card Scheme. It also includes all UK reports submitted by the Marketing Authorisation holders for Celvapan (Baxter) and Pandemrix (GSK) as part of their legal requirements.

The suspected adverse reactions listed in the attached Vaccine Analysis Prints have been coded using 'MedDRA' terminology[2].

It is important to note that a report of a reaction does not necessarily mean that it has been caused by the vaccine in question. We encourage reporters to report *suspected* adverse reactions i.e. the reporter does not have to be sure that the vaccine caused the reaction – a mere suspicion will suffice. Therefore, reports submitted to MHRA may be true adverse effects of the vaccine, psychogenic reactions related to the process of vaccination rather than to the specific vaccine itself (e.g. nervousness or anxiety about needles or vaccination); or they may be purely coincidental events that would have occurred anyway in the absence of vaccination (e.g. events due to underlying medical conditions). For this reason **this summary is not a list of known or proven adverse reactions to H1N1 vaccines and must not be interpreted and used as such**. A list of the recognised adverse effects of Celvapan and Pandemrix is provided in the product information for healthcare professionals (Summary of Product Characteristics) and patients (Patient Information Leaflet), copies of which are available on our website (www.mhra.gov.uk/swineflu).

Suspected adverse reaction reporting rates are highly variable and are dependent on many factors. Therefore these data cannot be used to determine the frequency of occurrence of adverse reactions to the H1N1 vaccines. Furthermore, the use of the two H1N1 vaccines available in the UK is expected to differ considerably in terms of the level of exposure and patient populations exposed (most will receive the Pandemrix brand). For these reasons **the data included in this report can not be used to directly compare the relative safety of Pandemrix and Celvapan.**

All reports of suspected adverse reactions to Celvapan and Pandemrix are closely monitored by a dedicated team of safety specialists at the MHRA.

[1] Suspected ADR data are released with a 1 week delay in order to ensure that MHRA has time to validate, extract and assess the data before publication.
[2] MedDRA - the Medical Dictionary for Regulatory Activities - is a standardised, medically validated adverse event terminology system used within the international medicines regulatory environment.

Medicines and Healthcare products Regulatory Agency
Market Towers 1 Nine Elms Lane London SW8 5NQ
T 020 7084 2000 F 020 7084 2353 www.mhra.gov.uk

Headline summary:

1. Up to and including Thursday 5th November 2009, MHRA has received a total of 188 UK reports of suspected ADRs to the H1N1 vaccines. The 188 reports include a total of 460 suspected reactions (a single report may contain more than one reaction).

2. Reports of suspected adverse reactions to Pandemrix make up 91% (n=172) of all reports received for H1N1 vaccines to date. This is not unexpected given the *presumed* difference in the extent of use of the two vaccines[3]. The vaccine brand was not reported in 6% (n=12) of reports.

3. Further information on the type of suspected adverse reactions reported for each of the vaccines is provided in Annexes 1 (Celvapan), 2 (Pandemrix) and 3 (brand unknown).

4. The most frequently reported suspected adverse reactions are non-serious injection site reactions (e.g. pain, swelling, redness), or are well established minor adverse effects of many vaccines, including the swine flu vaccines (e.g. nausea, vomiting, dizziness muscle pain, fever, fatigue, headache, swollen glands).

5. No new safety issues have been identified from reports received to date.

6. **The balance of benefits and risks for Celvapan and Pandemrix remains positive**

7. When identified, information on new and emerging safety signals will be provided in this report together with details of any resulting regulatory action or changes to prescribing advice deemed necessary.

[3] Data on relative usage of each vaccine are not currently available to MHRA. When such information is available, we will include it in these updates.

1. ADVERSE REACTION REPORTING TRENDS

Up to and including Thursday 5th November 2009, a total of 188 reports of suspected adverse reactions to H1N1 vaccines have been reported in the UK. These 188 reports include 460 suspected reactions; a single report may include more than one suspected reaction.

A breakdown of the number of reports received by vaccine brand is provided in Table 1 below. The distribution of reports between Celvapan and Pandemrix is not unexpected given the presumed[3] difference in the extent of use of the two vaccines in the UK.

Table 1: Number of reports of suspected reactions received for Celvapan and Pandemrix in the UK

Vaccine	Number of Reports (%)	Number of Reactions
Celvapan	4 (2%)	8
Pandemrix	172 (91%)	412
Brand not reported	12 (6%)	40
Total	**188**	**460**[4]

Further information and analysis of suspected adverse reactions reported for each of the vaccines is provided in Section 2 below.

2. ANALYSIS OF REPORTED SUSPECTED ADVERSE REACTIONS

2.1 Celvapan

A line-listing of all UK suspected reactions reported for Celvapan can be found in Annex 1. To date only four reports (of 8 suspected adverse reactions) have been received for Celvapan. These are generally non-serious events and no fatal reactions have been reported.

2.1.1 Nervous system disorders

Although just over a half of reactions (5/8) reported for Celvapan fall into the nervous system disorders system organ class (SOC), these are generally non-serious and are recognised side-effects of the vaccine (dizziness; pins and needles).

2.1.2 Symptoms of allergic or anaphylactic reactions

One case of swollen lips has been reported for Celvapan. This was not indicative of a serious allergic reaction. Allergic reactions are recognised adverse effects of Celvapan.

2.1.3 Pregnant women

No reports of suspected adverse reactions in pregnant women have been received.

2.1.4 Children

No reports in children aged below 15 years have been received.

2.2 Pandemrix

Ninety-one per cent (172/188) of the total reports received for H1N1 vaccines in the UK to date are for Pandemrix. This most likely reflects greater usage of this vaccine in the UK to date[3]. A line-listing of all suspected reactions reported in the UK for Pandemrix can be found in Annex 2. Generally, these are non-serious events and no fatal reactions have been reported via the swine flu ADR portal.

[4] A single report may contain more than one suspected reaction.

The most frequently reported reactions are injection site reactions (including pain, swelling, redness, numbness and bruising) and symptoms that are common effects of many vaccines such as dizziness, headache, fatigue, muscle aches, malaise, mild fever, swollen glands, nausea and vomiting.

2.2.1 Nervous system disorders

The nervous system disorders reported are generally non-serious events (headache, dizziness, pins and needles) and are recognised adverse effects of the vaccine.

Fainting episodes (syncope) very shortly after vaccination are not uncommon with any vaccination. This is not a side effect of the vaccine, but a 'psychogenic' response to the injection (usually because of fear or anticipation of the needle injection). The one report of loss of consciousness is being followed-up to establish if this was a fainting episode. The case of eyelid ptosis (droopy eyelid) was associated with swelling of the eyelid and so is therefore most likely to be of allergic than neurological origin.

One report of convulsion in a patient with a history of seizures has been reported. This case is discussed further in section 2.2.4 below.

There has been one report of trigeminal nerve neuritis reported for Pandemrix to date. The information currently available for this case suggests that it is unlikely that the neuritis was caused by Pandemrix.

2.2.2 Symptoms of allergic or anaphylactic reactions

One case of angioedema, two cases of facial swelling and one case of lip swelling have been reported. No cases of anaphylaxis have been reported to date.

Allergic reactions are a recognised side-effect of flu vaccines. The cases reported to date are not considered to be serious or life-threatening allergic reactions and do not raise any new safety concerns.

2.2.3 Pregnant women

No reports of suspected adverse reactions in pregnant women have been received.

2.2.4 Children

Ten reports of suspected reactions in children under the age of 16-years have been reported for Pandemrix. The majority of the reported suspected reactions in children are non-serious, recognised side effects of many vaccines including Pandemrix, or can be attributed to the process of vaccination rather than the vaccine itself (e.g. injection site reactions (redness, rash and swelling); generalised rash; faints; tiredness, fatigue, ear pain, headache and fever).

One case of seizure in a child with a history of epilepsy has been reported for Pandemrix. The available evidence does not allow a link with the vaccination to be confirmed.

2.3 H1N1 vaccine brand unknown

A total of 12 reports (of 40 suspected reactions) have been reported for H1N1 vaccines in which the brand is not provided. All reported events are non-serious and are consistent with symptoms commonly experienced after any vaccination (flu-like illness, fever, injection site pain, headache, malaise, aches and pains, flushing, and nausea).

2.4 Overall Conclusions

The vast majority of reports of suspected adverse reactions to H1N1 vaccines received to date are for Pandemrix. This is not unexpected given the presumed[3] greater usage of Pandemrix in the UK to date.

The most frequently reported suspected adverse reactions are non-serious and expected in some people – i.e. injection site reactions (e.g. local pain, swelling, redness or bruising) and general symptoms including nausea, vomiting, dizziness, muscle pains, fever, fatigue, headache, swollen glands). No new safety issues have been identified from UK data to date. The benefit – risk balance for Celvapan and Pandemrix remain positive.

ANNEX 1 - CELVAPAN

Vaccine Analysis Print
Vaccine Name: Celvapan

Run Date: Unspecified to 5 November 2009		
Total number of reactions: 8	**Total number of ADR reports:** 4	**Total number of fatal ADR reports:** **0**

System Organ Class	Reactions	Fatal Reactions
Gastrointestinal disorders	1	0
General disorders and administration site conditions	2	0
Nervous system disorders	5	0
Total	8	0

Glossary/Abbreviations

ADR - Adverse Drug Reaction

Age group - lists which age groups are included in the Drug Analysis Print - either ALL, Adolescent, Adult, Child, Elderly, Infant or Neonate

Data lock date - shows data on the database at this specified date and time

HLT - High Level Term - see definition of MedDRA

MEDRA - this stands for Medical Dictionary for Regulatory Activities, which is the internationally agreed list of terms used for Medicines Regulation. MedDRA groups related adverse drug reaction terms in a hierarchical structure whereby the 'preferred term' (PT) (e.g. tunnel vision) is grouped under the broader heading the 'high level term' (HLT) (e.g. visual field disorders). 'High level terms' are contained within the 'system organ class' (SOC) (e.g. eye disorders). The 'preferred term' is the most specific term on the Drug Analysis Print, while the 'system organ class' is the most general

Multi active constituent products - contain the drug constituent of interest plus one or more other drug constituents (e.g. co-codamol contains paracetamol and codeine)

NEC - appears in MedDRA and stands for Not Elsewhere Classified

NOS - appears in MedDRA and stands for Not Otherwise Specified

PBG - Product Brand Generic - this means drug brand name e.g. Amoxil is a PBG for the drug substance amoxicillin.

Products included in this print - this is a list of the products for which at least one suspected Adverse Drug Reaction (ADR) report has been received that specifies that product as a 'suspected drug' (i.e. suspected causal association with the reaction). It does not provide an exhaustive list of the products which contain the named drug substance

PT - Preferred Term - see definition of MedDRA

Reaction - defines which ADRs are included in the Drug Analysis Print - either ALL, Serious or Non-Serious

Reporter type - lists the reporter types which are included in the Drug Analysis Print - either Patient, Health Professional or ALL (i.e. both)

Report run date - the date the Drug Analysis Print was produced

Route of admin - lists the route of administration of the suspect drug for which reports are included in the Drug Analysis Print, e.g. ORAL only includes reports where the suspect drug was specified as having been taken by the oral route, or ALL which includes all routes of administration

Spontaneous - suspected ADR reports sent in to the Yellow Card Scheme are called spontaneous reports

Single active constituent products - contain only the drug substance of interest

System Organ Class (SOC) - this is the highest level in MedDRA which groups together reactions that affect similar systems/organs in the body

Vaccine Analysis Print
Vaccine Name: Celvapan

Reaction Name	Reactions	Fatal Reactions
SOC		
HLT		
PT		
Gastrointestinal disorders		
Oral soft tissue disorders NEC		
Lip swelling	1	0
Gastrointestinal disorders SOC Total	1	0

Vaccine Analysis Print
Vaccine Name: Celvapan

Reaction Name	Reactions	Fatal Reactions
SOC		
HLT		
PT		
General disorders and administration site conditions		
Asthenic conditions		
Fatigue	2	0
General disorders and administration site conditions SOC Total	2	0

Vaccine Analysis Print
Vaccine Name: Celvapan

Reaction Name	Reactions	Fatal Reactions
SOC		
HLT		
PT		
Nervous system disorders		
Neurological signs and symptoms NEC		
Dizziness	2	0
Paraesthesias and dysaesthesias		
Paraesthesia	2	0
Speech and language abnormalities		
Dysarthria	1	0
Nervous system disorders SOC Total	5	0

ANNEX 2 - PANDEMRIX

Vaccine Analysis Print
Vaccine Name: Pandemrix

Run Date: Unspecified to 5 November 2009		
Total number of reactions: 412	**Total number of ADR reports:** 172	**Total number of fatal ADR reports: 0**

System Organ Class	Reactions	Fatal Reactions
Blood and lymphatic system disorders	5	0
Cardiac disorders	6	0
Ear and labyrinth disorders	1	0
Eye disorders	4	0
Gastrointestinal disorders	49	0
General disorders and administration site conditions	141	0
Immune system disorders	1	0
Infections and infestations	4	0
Injury, poisoning and procedural complications	6	0
Investigations	9	0
Musculoskeletal and connective tissue disorders	68	0
Nervous system disorders	65	0
Psychiatric disorders	7	0
Respiratory, thoracic and mediastinal disorders	11	0
Skin and subcutaneous tissue disorders	28	0
Vascular disorders	5	0
Total	410	0

Glossary/Abbreviations

ADR - Adverse Drug Reaction

Age group - lists which age groups are included in the Drug Analysis Print - either ALL, Adolescent, Adult, Child, Elderly, Infant or Neonate

Data lock date - shows data on the database at this specified date and time

HLT - High Level Term - see definition of MedDRA

MEDRA - this stands for Medical Dictionary for Regulatory Activities, which is the internationally agreed list of terms used for Medicines Regulation. MedDRA groups related adverse drug reaction terms in a hierarchical structure whereby the 'preferred term' (PT) (e.g. tunnel vision) is grouped under the broader heading the 'high level term' (HLT) (e.g. visual field disorders). 'High level terms' are contained within the 'system organ class' (SOC) (e.g. eye disorders). The 'preferred term' is the most specific term on the Drug Analysis Print, while the 'system organ class' is the most general

Multi active constituent products - contain the drug constituent of interest plus one or more other drug constituents (e.g. co-codamol contains paracetamol and codeine)

NEC - appears in MedDRA and stands for Not Elsewhere Classified

NOS - appears in MedDRA and stands for Not Otherwise Specified

PBG - Product Brand Generic - this means drug brand name e.g. Amoxil is a PBG for the drug substance amoxicillin.

Products included in this print - this is a list of the products for which at least one suspected Adverse Drug Reaction (ADR) report has been received that specifies that product as a 'suspected drug' (i.e. suspected causal association with the reaction). It does not provide an exhaustive list of the products which contain the named drug substance

PT - Preferred Term - see definition of MedDRA

Reaction - defines which ADRs are included in the Drug Analysis Print - either ALL, Serious or Non-Serious

Reporter type - lists the reporter types which are included in the Drug Analysis Print - either Patient, Health Professional or ALL (i.e. both)

Report run date - the date the Drug Analysis Print was produced

Route of admin - lists the route of administration of the suspect drug for which reports are included in the Drug Analysis Print, e.g. ORAL only includes reports where the suspect drug was specified as having been taken by the oral route, or ALL which includes all routes of administration

Spontaneous - suspected ADR reports sent in to the Yellow Card Scheme are called spontaneous reports

Single active constituent products - contain only the drug substance of interest

System Organ Class (SOC) - this is the highest level in MedDRA which groups together reactions that affect similar systems/organs in the body

Vaccine Analysis Print
Vaccine Name: Pandemrix

Reaction Name	Reactions	Fatal Reactions
SOC		
HLT		
PT		
Blood and lymphatic system disorders		
Lymphatic system disorders NEC		
Lymph node pain	1	0
Lymphadenitis	1	0
Lymphadenopathy	3	0
Blood and lymphatic system disorders SOC Total	5	0

Vaccine Analysis Print
Vaccine Name: Pandemrix

Reaction Name	Reactions	Fatal Reactions
SOC		
HLT		
PT		
Cardiac disorders		
Cardiac signs and symptoms NEC		
Palpitations	4	0
Rate and rhythm disorders NEC		
Tachycardia	2	0
Cardiac disorders SOC Total	6	0

Vaccine Analysis Print
Vaccine Name: Pandemrix

Reaction Name	Reactions	Fatal Reactions
SOC		
HLT		
PT		
Ear and labyrinth disorders		
Ear disorders NEC		
Ear pain	1	0
Ear and labyrinth disorders SOC Total	1	0

Vaccine Analysis Print
Vaccine Name: Pandemrix

Reaction Name	Reactions	Fatal Reactions
SOC		
HLT		
PT		
Eye disorders		
Eyelid movement disorders		
Eyelid ptosis	1	0
Lid, lash and lacrimal infections, irritations and inflammations		
Eyelid oedema	1	0
Ocular disorders NEC		
Eye pain	1	0
Ocular infections, inflammations and associated manifestations		
Ocular sensation disorders		
Photophobia	1	0
Eye disorders SOC Total	4	0

Vaccine Analysis Print
Vaccine Name: Pandemrix

Reaction Name	Reactions	Fatal Reactions
SOC		
HLT		
PT		
Gastrointestinal disorders		
Diarrhoea (excl infective)		
Diarrhoea	4	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain	4	0
Abdominal pain upper	2	0
Nausea and vomiting symptoms		
Nausea	25	0
Vomiting	10	0
Oral dryness and saliva altered		
Dry mouth	1	0
Oral soft tissue pain and paraesthesia		
Paraesthesia oral	1	0
Oral soft tissue signs and symptoms		
Hypoaesthesia oral	1	0
Tongue disorders		
Tongue ulceration	1	0
Gastrointestinal disorders SOC Total	49	0

Vaccine Analysis Print
Vaccine Name: Pandemrix

Reaction Name	Reactions	Fatal Reactions
SOC		
HLT		
PT		
General disorders and administration site conditions		
Application and instillation site reactions		
Application site pain	3	0
Application site pruritus	1	0
Application site haematoma	2	0
Asthenic conditions		
Asthenia	2	0
Fatigue	12	0
Malaise	8	0
Febrile disorders		
Pyrexia	24	0
General signs and symptoms NEC		
Influenza like illness	14	0
Local reaction	9	0
Swelling	1	0
Inflammations		
Inflammation	1	0
Injection and infusion site reactions		
Injection site erythema	6	0
Injection site induration	1	0
Injection site inflammation	4	0
Injection site pain	5	0
Injection site phlebitis	1	0
Injection site rash	1	0
Injection site warmth	1	0
Injection site swelling	3	0
Oedema NEC		
Oedema peripheral	10	0
Pain and discomfort NEC		
Chest discomfort	3	0
Pain	10	0
Non-cardiac chest pain	1	0
Feelings and sensations NEC		
Chills	12	0

Feeling hot	4	0
Feeling of body temperature change	2	0
General disorders and administration site conditions SOC Total	141	0

Vaccine Analysis Print
Vaccine Name: Pandemrix

Reaction Name	Reactions	Fatal Reactions
SOC		
HLT		
PT		
Immune system disorders		
Anaphylactic responses		
Anaphylactic reaction	1	0
Immune system disorders SOC Total	1	0

Vaccine Analysis Print
Vaccine Name: Pandemrix

Reaction Name	Reactions	Fatal Reactions
SOC		
HLT		
PT		
Infections and infestations		
Bacterial infections NEC		
Cellulitis	1	0
Eye and eyelid infections		
Eye infection	1	0
Influenza viral infections		
Influenza	1	0
Viral infections NEC		
Sweating fever	1	0
Infections and infestations SOC Total	4	0

Vaccine Analysis Print
Vaccine Name: Pandemrix

Reaction Name	Reactions	Fatal Reactions
SOC		
HLT		
PT		
Injury, poisoning and procedural complications		
Skin injuries NEC		
Contusion	1	0
Vaccination related complications		
Post vaccination syndrome	3	0
Vaccination complication	2	0
Injury, poisoning and procedural complications SOC Total	6	0

Vaccine Analysis Print
Vaccine Name: Pandemrix

Reaction Name	Reactions	Fatal Reactions
SOC		
HLT		
PT		
Investigations		
Physical examination procedures		
Body temperature increased	7	0
Vascular tests NEC (incl blood pressure)		
Blood pressure decreased	1	0
Heart rate and pulse investigations		
Heart rate increased	1	0
Investigations SOC Total	9	0

Vaccine Analysis Print
Vaccine Name: Pandemrix

Reaction Name	Reactions	Fatal Reactions
SOC		
HLT		
PT		
Musculoskeletal and connective tissue disorders		
Arthropathies NEC		
Arthritis reactive	1	0
Bone related signs and symptoms		
Pain in jaw	1	0
Joint related signs and symptoms		
Arthralgia	12	0
Musculoskeletal and connective tissue signs and symptoms NEC		
Sensation of heaviness	3	0
Musculoskeletal stiffness	2	0
Muscle pains		
Myalgia	12	0
Muscle related signs and symptoms NEC		
Muscle spasms	1	0
Muscle swelling	1	0
Muscle weakness conditions		
Muscular weakness	1	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	5	0
Musculoskeletal pain	8	0
Neck pain	4	0
Pain in extremity	15	0
Limb discomfort	2	0
Musculoskeletal and connective tissue disorders SOC Total	68	0

Vaccine Analysis Print
Vaccine Name: Pandemrix

Reaction Name	Reactions	Fatal Reactions
SOC		
HLT		
PT		
Nervous system disorders		
Disturbances in consciousness NEC		
Lethargy	3	0
Loss of consciousness	1	0
Syncope	1	0
Dyskinesias and movement disorders NEC		
Hypokinesia	1	0
Headaches NEC		
Headache	31	0
Sinus headache	1	0
Migraine headaches		
Migraine	3	0
Neurological signs and symptoms NEC		
Dizziness	8	0
Dizziness postural	1	0
Neuromuscular disorders NEC		
Paraesthesias and dysaesthesias		
Hyperaesthesia	1	0
Paraesthesia	3	0
Seizures and seizure disorders NEC		
Convulsion	1	0
Sensory abnormalities NEC		
Dysgeusia	2	0
Hypoaesthesia	4	0
Sensory loss	1	0
Speech and language abnormalities		
Aphonia	1	0
Tremor (excl congenital)		
Tremor	1	0
Trigeminal disorders		
Trigeminal nerve paresis	1	0
Nervous system disorders SOC Total	65	0

Vaccine Analysis Print
Vaccine Name: Pandemrix

Reaction Name	Reactions	Fatal Reactions
SOC		
HLT		
PT		
Psychiatric disorders		
Confusion and disorientation		
Disorientation	2	0
Disturbances in initiating and maintaining sleep		
Insomnia	4	0
Mood disorders NEC		
Stereotypies and automatisms		
Head banging	1	0
Psychiatric disorders SOC Total	7	0

Vaccine Analysis Print
Vaccine Name: Pandemrix

Reaction Name	Reactions	Fatal Reactions
SOC		
HLT		
PT		
Respiratory, thoracic and mediastinal disorders		
Breathing abnormalities		
Dyspnoea	3	0
Tachypnoea	2	0
Bronchospasm and obstruction		
Wheezing	1	0
Nasal disorders NEC		
Epistaxis	1	0
Nasal congestion and inflammations		
Nasal congestion	1	0
Upper respiratory tract signs and symptoms		
Oropharyngeal pain	3	0
Respiratory, thoracic and mediastinal disorders SOC Total	11	0

Vaccine Analysis Print
Vaccine Name: Pandemrix

Reaction Name	Reactions	Fatal Reactions
SOC		
HLT		
PT		
Skin and subcutaneous tissue disorders		
Angioedemas		
Angioedema	1	0
Apocrine and eccrine gland disorders		
Cold sweat	1	0
Hyperhidrosis	5	0
Sweat gland disorder	1	0
Dermal and epidermal conditions NEC		
Skin discomfort	1	0
Swelling face	2	0
Dermatitis and eczema		
Skin irritation	1	0
Erythemas		
Erythema	4	0
Rash erythematous	1	0
Photosensitivity conditions		
Photosensitivity reaction	1	0
Skin injuries and mechanical dermatoses		
Urticarias		
Urticaria	1	0
Pruritus NEC		
Pruritus generalised	1	0
Rashes, eruptions and exanthems NEC		
Rash	4	0
Rash generalised	2	0
Rash macular	1	0
Rash maculo-papular	1	0
Skin and subcutaneous tissue disorders SOC Total	28	0

Vaccine Analysis Print
Vaccine Name: Pandemrix

Reaction Name	Reactions	Fatal Reactions
SOC		
HLT		
PT		
Vascular disorders		
Circulatory collapse and shock		
Peripheral circulatory failure	1	0
Haemorrhages NEC		
Vascular hypertensive disorders NEC		
Hypertension	1	0
Peripheral vascular disorders NEC		
Hot flush	2	0
Vascular hypotensive disorders		
Site specific vascular disorders NEC		
Pallor	1	0
Vascular disorders SOC Total	5	0

ANNEX 3 – Brand unknown

Vaccine Analysis Print
Vaccine Name: H1N1 Vaccine brand unknown

Run Date: Unspecified to 5 November 2009		
Total number of reactions: 40	**Total number of ADR reports:** 12	**Total number of fatal ADR reports: 0**

System Organ Class	Reactions	Fatal Reactions
Gastrointestinal disorders	3	0
General disorders and administration site conditions	15	0
Investigations	1	0
Musculoskeletal and connective tissue disorders	11	0
Nervous system disorders	3	0
Psychiatric disorders	2	0
Skin and subcutaneous tissue disorders	4	0
Vascular disorders	1	0
Total	40	0

Glossary/Abbreviations

ADR - Adverse Drug Reaction

Age group - lists which age groups are included in the Drug Analysis Print - either ALL, Adolescent, Adult, Child, Elderly, Infant or Neonate

Data lock date - shows data on the database at this specified date and time

HLT - High Level Term - see definition of MedDRA

MEDRA - this stands for Medical Dictionary for Regulatory Activities, which is the internationally agreed list of terms used for Medicines Regulation. MedDRA groups related adverse drug reaction terms in a hierarchical structure whereby the 'preferred term' (PT) (e.g. tunnel vision) is grouped under the broader heading the 'high level term' (HLT) (e.g. visual field disorders). 'High level terms' are contained within the 'system organ class' (SOC) (e.g. eye disorders). The 'preferred term' is the most specific term on the Drug Analysis Print, while the 'system organ class' is the most general

Multi active constituent products - contain the drug constituent of interest plus one or more other drug constituents (e.g. co-codamol contains paracetamol and codeine)

NEC - appears in MedDRA and stands for Not Elsewhere Classified

NOS - appears in MedDRA and stands for Not Otherwise Specified

PBG - Product Brand Generic - this means drug brand name e.g. Amoxil is a PBG for the drug substance amoxicillin.

Products included in this print - this is a list of the products for which at least one suspected Adverse Drug Reaction (ADR) report has been received that specifies that product as a 'suspected drug' (i.e. suspected causal association with the reaction). It does not provide an exhaustive list of the products which contain the named drug substance

PT - Preferred Term - see definition of MedDRA

Reaction - defines which ADRs are included in the Drug Analysis Print - either ALL, Serious or Non-Serious

Reporter type - lists the reporter types which are included in the Drug Analysis Print - either Patient, Health Professional or ALL (i.e. both)

Report run date - the date the Drug Analysis Print was produced

Route of admin - lists the route of administration of the suspect drug for which reports are included in the Drug Analysis Print, e.g. ORAL only includes reports where the suspect drug was specified as having been taken by the oral route, or ALL which includes all routes of administration

Spontaneous - suspected ADR reports sent in to the Yellow Card Scheme are called spontaneous reports

Single active constituent products - contain only the drug substance of interest

System Organ Class (SOC) - this is the highest level in MedDRA which groups together reactions that affect similar systems/organs in the body

Vaccine Analysis Print
Vaccine Name: H1N1 Vaccine brand unknown

Reaction Name	Reactions	Fatal Reactions
SOC		
HLT		
PT		
Gastrointestinal disorders		
Nausea and vomiting symptoms		
Nausea	2	0
Stomatitis and ulceration		
Mouth ulceration	1	0
Gastrointestinal disorders SOC Total	3	0

Vaccine Analysis Print
Vaccine Name: H1N1 Vaccine brand unknown

Reaction Name	Reactions	Fatal Reactions
SOC		
HLT		
PT		
General disorders and administration site conditions		
Asthenic conditions		
Malaise	1	0
Febrile disorders		
Pyrexia	5	0
General signs and symptoms NEC		
Influenza like illness	3	0
Local reaction	1	0
Injection and infusion site reactions		
Injection site erythema	1	0
Injection site swelling	1	0
Feelings and sensations NEC		
Chills	2	0
Peripheral coldness	1	0
General disorders and administration site conditions SOC Total	15	0

Vaccine Analysis Print
Vaccine Name: H1N1 Vaccine brand unknown

Reaction Name	Reactions	Fatal Reactions
SOC		
HLT		
PT		
Investigations		
Heart rate and pulse investigations		
Heart rate increased	1	0
Investigations SOC Total	1	0

Vaccine Analysis Print
Vaccine Name: H1N1 Vaccine brand unknown

Reaction Name	Reactions	Fatal Reactions
SOC		
HLT		
PT		
Musculoskeletal and connective tissue disorders		
Joint related signs and symptoms		
Arthralgia	1	0
Joint stiffness	1	0
Musculoskeletal and connective tissue signs and symptoms NEC		
Musculoskeletal stiffness	1	0
Muscle pains		
Myalgia	4	0
Muscle related signs and symptoms NEC		
Musculoskeletal and connective tissue pain and discomfort		
Pain in extremity	4	0
Musculoskeletal and connective tissue disorders SOC Total	11	0

Vaccine Analysis Print
Vaccine Name: H1N1 Vaccine brand unknown

Reaction Name	Reactions	Fatal Reactions
SOC		
HLT		
PT		
Nervous system disorders		
Headaches NEC		
Headache	2	0
Migraine headaches		
Migraine	1	0
Nervous system disorders SOC Total	3	0

Vaccine Analysis Print
Vaccine Name: H1N1 Vaccine brand unknown

Reaction Name	Reactions	Fatal Reactions
SOC		
HLT		
PT		
Psychiatric disorders		
Disturbances in initiating and maintaining sleep		
Insomnia	1	0
Sleep disorders NEC		
Sleep disorder	1	0
Psychiatric disorders SOC Total	2	0

Vaccine Analysis Print
Vaccine Name: H1N1 Vaccine brand unknown

Reaction Name	Reactions	Fatal Reactions
SOC		
HLT		
PT		
Skin and subcutaneous tissue disorders		
Apocrine and eccrine gland disorders		
Hyperhidrosis	1	0
Bullous conditions		
Blister	1	0
Dermal and epidermal conditions NEC		
Skin reaction	1	0
Dermatitis and eczema		
Dermatitis allergic	1	0
Skin and subcutaneous tissue disorders SOC Total	4	0

Vaccine Analysis Print
Vaccine Name: H1N1 Vaccine brand unknown

Reaction Name	Reactions	Fatal Reactions
SOC		
HLT		
PT		
Vascular disorders		
Peripheral vascular disorders NEC		
Flushing	1	0
Vascular disorders SOC Total	1	0